

Department of Defense

Anthrax Vaccine Immunization Program Information



“...I have a message for our military: Be Ready.”

President Bush, September 20, 2001
speech to the Joint Session of Congress
following attacks on America

Contact us at vaccines@amedd.army.mil or call 877-GET-VACC (877-438-8222)

Visit our website at www.anthrax.mil

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Department of Defense Policy

The Department of Defense conducts the Anthrax Vaccine Immunization Program (AVIP) consistent with U.S. Food and Drug Administration approved labeling and the best practice of medicine. Our policy is to immunize military personnel, Emergency-Essential DoD civilians and contractor personnel, assigned to or deployed for more than 15 days in higher threat areas whose performance is essential for certain mission critical capabilities.

Frequently Asked Questions

What Is Anthrax ?

- Anthrax is a robust spore-forming bacterium (*Bacillus anthracis*) that can be stored for years, loaded into a variety of weapons, and produced in large quantities without sophisticated equipment. Inhaled anthrax is 99% lethal in an unprotected, unvaccinated population, left untreated.

Is Anthrax A Biological Warfare Threat ?

- The threat is real and failure to prepare would result in grave consequences. A former Director of the Central Intelligence Agency, James Woolsey, referred to it as “the single most dangerous threat to our national security in the foreseeable future.”
- Several countries have or are developing an offensive biological warfare capability using anthrax.
- What we know about Iraq’s offensive biological warfare capability to deliver anthrax and their intent to use it: Iraq conducted weapons tests in 1990; biological warfare bombs and warheads were moved to forward locations during the Gulf War; thousands of pounds of anthrax agent were loaded into missiles, aerial bombs, and spray tanks; and blood testing of Iraqi defectors yielded evidence of immunization against anthrax.
- Admissions in the post-Cold War era of the former Soviet Union’s massive biological warfare capability confirmed their anthrax and smallpox programs were highly developed.

Why Not A Voluntary Program For Servicemembers ?

- It is important that Department of Defense personnel whose duties are essential to mission critical capabilities are vaccinated against anthrax, both for their personal protection and for success of the military mission. So vaccination will be mandatory, except as provided under applicable medical and administrative exemption policies, similar to those DoD always had in place. Vaccination offers an extra layer of protection in addition to antibiotics and other measures that is needed for certain members of the Armed Forces.
- We provide many different vaccines and medical procedures on a mandatory basis, when it is known that the vaccine or medical measure is safe and effective, and exposure or possible exposure to an agent poses a real risk. Also, we fight and win as teams—if one or several

team members in areas of higher risk are not vaccinated and fall victim to anthrax, they could jeopardize the lives of other team members and mission success.

- There is a long history of compulsory vaccination within the U.S. Armed Forces—tetanus, typhoid, and yellow fever vaccines were required of World War II soldiers with the following results:
 - 0 cases of yellow fever
 - 12 cases of tetanus—despite 2.7 million hospital admissions for wounds and injuries
 - 5 cases per 100,000 of typhoid fever—compared to 42 cases per 100,000 in World War I.
- The Centers for Disease Control and Prevention's (CDC) use of anthrax vaccine recently with Congressional and Postal Service employees was done with informed consent...some insist the Department of Defense should obtain informed consent of Service Members before anthrax vaccination. The Department of Defense's use of anthrax vaccine in the Anthrax Vaccine Immunization Program for pre-exposure prevention using six doses over 18 months is consistent with the Food and Drug Administration-licensed use of the vaccine. The Centers for Disease Control and Prevention offer of anthrax vaccine for Congressional and U.S. Postal Service workers used anthrax vaccine for "post-exposure prophylaxis" in three doses. This is not a Food and Drug Administration-licensed use of the vaccine. Therefore, in that case (post exposure), the vaccine was administered under an "investigational new drug" protocol, which required informed consent.
- Some persons say just use antibiotics instead of anthrax vaccine, but there is no better round-the-clock protection against anthrax infection than the anthrax vaccine. Antibiotics are effective when started immediately or very soon after exposure. However, not all exposures can be predicted in advance or even determined in very early stages, particularly in certain military situations. In such situations, the consequences for military personnel and their mission could be dire. This is not a risk we can afford to take. DoD will therefore vaccinate ahead of time for the best protection.

Is Disciplinary Action Taken Against Servicemembers Who Refuse ?

- We anticipate that very few, if any, servicemembers will refuse to be vaccinated given more recent knowledge about the threat of anthrax and also about the validated safety and effectiveness of the vaccine. However, we begin with the assumption that any servicemember covered by this new mandatory policy who refuses vaccination may be uninformed about the facts related to the deadly effects of the anthrax agent and the safe protection afforded by the vaccine. Our first action with those who might refuse the vaccine will be to determine their concern and provide information.
- This is a force health protection issue. If a servicemember continues to refuse the vaccine, then a commander will manage the situation as he or she would for any failure to obey a lawful order, including educating the members about the AVIP as appropriate.
- We expect servicemembers to comply with administration of this vaccine as for any other mandatory vaccination. It is comparable to an order to wear body armor during armed engagement, or to don a protective mask in a suspected chemically or biologically contaminated environment. Any servicemember who does not comply with these measures endangers his/her own health, and places both their unit and mission accomplishment at risk.
- Military and civilian judges uniformly have found orders for members to be vaccinated to be lawful orders.

Vaccine Efficacy Studies Against Anthrax ?

- Field studies conducted in the late 1950s by Centers for Disease Control and Prevention researchers demonstrated more than 90 percent vaccine effectiveness in humans (jointly against cutaneous and inhaled anthrax).
- Animal studies consistently demonstrate protection—non-human primates with only one or two doses survived lethal challenges over 500 times the median lethal dose (LD₅₀) up to 2 years later. In all, 62 of 65 vaccinated monkeys (95 percent) survived inhalation challenge, but 0 of 18 unvaccinated monkeys (0 percent) survived. Similarly, 114 of 117 vaccinated rabbits survived, but unvaccinated rabbits died.
- The Food and Drug Administration licensed anthrax vaccine as a safe and effective prevention against *Bacillus anthracis*—the bacterium causing anthrax. The Food and Drug Administration reaffirmed this position in numerous testimonies to Congressional committees over the past three years. Based on human and animal data, the National Academy of Sciences' Institute of Medicine concluded in March 2002 that anthrax vaccine is “an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of *Bacillus anthracis*.”

Is Anthrax Vaccine Safe ?

- 18 safety studies of more than 500,000 vaccine recipients establish the safety of anthrax vaccine.
- Based on over 30 years of anthrax vaccine use, we know that severe, albeit transient, injection site reactions do occur. Mild injection site reactions, such as redness, swelling, and tenderness (less than one inch), occur in up to 30 percent of men and 60 percent of women. About 1 in 100 develops a reaction five inches or larger. Such symptoms resolve on their own in a few days.
- The rate of side effects away from the injection site—like fatigue, headache, muscle or joint pain—occur in 5 to 35 percent of vaccine recipients; again, they typically resolve within 24 to 48 hours. As the National Academy of Sciences noted in their March 2002 report, these rates are similar to other vaccines.
- Anthrax vaccine is as safe as any other vaccine. Like any vaccine, death can occur after vaccination, but so few deaths can plausibly be associated to a specific vaccine or event that it is hard to evaluate the risk. For any vaccine, any death reported to the Vaccine Adverse Event Reporting System (VAERS) is thoroughly examined to ensure that it is not related to a new vaccine related problem. The Department of Defense, Food and Drug Administration, Centers for Disease Control and Prevention, and an independent panel of civilian physicians review reports of death or serious illness that might possibly be associated with anthrax vaccination. These groups all agree that anthrax vaccine is not associated with any unexpected patterns of adverse events. The National Academy of Sciences' Institute of Medicine reported in March 2002, “There is no evidence that life-threatening or permanently disabling immediate-onset adverse events occur at higher rates in individuals who have received AVA [U.S. anthrax vaccine] than in the general population.” In rare cases, patients experience serious adverse effects; these are treated and followed appropriately. ”
- If a servicemember has a serious reaction to anthrax vaccine, he/she will be exempted from further doses and will receive full medical care. This policy is the same policy as for any vaccination or any service-connected event.

- Between March 1998 and January 2004, more than 1 million people have been vaccinated against anthrax.
- The anthrax vaccine was invented using mid-century technology that also led to highly successful vaccines against tetanus, diphtheria, and other infectious diseases. Today's manufacturing of anthrax vaccine by BioPort meets all current Food and Drug Administration standards of production.
- The Food and Drug Administration approved the renovations to BioPort's anthrax vaccine manufacturing facilities and processes. The license to manufacture anthrax vaccine has been valid without interruption since 1970. BioPort's license was amended and approved by the FDA to reflect the renovated facilities and processes.

Have Long-Term Cancer And Fertility Studies Been Conducted On Anthrax Vaccine ?

- Virtually no vaccine is studied longitudinally for cancer or effects on reproductive health, largely because such problems have not previously been seen with any vaccine. Prevailing scientific knowledge, based on literally billions of vaccinations administered since 1796, is that vaccines do not cause such problems; the manufacturing process and constituents of anthrax vaccine are essentially the same as other vaccines.
- Polio, hepatitis B, tetanus, diphtheria, typhoid, measles-mumps-rubella (MMR), and many other vaccines have nearly identical comments in their product labeling regarding the lack of long-term studies for cancer and fertility.

If Personnel Deferred Dosing During The "Slowdown," Do They Have To Start The 6-Shot Series Over Again?

- No. Based on experience with anthrax vaccine and other vaccines, there is no need to restart a multi-dose vaccine series. Civilian medical experts advising the Centers for Disease Control and Prevention recommend this practice. Each dose is like climbing a set of stairs toward full immunity. DoD will continue to study the protection conferred with fewer than six doses.

What About Allegations Of Expired And Contaminated Lots Of Vaccine?

- The Food and Drug Administration individually approves each lot before release.

Is DoD Planning To Use All Of the Anthrax Vaccine Produced By BioPort?

- No. DoD's policy took into account other national security considerations beyond the needs for military personnel. A certain amount of the produced vaccine will be reserved for contingency use by other federal agencies.
- The Office of Homeland Security heads the planning effort among federal agencies for contingency use of the vaccine.

Are There Vaccine-Resistant Strains Of Anthrax ?

- Every disease-causing strain of *Bacillus anthracis* produces the same protein, a protein that is required to cause disease. The vaccine induces the production of antibodies that neutralize that protein. The National Academy of Sciences' Institute of Medicine concluded in March 2002 that "it is unlikely that either naturally occurring or anthrax strains with bioengineered protective antigen could both evade AVA [the U.S. anthrax vaccine] and cause the toxicity associated with anthrax."

What About Squalene?

- Squalene (a substance naturally found in the human body) has never been added to anthrax vaccine. Food and Drug Administration (FDA) scientists found trace quantities of squalene in anthrax, diphtheria, and tetanus vaccines (less than the natural level of squalene in the human bloodstream). The FDA notes that these minute quantities could have come from processing during FDA tests (squalene is present in the oil in fingerprints). The FDA called squalene in vaccines "naturally occurring and safe."