

Anthrax Vaccine

A RESOURCE FOR VETERANS, SERVICE MEMBERS, AND THEIR FAMILIES

People in the military may receive the anthrax vaccine for protection against anthrax. This fact sheet may help answer questions about the vaccine and its health effects.

WHAT IS ANTHRAX?

- Anthrax is a serious disease that can affect both animals and humans. It is caused by bacteria called *Bacillus (B.) anthracis*. People can get anthrax from contact with infected animals, wool, meat, or hide.
- Anthrax disease is rare and occurs in four forms:
 - Cutaneous Anthrax: This skin disease is the most common form of anthrax and occurs when anthrax spores get into a cut or scrap on the skin. Common symptoms include skin vesicles filled with fluid that turn into ulcers with black centers. Swelling around the ulcer is often present.
 - Gastrointestinal Anthrax: This type of anthrax occurs when people eat raw or undercooked meat infected with anthrax spores. Common symptoms may include fever, nausea, vomiting, abdominal pain, diarrhea, and blood in the stool. Symptoms may lead to shock and death.
 - Inhalation Anthrax: This type of anthrax occurs when anthrax spores are inhaled. First symptoms include cough, mild fever, and fatigue. Within days, symptoms are followed by severe breathing problems. Shock and meningitis (inflammation of the brain and spinal cord covering) may occur. This form of anthrax is the most serious and requires hospitalization and aggressive treatment with antibiotics.
 - Injection Anthrax: This type of anthrax disease has not been identified in the United States but has been reported in heroin injecting drug users in northern Europe. Symptoms are similar to cutaneous anthrax where the infection occurs near the site of the drug injection.
- The mortality rate for anthrax disease is high even with treatment, ranging from <2% for cutaneous anthrax to 45% for inhalation anthrax and 92% for anthrax meningitis.



WHAT IS THE ANTHRAX VACCINE?

- The Anthrax Vaccine Adsorbed (AVA) is an inactivated vaccine made by BioThrax. It was licensed in 1970 and is made from an avirulent strain of *Bacillus anthracis*. It does not cause anthrax.
- Service members are typically administered the anthrax vaccine to prevent anthrax disease (this is called pre-exposure prophylaxis). Originally, the anthrax vaccine schedule was a series of 6 subcutaneous injections over 18 months with annual boosters. Since 2008, the Food and Drug Administration (FDA) approved a series of 5 intramuscular injections (0.5ml) administered at 0, 1, 6, 12, and 18 months with annual boosters to lessen the likelihood of localized reactions at the vaccine site.



WHY ARE SERVICE MEMBERS GIVEN THE ANTHRAX VACCINE?

- Given the deadly nature of anthrax and the fact that inhalational anthrax may be used as a biological warfare weapon, the Department of Defense (DoD) administers the anthrax vaccine to protect its troops against this deadly disease.
- When full immunization is combined with proper use of protective masks, detection devices, surveillance, and post-exposure antibiotics, the threat of anthrax disease is substantially reduced.



DOES THE ANTHRAX VACCINE WORK?

- Based on human and animal data, the National Academy of Sciences' Institute of Medicine (IOM) concluded in April 2002 that the anthrax vaccine is "an effective vaccine for the protection of humans against anthrax, including inhalation anthrax, caused by all known or plausible engineered strains of anthrax." Animal studies indicate the vaccine is effective. There is limited human vaccine data. Based on the available data, it is estimated that the anthrax vaccine is 93% effective in protecting against anthrax disease and greatly increases the likelihood of service members surviving exposure to inhalation anthrax.



ANTHRAX VACCINE SIDE EFFECTS

- Like all vaccines, the anthrax vaccine can have adverse effects. However, the risk of serious harm from this vaccine is small and similar to other vaccines. Less than 10% of all adverse events are considered serious.
- Mild to Moderate Side Effects: Localized reactions include tenderness, redness, itching, lump or bruise at the vaccination site. Muscle aches, fatigue, low-grade fever, and headache also may occur. These symptoms usually are short-lived, resolving in days to a couple of weeks.

- Severe Side Effects: In rare instances, serious allergic reactions may occur. Serious side effects may include difficulty breathing, swelling of the tongue or throat, a fast heartbeat, hives, dizziness, or weakness. Other rare serious events like autoimmune diseases and Guillain-Barre syndrome have been reported.
- Some service members have reported concerns about the anthrax vaccine causing prolonged fatigue and/or joint pain. At this time, a direct vaccine cause has yet to be proven.
- The anthrax vaccine is contraindicated in people with a history of severe allergic reactions and pregnant woman when anthrax exposure risk is low.



ANTHRAX VACCINE AND GULF WAR ILLNESS

- According to a report written by IOM in 2000, "there is inadequate/insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health effects."
- Available studies have not been considered high enough quality in how they were conducted, had inconsistent findings between the studies, or were not large enough to produce generalizable conclusions for broader populations.
- Long-term studies continue to investigate the health effects for Veterans, including one study that examines the complex symptoms reported by Veterans of the Gulf War.
- To date, several independent nationally renowned scientific groups have found no evidence to link the anthrax vaccine with illnesses among Gulf War Veterans.



SQUALENE AND TAINTED ANTHRAX VACCINE CONCERNS

- Squalene is a naturally occurring compound found in plants, animals, and humans. In 1999, the FDA found trace amounts of squalene in 3 vaccines: tetanus, diphtheria, and anthrax. There is no evidence that the squalene was intentionally added to the anthrax vaccine.
- Concerns about anthrax vaccine health issues were raised in Tulane University studies in 2000 and 2002. More research followed, and the World Health Organization (WHO) and other public health agencies concluded that squalene was not linked to Gulf War Illness (GWI) or other health conditions.
- Social media rumors began to circulate with a memorandum stating that service members were eligible for 100% VA disability rating for "tainted anthrax vaccine." The VA and DoD issued statements saying this was not true.



WHY DID DoD STOP GIVING THE ANTHRAX VACCINE TO SERVICE MEMBERS?

- Following a suit filed by several service members, the US District Court of Washington, DC placed an injunction against the DoD's mandatory anthrax vaccination program on October 27, 2004. As a result, DoD stopped anthrax vaccinations for all personnel, pending resolution of all legal issues. The DoD then sought an Emergency Use Authorization (EUA) for military personal at high-risk for exposure to inhalation anthrax. After reviewing the evidence regarding the safety and effectiveness of the anthrax vaccine, the FDA issued the EUA on January 27, 2005.
- On April 6, 2005, the District Court modified its injunction to allow program resumption under the EUA. On October 12, 2006, the Deputy Secretary of Defense approved resumption of a mandatory AVIP program for military and civilian personnel in higher risk areas or with special mission roles. The policy allows voluntary vaccinations for other groups.



NEXT STEPS

- If you are a Veteran concerned about health effects from anthrax vaccine, please contact the DoD Immunization Healthcare Branch (IHB) at 1-877-438-8222, or visit: <https://health.mil/vaccines>. The IHB has immunization experts who can provide information and address questions related to vaccines received while on active duty.
- Veterans who had an adverse reaction to the anthrax vaccine or other vaccines are encouraged to follow up with their health care provider to submit this information to the Department of Health and Human Service's Vaccine Adverse Event Reporting System (VAERS) which monitors and tracks vaccine adverse events. More information is available at <https://vaers.hhs.gov/>
- Veterans deployed to the Persian Gulf or Southeast Asia may contact their local VA to set up a Registry appointment to discuss any deployment exposure concerns (including vaccines) with a Registry health care provider. Learn more about your local VA Registry team at <https://www.publichealth.va.gov/exposures/coordinators.asp>. VA Toxic Exposure Screens are available to all Veterans at their local VA.

**THIS FACT SHEET WAS ADAPTED FROM THE FOLLOWING RESOURCES AND REFERENCES**

- VA Office of Public Health <https://www.publichealth.va.gov/exposures/gulfwar/sources/vaccinations.asp>
- DOD (Defense Health Agency) <https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Anthrax>
- Center for Disease Control (CDC) <https://www.cdc.gov/anthrax/>
- Institute of Medicine (2002). The Anthrax Vaccine: Is it Safe? Does it Work? Washington, D.C.: National Academies Press.
- Centers for Disease Control and Prevention. Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2019. MMWR, 68 (4), 1-13.
- DoD Memorandum – Guidance for Smallpox and Anthrax Vaccine Immunization Programs – 2015 Nov 12.
- World Health Organization – Squalene based adjuvants in vaccines. Accessed at <https://health.mil/Reference/Anthrax-Vaccine-and-Squalene-Questions-and-Answers>, 2020 Feb 12.
- Holty JE, Bravata DM, Liu H, Olshen RA, McDonald KM, Owens DK. Systematic review: a century of inhalational anthrax cases from 1900 to 2005. Ann Intern Med 2006; 144:270-80.
- Sulsky SI, Luippold R, Garman P et al. (2012). Disability among U.S. Army personnel vaccinated against anthrax. Vaccine, 30(43), 6150-6.
- Mahan CM, Kang HK, Dalager NA et al. (2004). Anthrax vaccination and self-reported symptoms, functional status, and medical conditions in the National Health Survey of Gulf War era Veterans and their families. Ann Epidemiol, 14, 81-88.
- Marano N, Plikaytis BD, Martin SW et al. (2008). Effects of a reduced dose schedule and intramuscular administration of anthrax vaccine adsorbed on immunogenicity and safety at 7 months. JAMA, 300(13), 1532-1542.
- Moro PL, Cragan J, Lewis P et al. (2017). Major birth defects after vaccination reported to the vaccine adverse events reporting system (VAERS), 1990-2014. Birth Defects Res, 109 (13), 1057-1062.
- Niu MT, Ball R, Woo EJ et al. (2009). Adverse events after anthrax vaccination reported to the Vaccine Adverse Event Reporting System (VAERS), 1990-2007. Vaccine, 27, 290-297.

- Phillips CJ, Matyas GR, Hansen CJ et al (2009). Antibodies to squalene in US Navy Persian Gulf War veterans with chronic multi-symptom illness. *Vaccine*, Jun 12; 27 (9): 3921-6.
- Pittman PR, Cavicchia MA, Kingsburg JL et al (2014). Anthrax vaccine adsorbed: further evidence supporting continuing the vaccination series rather than restarting the series when doses are delayed. *Vaccine*, 32, 5131-5139.
- Asa PB, Cao Y, Garry RF (2000). Antibodies to squalene in Gulf War syndrome. *Exp Mol Pathol*. Feb;68(1):55-64.
- Asa PB, Wilson RB, Garry RF (2002). Antibodies to squalene in recipients of anthrax vaccine. *Exp Mol Pathol*. Aug;73(1):19-27.
- Jernigan DP, Raghunathan PL, Bell BP et al. (2002). Investigation of bioterrorism-related anthrax, United States, 2001: epidemiological findings. *Emerg Infect Dis*, 8(10), 1019-1028.
- Conlin AM, Sevick CJ, Gumbs GR et al. (2017). Safety of inadvertent anthrax vaccination during pregnancy: an analysis of birth defects in the U.S. military population, 2003-2010. *Vaccine*, 35, 4414-4420.

This document was developed by the War Related Illness & Injury Study Center (WRIISC)
Health Outcomes Military Exposures, Patient Care Services
Department of Veterans Affairs (VA)
Last Updated: July 2024