



Department of Defense  
Individual's Briefing

## ANTHRAX VACCINE

18 Aug 09



## Briefing Outline

- Key Messages
- Policy, Threat and Disease
- Vaccine Facts and Safety
- Exemptions and Pregnancy
- Adverse Event Reporting



## Key Messages

- Your health and safety is our # 1 concern
- Receiving the vaccination is the only round-the-clock protection available to protect service members against this very real threat
- The Food and Drug Administration say the anthrax vaccine protects against all forms of anthrax disease and is safe
- Vaccination protects you, your unit, and your mission



## Policy History of the AVIP

- Dec 97: Secretary of Defense ordered the AVIP
- Mar 98: Vaccinations began in Southwest Asia
- Aug 98: Vaccinations began in Korea
- 2000-01: Slowdowns due to shortage. After supply restored, program resumed in 2002
- Oct 04: Injunction issued against DoD
- Jan 05: FDA issues Emergency Use Authorization (EUA)
- Dec 05: FDA formally issues Final Rule/Final Order
- Oct 06: Deputy Secretary of Defense issued AVIP policy to re-establish a mandatory program for those in higher risk areas and with special roles; policy allows voluntary vaccinations for other groups
- Dec 06: Under Secretary of Defense for Personnel and Readiness released DoD implementation guidance for the AVIP policy
- Dec 08: Vaccine route and dosing schedule change



### Mandatory and Voluntary Vaccinations

- Vaccinations are mandatory for DoD service members, emergency essential designated civilians, and contractor personnel performing mission-essential services assigned to:
  - Central Command area of responsibility, the Korean Peninsula, and the Horn of Africa for 15 or more consecutive days
  - Special units with biowarfare or bioterrorism related missions
  - Specialty units with approved exception to policy
- Vaccinations shall begin, to the extent feasible, up to 120 days prior to deployment or arrival in higher threat areas



## Current Policy Implementation

- Vaccinations are voluntary for DoD service members who are not in the mandatory groups and have received at least one dose of Anthrax Vaccine Adsorbed during or after 1998
- Vaccinations are voluntary for DoD civilians and adult family members; contractors and their accompanying US citizen family members:
  - Residing in Central Command area of responsibility, the Korean Peninsula, and the Horn of Africa for 15 or more consecutive days
- DoD Civilian Personnel Management Service concluded notification to national unions on 12 Jan 07



## Threat

- Inhalation anthrax is 99% lethal if unprotected, unvaccinated, or untreated
- Anthrax spores are the most likely bioweapon
  - Relatively easy and cheap to produce
  - Extremely stable – can withstand harsh environmental conditions and remain dormant up to 50 years
  - Can be aerosolized and delivered in a variety of methods
  - Odorless, colorless, tasteless, difficult to detect



## Anthrax Infections

- Recognized as an illness for centuries
- Once common where livestock were raised, now controlled using vaccine for livestock
- Human infection from direct contact with infected animals, animal products, or anthrax spores
- Still a problem in Asia and Africa
- Terror attacks via US mail in Fall 2001





## Pathogenesis

- Spore enters through broken skin, gastrointestinal tract, or the lungs
- Collected by white blood cells
- Transported to nearest lymph nodes
- Bacteria multiply in lymph nodes
- Produce deadly toxins
- Toxins cause swelling, bleeding and death of the tissue and organs (lungs, brain, GI tract)

- Three types of Anthrax infection
  - Cutaneous Anthrax (Skin)
  - Gastrointestinal Anthrax (GI tract)
  - Inhalational Anthrax (lungs)



## Cutaneous Anthrax

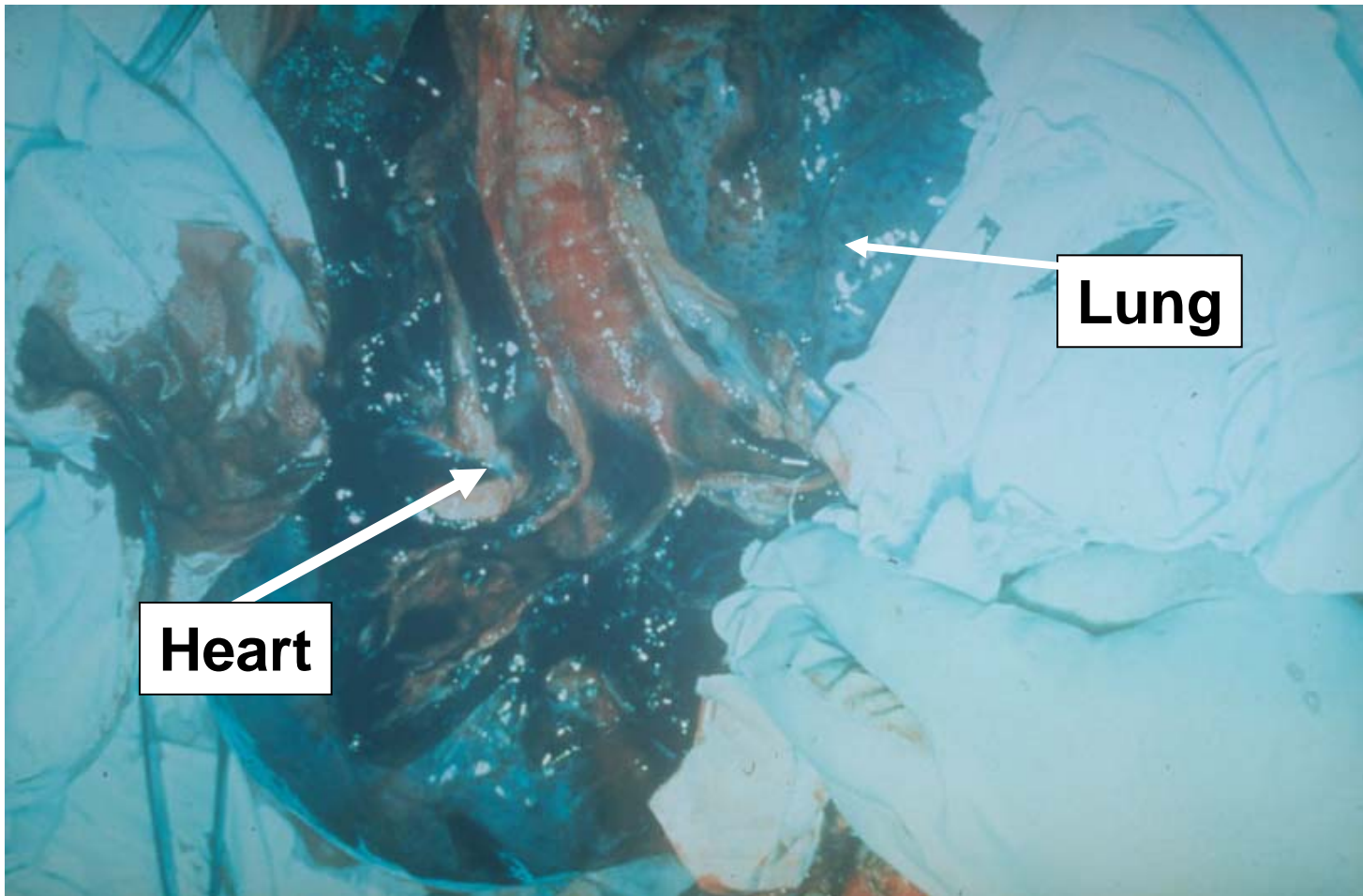
- Cutaneous: Contact with spore-infected animal hides or products through a break in the skin
- Incubation period: 1-5 days
- Symptoms: Papule forms in 1-2 days; changes to vesicle; ruptures to form ulcer and develops black eschar (scab); lasts 2-3 weeks



- Gastrointestinal: Ingesting poorly- or undercooked infected meat
- Incubation period: 2-5 days
- Symptoms: Fever, abdominal pain, nausea, vomiting of blood, and bloody diarrhea
- Mortality up to 50% due to late diagnosis, GI hemorrhage, massive fluid retention
- Oropharyngeal anthrax -> compromised airway

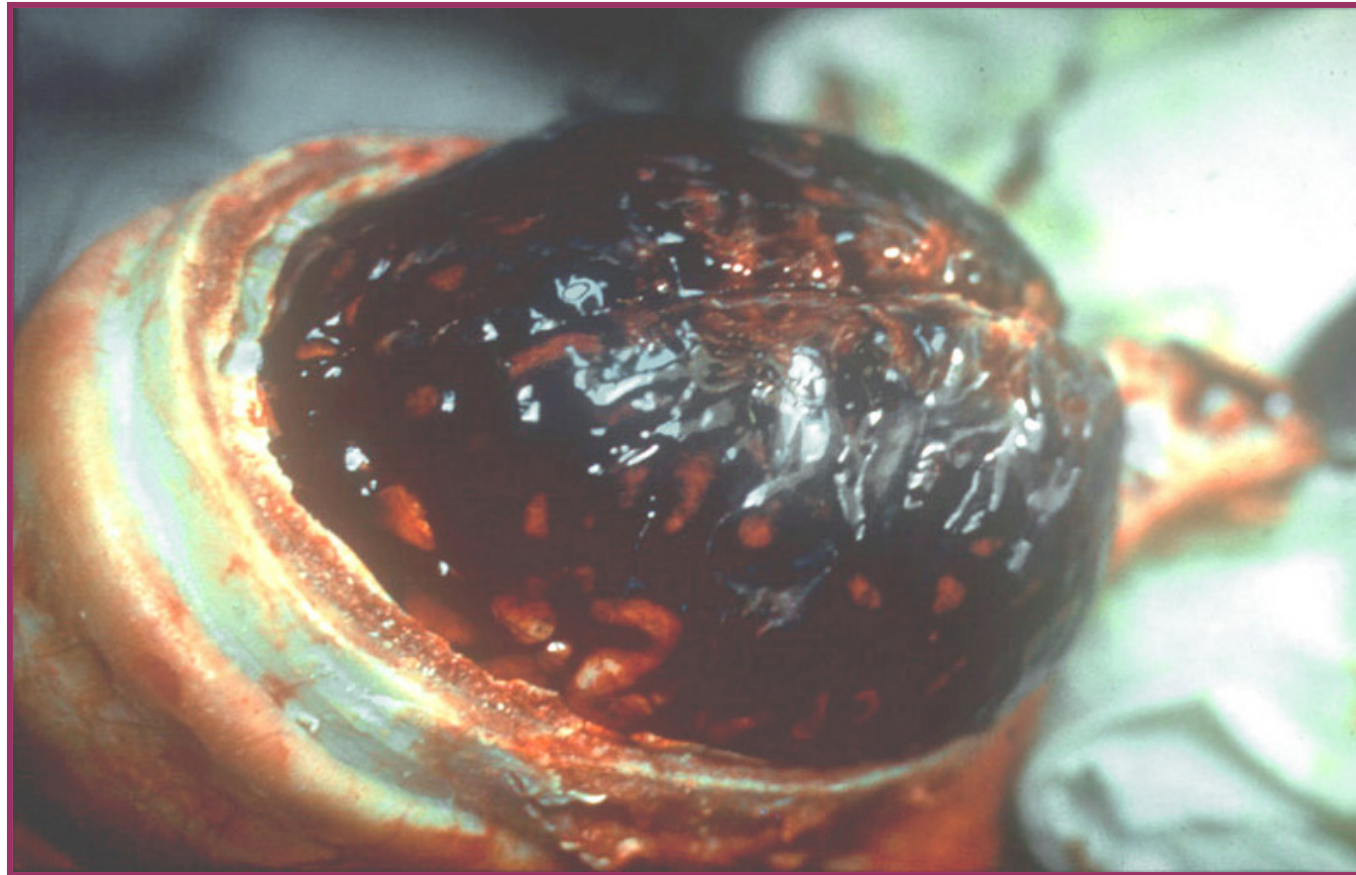


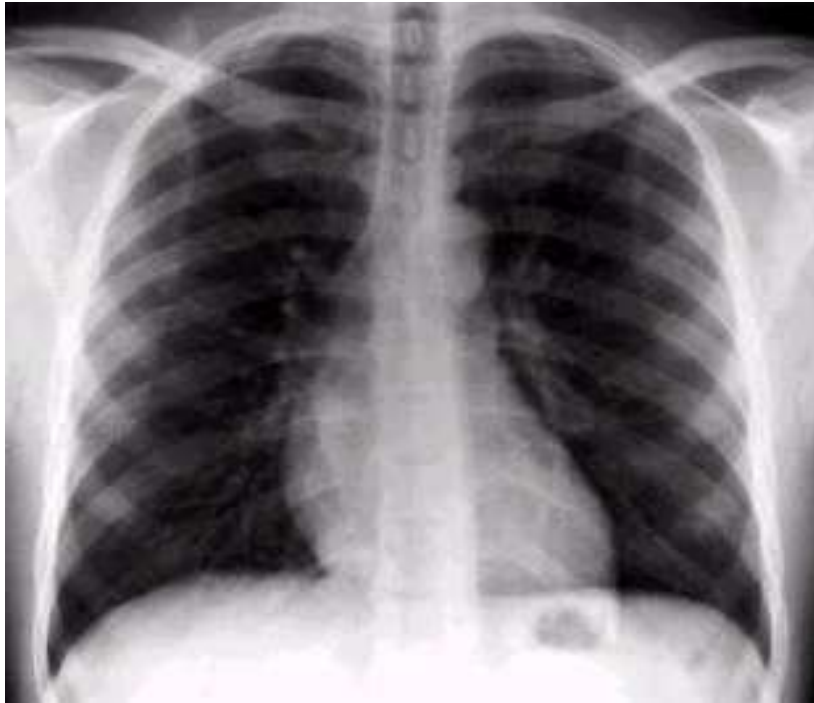
- Inhalation: Spores enter lungs, collected by white blood cells, travel to lymph nodes. Spores rapidly multiply and produce toxins
- Incubation period: 1-6 days
- Symptoms:
  - Initially flu-like: Mild fever, myalgias and malaise, cough, chest discomfort, 2-4 days
  - Slight improvement, hours to days
  - Severe respiratory distress quickly progresses to shock and death in hours to days
- Toxins cause destruction of pulmonary and thoracic tissues, result in multiple organ failure



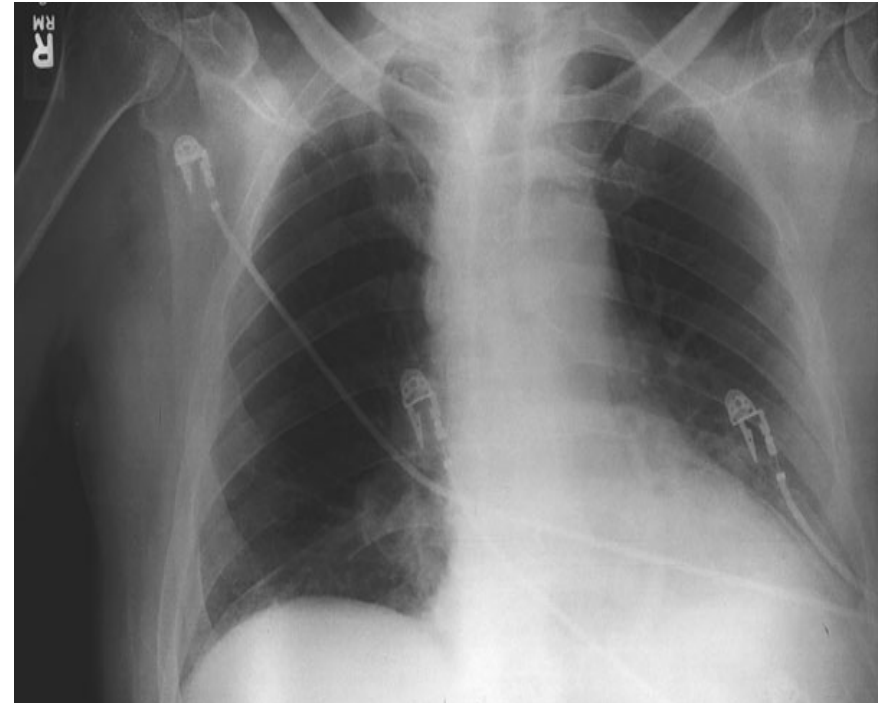


## Brain Autopsy of Lethal Case of Inhalation Anthrax





**Normal Chest X-ray**



**Chest X-ray of Inhalation Anthrax  
Victim**





## Anthrax Vaccine Facts

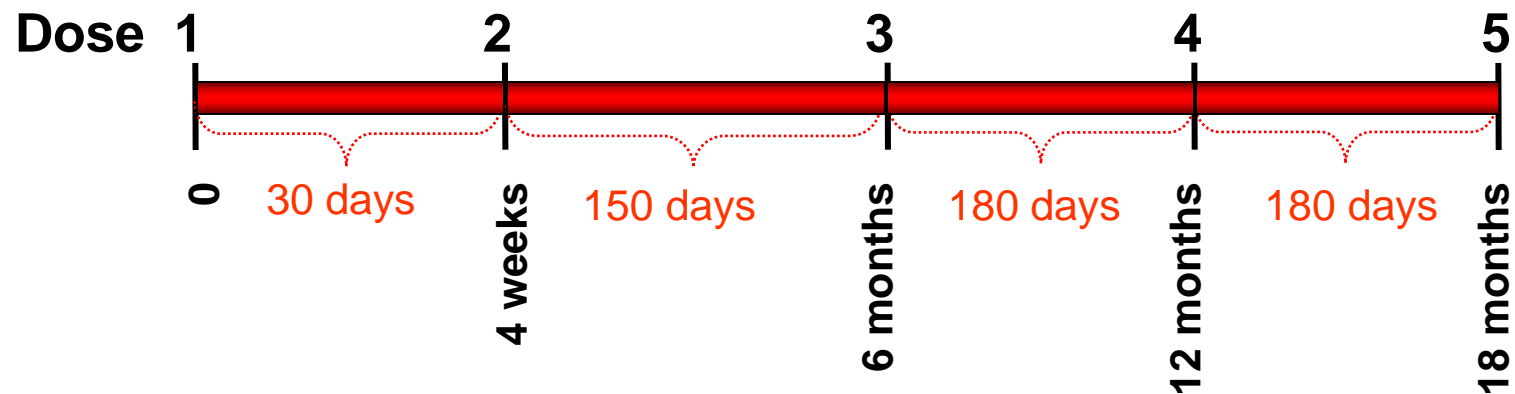
- Licensed by the Federal government since 1970
  - Administered in US to at-risk veterinarians, laboratory workers, and livestock handlers
  - Over 8.9 million doses to more than 2.2 million people since Mar 98
- Vaccine primes immune system to fight anthrax
- Manufactured in US by Emergent BioSolutions
  - “AVA,” *BioThrax*<sup>™</sup>. Package insert with each vial.
  - Official name: Anthrax Vaccine Adsorbed

This vaccine contains no whole or live anthrax bacteria;  
therefore, it is impossible to contract the disease from it.



## Immunization Schedule

- 5 doses over 18 months; annual booster
- Do not compress schedule
- Adjust schedule for individual delays
- Do not “restart” series if it has been interrupted





## Injection Site Reactions

Many may experience temporary pain and swelling after the shot

Mild side effects such as redness and tenderness at the site of vaccination are common

- For both genders, IM administration significantly reduces adverse events at injection sites
- Monitoring of all adverse events
  - Burning
  - Soreness
  - Redness
  - Itching
  - Swelling
  - Local pain at the injection site



## Exemptions from Vaccination

TEMPORARY

PERMANENT

- Some people should not get anthrax vaccine
- Temporary medical exemptions include
  - Women who are pregnant, or uncertain if pregnant
  - Short-term immune suppression
  - Acute diseases, surgery
  - Medical evaluation or condition pending
- Permanent exemptions can include
  - Severe allergic reaction or other serious reaction after a previous dose of anthrax vaccine
  - People with a history of severe latex sensitivity
  - HIV infection or other chronic immune deficiencies
  - People who had Guillain-Barré Syndrome (GBS)
  - Recovery from previous anthrax infection

Anthrax vaccine is licensed for individuals from 18 to 65 years of age



## Pregnancy

According to the CDC's Advisory Committee on Immunization Practices (ACIP):

*“there is no convincing evidence of risk from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids.”*

- Vaccinations routinely deferred during pregnancy
- Before vaccination, ask each woman if she is pregnant or if there is the possibility of trying to become pregnant
- No reason to delay conception after vaccination
  - Anthrax-vaccinated & -unvaccinated women at Fort Stewart (*JAMA*, 2002): same rates of conception, delivery
  - Anthrax-vaccinated & -unvaccinated men at fertility clinic: same sperm concentration, rate of pregnancy
- Vaccination during pregnancy
  - Do not vaccinate pregnant women unless potential benefits of vaccination outweigh potential risk to fetus



## Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS)
  - FDA and CDC review 100% of adverse-event reports
  - All VAERS forms reviewed by independent panel of expert civilian physicians for 4 years
- DoD requires healthcare workers submit a VAERS Form for
  - Loss of duty 24 hours or longer ( $\geq 1$  duty day)
  - Hospitalization
  - Suspected vaccine vial contamination
- Other submissions are encouraged
- Anyone can submit a VAERS Form

When in doubt, report it!

1-800-822-7967

[www.vaers.hhs.gov](http://www.vaers.hhs.gov)



## Reserve Component Adverse Event Guidance

- If someone experiences an adverse event in a non-duty status that is possibly associated with a vaccination
  - Should seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
  - Should Report the event to your unit Commander or designated representative as soon as possible
  - Should see local medical department or squadron for guidance
- Commander will determine Line of Duty and/or Notice of Eligibility status, if required
- Submit VAERS for any suspected adverse event

888-647-6676

[www.tricare.mil/tma/MMSO](http://www.tricare.mil/tma/MMSO)



## Resources

- **MILVAX Agency**
  - [www.vaccines.mil](http://www.vaccines.mil)
  - [www.anthrax.mil](http://www.anthrax.mil)
  - [www.vaccines.mil/anthrax](http://www.vaccines.mil/anthrax)
  - [vaccines@amedd.army.mil](mailto:vaccines@amedd.army.mil)
  - 877.GET.VACC
- **DoD Vaccine Clinical Call Center**
  - 866.210.6469
- **Vaccine Healthcare Centers** *for help with adverse event management*
  - [www.vhcinfo.org](http://www.vhcinfo.org)
  - 202.782.0411
- **Information for Civilian Healthcare Providers**

*Call the Military Treatment Facility (MTF) where the member is enrolled OR contact the Military Medical Support Office (MMSO)*

  - [www.tricare.mil/tma/MMSO](http://www.tricare.mil/tma/MMSO)
  - 888.647.6676 *if the member is not enrolled to an MTF*
- **USAMMA DOC**
  - [www.usamma.army.mil](http://www.usamma.army.mil)
  - 301.619.4318







[www.vaccines.mil](http://www.vaccines.mil)



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