

Anthrax
Vaccine
Immunization
Program

Individual Briefing



History of the Anthrax Vaccine Immunization Program (AVIP)

- Secretary of Defense ordered the AVIP in Dec 97
- Vaccinations began in Southwest Asia in Mar 98 / Vaccinations began in Korea in Aug 98
- Slowdowns in 2000-01. After supply restored, program resumed 2002
- Injunction issued against DoD in Oct 04
- FDA issues Emergency Use Authorization (EUA) in Jan 05
- FDA formally issues Final Rule/Final Order on 19 DEC 05
- AVIP continued as during EUA: same people, voluntary basis
- Deputy Secretary of Defense issued AVIP policy in Oct 06 to reestablished a mandatory program for those in higher risk areas and with special roles; policy allows voluntary vaccinations for other groups
- Under Secretary of Defense for Personnel and Readiness released DoD implementation guidance for the AVIP policy in Dec 06

Current Policy Implementation

- Vaccinations are <u>mandatory</u> for DoD Servicemembers, emergency essential designated civilians, and contractor personnel performing mission-essential services assigned to:
 - Central Command area of responsibility for 15 or more consecutive days.
 - Korean Peninsula for 15 or more consecutive days
 - Special units with Bio-warfare or Bio-terrorism 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 <u>voluntary</u> for DoD Servicemembers who are not in the mandatory groups and have received at least one dose of anthrax vaccine absorbed during or after 1998
- Vaccinations are <u>voluntary</u> for DoD civilians and adult family members; contractors and their accompanying US citizen family members:
 - Residing in Central Command area of responsibility for 15 or more consecutive days
 - or -
 - Residing on Korean Peninsula for 15 or more consecutive days
- DoD Civilian Personnel Management Service concluded notification to National Unions on 12 Jan 07

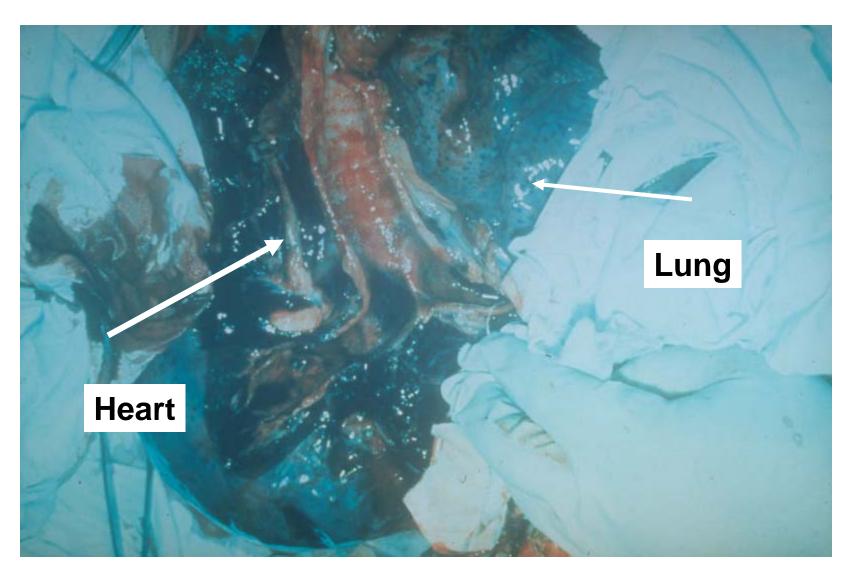
Anthrax Spores

- Highly lethal Inhaling spores can kill 99% of unprotected, unvaccinated, untreated people
- Extremely stable withstands harsh conditions, remains inactive for up to 50 years
- Resists heat, ultraviolet light, gamma radiation, bleach
- Easily weaponized and deployed bombs, missiles, mailed packages, aerosols
- Colorless, odorless, difficult to detect
- At least 7 potential adversaries suspected of researching, developing, or weaponizing anthrax
- You can be infected and not know it, until it's too late.

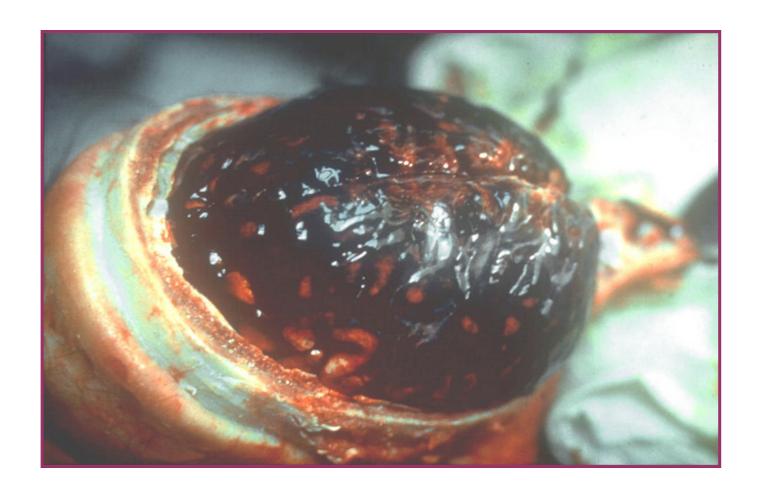
Largest Human Outbreak of Anthrax

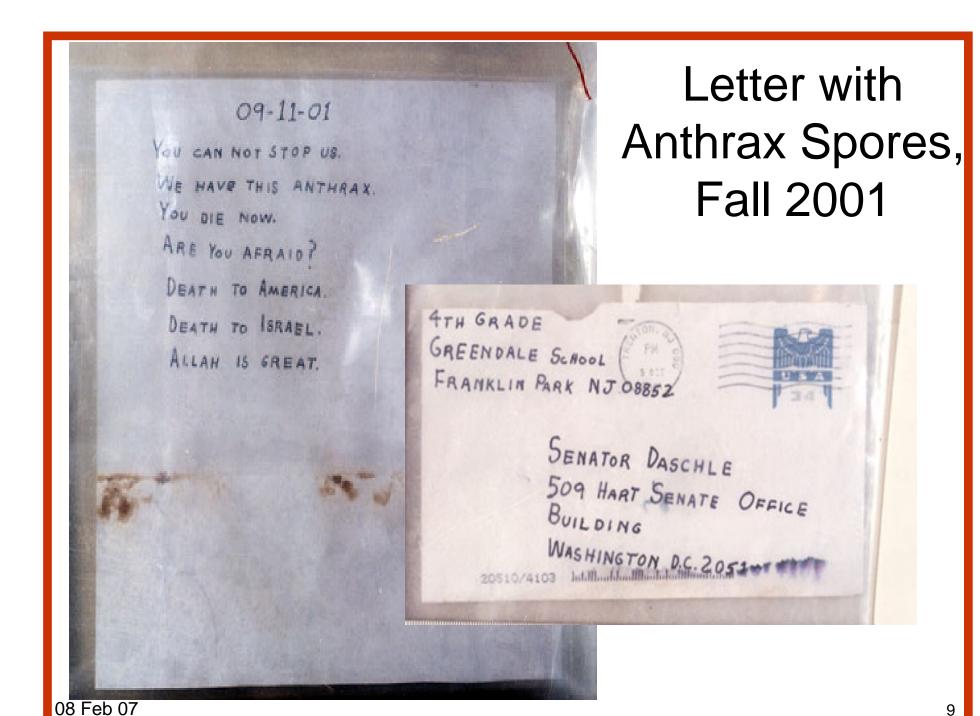
- Sverdlovsk, USSR, 1979
- Anthrax spores accidentally released from a military microbiology facility
- 77 people infected
- 66 of these people died (86% death rate)
- Most victims worked or lived within 4-kilometer zone south of the city
 - Investigators concluded anthrax spores spread where the wind blew

Lethal Case of Inhalation Anthrax



Lethal Case of Inhalation Anthrax





October 2001 Anthrax Attacks

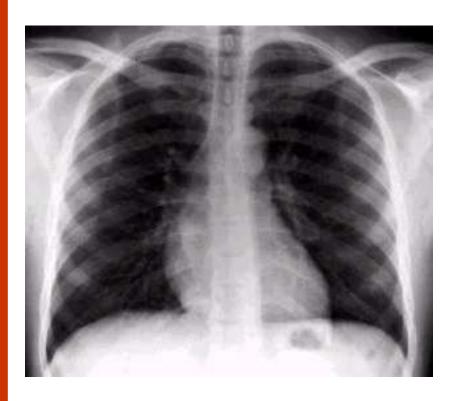
- Several letters containing anthrax spores sent in mail
- 4 regions affected in US
 - Florida
 - New York / New Jersey
 - Washington, DC, metropolitan area
 - Connecticut
- Additional contamination of other postal facilities
- Nationwide effects
- 22 people infected:
 - 11 inhalation cases, 5 died (45% death rate)
 - 11 cutaneous (skin) cases, 7 confirmed cases (including a baby), plus 4 suspected cases
- Over 33,000 people given antibiotics

Timeline of Anthrax Postal Attacks

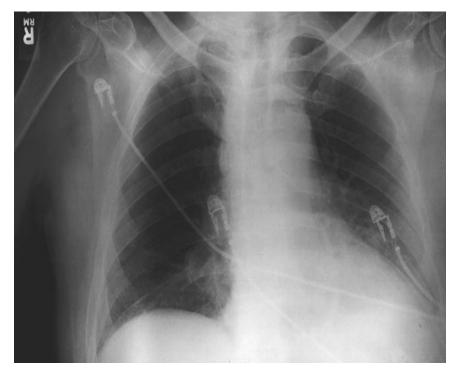
- 4 Oct 01. American Media Inc. (AMI) photo editor diagnosed with inhalation anthrax. He died the next day.
- 16 Oct 01. Without knowing they had been exposed, four Washington area postal workers developed inhalation anthrax symptoms. Two died. The Brentwood postal facility is now named the Curseen-Morris Processing & Distribution Center in their memory.
- 25 Oct 01. A hospital supply worker in New York City with no obvious exposure becomes ill. She died 5 days later from inhalation anthrax.
- 14 Nov 01. A 94-year-old woman in rural Connecticut with no obvious exposure becomes ill. Diagnosis: inhalation anthrax. She died 1 week later.

Chest X-Ray in Anthrax

Florida photo editor who died 5 October 2001



Normal Chest X-ray



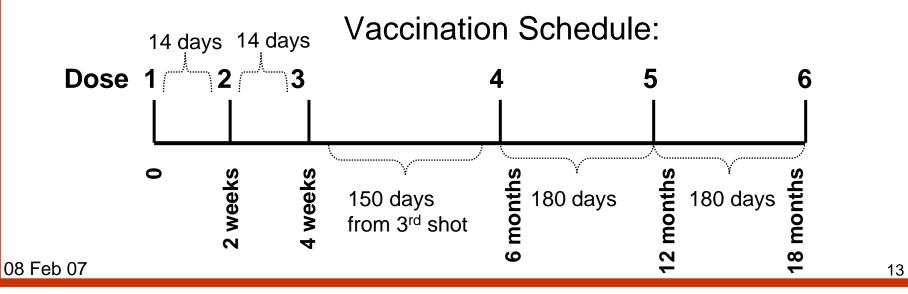
Chest X-ray of Inhalation Anthrax Victim

08 Feb 07

12

Anthrax Vaccine Facts

- Manufactured by Emergent Biosolutions in Lansing, MI
- A study in mill workers showed anthrax vaccine was 92.5% effective in preventing anthrax (including both cutaneous and inhalation anthrax)
- Each vaccine lot is okayed by FDA before shipment
- No other product is approved by FDA to prevent anthrax before exposure



Anthrax Vaccine Safety

- Over 1.4 million people vaccinated with over 5.8 million doses
- Injection-site reactions common:
 - 30% of men, 60% of women have injection-site reactions
 - Burning, soreness, redness, itching, swelling, or pain
- Systemic symptoms (beyond injection site):
 - 5% to 35% of both genders
 - Muscle or joint aches, headaches, rashes, chills, mild fever, fatigue, swelling may extend below elbow
- Acute allergic reactions after any vaccine, 1 in 100,000 doses
- The risk of any vaccine causing serious harm or death is very small
- Consult your health care provider if adverse events occur

Exemptions from Vaccination

- Some people should not get anthrax vaccine.
- Temporary medical exemptions include:
 - Women who are pregnant, or might be pregnant
 - Acute diseases, surgery
 - Short-term immune suppression
 - 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 possible history of latex sensitivity
 - HIV infection or other chronic immune deficiencies
 - People who had Guillain-Barré syndrome (GBS)
 - Recovery from previous anthrax infection

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 <u>requires</u> healthcare workers submit a VAERS Form 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.hhs.gov

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
 - 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 and safety are our #1 concern.
- The threat from anthrax spores is deadly and real.
- America's best scientists say that anthrax vaccine protects against all forms of anthrax disease and is safe.
- Vaccination protects you, your unit, and your mission.

For More Information

•Military Vaccine (MILVAX) Agency

Website: www.anthrax.mil www.vaccines.mil

➤ Toll-Free: 877.GET.VACC

E-Mail: vaccines@amedd.army.mil

For medical advice about <u>your</u> vaccination (24/7)

➤ DoD Vaccine Clinical Call Center: 866.210.6469

For clinical consultation or exemption assistance

Website: www.vhcinfo.org

E-Mail: askVHC@amedd.army.mil

CDC National Immunization Hotline

> Toll-Free: 800.232.2522