



# ANTHRAX VACCINE

## A RESOURCE FOR VETERANS, SERVICE MEMBERS, AND THEIR FAMILIES

Veterans are often concerned about the potential health effects of having received the anthrax vaccine for protection from anthrax.

### 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 hides. The anthrax disease occurs in three forms:

- 1. Cutaneous Anthrax.** Cutaneous anthrax is a skin disease that causes skin ulcers and usually, fever and fatigue. Up to 20% of these cases are fatal if untreated. Cutaneous anthrax is the most common form of anthrax disease.
- 2. Gastrointestinal Anthrax.** This form of anthrax can result from eating raw or undercooked infected meat. Symptoms can include fever, nausea, vomiting, sore throat, abdominal pain and swelling, and swollen lymph glands. Gastrointestinal anthrax can lead to blood infection, shock, and death.
- 3. Inhalation Anthrax.** This form of anthrax occurs when B. anthracis is inhaled and is very serious. The first symptoms can include a sore throat, mild fever, and muscle aches. Within several days these symptoms are followed by severe breathing problems, shock, and often meningitis (inflammation of the brain and spinal cord covering). This form of anthrax requires hospitalization and aggressive treatment with antibiotics. It is often fatal.

### ★ ANTHRAX VACCINE SIDE EFFECTS

Like any medicine, and like all vaccines, the anthrax vaccine can have adverse effects. However, the risk of serious harm from this vaccine is extremely small and similar to many more common vaccines. Of all adverse events reported, less than 10% are considered serious.

#### Mild-Moderate Side Effects

Reactions on the arm where the shot was given include tenderness, redness, itching, development of a lump or bruise, muscle aches, or temporary limitation of arm movement. Additional mild-moderate effects include headache, joint pain, rash, fatigue, and fever. Some service members have reported prolonged fatigue and/or joint pain that impacted their activities, but a direct vaccine cause has yet to be proven.

#### Severe Side Effects

In very rare instances (less than one in 100,000 doses administered), an individual may have a serious allergic reaction.

Signs of a serious allergic reaction can include difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the lips and throat.

Other rare serious events involving the skin and nervous system have been reported, but a direct vaccine cause has yet to be proven.

### WHY ARE SERVICE MEMBERS GIVEN THE ANTHRAX VACCINE?

Given its deadly nature, inhalational anthrax has the potential to be used as a biological warfare weapon. Given this potential, the Department of Defense (DoD) looks at how troops can be protected, such as wearing protective gear or taking antibiotics. Unfortunately, these means of protection have limitations. For example, service members cannot stay in protective gear for days on end and perform well.

Another important form of protection is the anthrax vaccine. The anthrax vaccine provides a very high level of protection against infection by the anthrax bacteria. The anthrax vaccine used in the United States, was licensed in 1970, does not contain B. anthracis cells, and it does not cause anthrax. 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.

### EVIDENCE THAT THE ANTHRAX VACCINE WORKS

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.”

The earliest studies done of the anthrax vaccine were conducted on textile workers. Those studies showed that the vaccine protected against anthrax. No inhalation anthrax occurred among the vaccinated workers, while five cases of inhalation anthrax occurred among workers who had not been vaccinated. In addition to the studies in textile workers, results from several animal studies provide additional evidence that the vaccine protects against anthrax exposure of more than 500 times the lethal dose of anthrax by inhalation. All of the studies done demonstrate that the anthrax vaccine greatly increases the chances of service members surviving exposure to inhalation anthrax.

**HEALTH EFFECTS FOR VETERANS**

At the request of Congress, the IOM was tasked to look at the health effects of serving in the Gulf War which included looking at the anthrax vaccine. According to a report written by the 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.” This means that available studies have either:

- Not been considered high enough quality in how they were designed or conducted;

- There have been inconsistent findings between the studies done; or
- There was not a large enough group in the study to apply the conclusions to other 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 addressed this issue and have found no evidence to link anthrax vaccine with illnesses among Gulf War Veterans.

An October 2004 review of over 716,000 active-duty service members’ discharge rates from service shows anthrax vaccination does not increase risk of disability.

**WHY DID THE DEPARTMENT OF DEFENSE (DoD) STOP GIVING THE ANTHRAX VACCINE TO SERVICE MEMBERS?**

Following a suit filed by several unnamed service members, the US District Court of Washington, DC placed an injunction against the DoD’s mandatory anthrax vaccination program on October 27, 2004. The DoD immediately issued orders to comply with the court decision, stopping anthrax vaccinations for all personnel that day, pending resolution of all legal issues. The DoD then sought an Emergency Use Authorization (EUA) for those military personal at high-risk for exposure to inhalation anthrax, and asked the

Food and Drug Administration (FDA) to approve.

The Commissioner of FDA considered evidence regarding the safety and effectiveness of the anthrax vaccine, consulted with the Centers of Disease Control and Prevention and the National Institutes of Health, and then issued the EUA on January 27, 2005. On April 6, 2005, the District Court modified its injunction to allow program resumption under 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. The Under Secretary of Defense for Personnel and Readiness released DoD implementation guidance for the Anthrax Vaccine Immunization Program (AVIP) on December 6, 2006.

Service implementation plans were approved by the Assistant Secretary of Defense for Health Affairs on February 8, 2007.

On December 11, 2008, the Food and Drug Administration (FDA) approved a change in route of administration and the dosing schedule for the anthrax vaccine.

**ARE YOU A VETERAN WITH CONCERNS ABOUT THE ANTHRAX VACCINE?**

If you are a Veteran concerned about health effects from anthrax vaccine





or any other vaccine, please contact the Department of Defense 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.

**REFERENCES:**

Content for this fact sheet was adapted from the following sources:

- VA Office of Public Health
  - <http://www.publichealth.va.gov/exposures/gulfwar/vaccinations.asp>
- DOD (Defense Health Agency)
  - <https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Anthrax>
- Center for Disease Control (CDC)
  - <https://www.cdc.gov/anthrax/>
- National Academy of Medicine (NAM)
  - [http://books.nap.edu/catalog.php?record\\_id=9953#toc](http://books.nap.edu/catalog.php?record_id=9953#toc)

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