



# Deployment Health and Family Readiness Library



## Anthrax Vaccine Immunization Program

*For Service members and their Families*

### Important Facts

- Your health and safety are our #1 concerns.
- The anthrax vaccine is safe and effective.
- The threat from anthrax is deadly and real.
- Vaccination offers a layer of protection in addition to antibiotics and other measures needed for certain members of the armed forces.

### What is Anthrax?

Anthrax is a serious disease caused by *Bacillus anthracis*, a bacterium that forms spores. A bacterium is a very small organism made up of one cell. Many bacteria can cause disease. A spore is like a seed that is dormant (asleep), but may come to life with the right conditions. There are three types of anthrax.

**Cutaneous (skin) anthrax** can occur when bacteria enter a break in the skin. Cutaneous anthrax, the most common naturally occurring type of anthrax, comes from handling contaminated animal products, such as bones, wool, or animal hides. Cutaneous anthrax begins as a small bump and progresses to a larger blister in 1-2 days. The blister then develops into a skin ulcer with a black area in the center. About 5% to 20% of untreated cases can result in death, but death is rare if the patient is treated with antibiotics.

**Gastrointestinal (stomach) anthrax** can occur when eating raw or undercooked contaminated meat. Gastrointestinal anthrax is a very rare disease. There was no documented U.S. case in the 20th century. Initial signs are nausea, loss of appetite, vomiting, and fever, followed by severe abdominal pain, vomiting blood, and severe diarrhea. Without treatment, death results in 25% to 60% of cases.

**Inhalation anthrax** can occur when inhaling (breathing) as few as 5,000-6,000 anthrax spores, which can occur in a single deep breath. Initial symptoms may develop in 1-6 days, and resemble the common cold or flu: sore throat, mild fever, muscle aches, and tiredness. Mild symptoms can progress very rapidly within a few days to severe breathing problems and shock. If left untreated, the death rate is more than 99%. Even when treated aggressively in a state-of-the-art hospital center, 45% to 80% of patients die once symptoms develop.

### Why is anthrax vaccination needed?

Anthrax is an attractive weapon of mass destruction for our enemies. Anthrax spores are tasteless, odorless, and invisible. They are highly lethal, relatively easy to produce in large quantities and easily spread in the air over a large area. They can be stored and remain dangerous for a long time. For these reasons, anthrax is considered the #1 biological warfare threat facing U.S. forces. U.S. forces may have little or no warning before an anthrax attack, which could be delivered by un-conventional means. As a result, U.S. military forces around the world face a very real threat of a surprise anthrax attack.

### Is anthrax vaccine safe?

Yes, anthrax vaccine has been safely administered to 1.3 million troops since 1998, plus at-risk veterinary and laboratory workers, livestock handlers, and service members since being licensed by the Food & Drug Administration (FDA) in 1970. One of FDA's main missions is to ensure that medications released for use by the American public are both safe and effective.

Like all vaccines, anthrax vaccine may cause soreness, redness, itching, swelling, and lumps at the injection site. About 30% of men and 60% of women report these local reactions, but they usually last only a short while. Between 1% and 5% report reactions of 1 to 5 inches in diameter. Larger reactions occur in about one in a hundred vaccine recipients.

Beyond the injection site, from 5% up to 35% will notice muscle aches, joint aches, fever, nausea, and other flu-like symptoms. Again, these symptoms usually go away after a few days.

Like all vaccines, most adverse events are minor and temporary. Serious events, such as those requiring hospitalization, are rare. They happen about once per 200,000 doses. Severe allergic reactions can occur after any vaccination, less than once per 100,000 doses. Anthrax vaccine is as safe as other vaccines. Like other vaccines, deaths have been reported rarely after anthrax vaccination. Each of these cases is carefully reviewed by the Centers for Disease Control and Prevention (CDC), FDA, and DoD, to make sure all vaccinations are as safe as possible.

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A collaborative effort between the Air Force Institute for Operational Health, the Deployment Health Clinical Center, Force Health Protection and Readiness, the Navy Environmental Health Center, the U.S. Army Center for Health Promotion and Preventive Medicine, and the OUSD(P&R)/Military Family and Community Policy



### Does anthrax vaccine protect against all forms of anthrax?

Anthrax vaccine prevents anthrax regardless of route of exposure. Based on human and animal data, the National Academy of Sciences' Institute of Medicine concluded in April 2002 that 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 original studies of anthrax vaccine in textile workers 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.

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. This and other encouraging information assures us that the vaccine will greatly increase the chances of Service members surviving exposure to inhalation anthrax. When full immunization is combined with proper use of protective masks, detection devices, surveillance and post-exposure antibiotics, the threat is even further reduced.

### Besides the FDA, who are the experts that endorse the anthrax vaccine?

Since 1978, seven independent civilian panels affirmed the safety and efficacy of anthrax vaccine. The National Academy of Sciences, a committee of the nation's premier scientists, stated that the anthrax vaccine is "an effective vaccine for the protection of humans against anthrax, including inhalation anthrax."

Today, there is a broad consensus that the FDA-licensed anthrax vaccine is safe and effective for people at high risk of exposure. Recent publications of the CDC, [www.cdc.gov/mmwr/PDF/rr/rr4915.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr4915.pdf), and the Johns Hopkins Center for Civilian Bio-defense Studies, <http://jama.amaassn.org/cgi/content/short/287/17/2236>, recognize the anthrax vaccine as part of the national preparedness against biological terrorism.

### Wasn't there a recent injunction against the Department of Defense (DoD) giving the anthrax vaccine to its Service members?

On October 27, 2004, the United States District Court for the District of Columbia issued an injunction against the current operation of the Anthrax Vaccine Immunization Program (AVIP). The injunction is based on a conclusion by the Court that FDA was required by its regulations to solicit additional public comments before finalizing its conclusion that anthrax vaccine is safe and effective for protection against inhalation anthrax. That comment period closed on March 29, 2005. While the DoD, FDA, and Justice Department proceed with steps to clarify these legal issues, DoD remains convinced that the AVIP complies with legal requirements and that anthrax vaccine is safe and effective.

### What is DoD doing to protect Service members during the injunction?

On April 25, 2005, the Deputy Secretary of Defense directed resumption of anthrax vaccinations for personnel in high-threat areas, subject to conditions set by the FDA. Notably, the conditions include providing each vaccine with a trifold brochure describing an option to refuse vaccination without penalty. The injunction against mandatory vaccinations continues in force.

### Where can I find additional information about the scientific foundation for the safety and effectiveness of anthrax vaccination? What about more information regarding the AVIP?

Additional information can be found at the following locations:

- The National Academy of Sciences report on the safety and effectiveness of anthrax vaccine: [www.nap.edu/catalog/10310.html](http://www.nap.edu/catalog/10310.html)
- Summary for General Public: [www.iom.edu/Object.File/Master/4/149/0.pdf](http://www.iom.edu/Object.File/Master/4/149/0.pdf)
- Detailed programmatic and safety information: [www.anthrax.mil](http://www.anthrax.mil)

### Where Do I Get More Information?

#### DoD Deployment Health Clinical Center (DHCC)

Phone: (866) 559-1627  
<http://www.pdhealth.mil/>

#### DoD Force Health Protection & Readiness (FHP & R)

Phone: (800) 497-6261  
<http://fhp.osd.mil>

#### Air Force Institute for Operational Health (AFIOH)

Phone: (888) 232-3764  
<http://www.brooks.af.mil/afioh/>

#### Navy Environmental Health Center (NEHC)

Phone: (757) 953-0700  
<http://www.nehc.med.navy.mil>

#### U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM)

Phone: (800) 222-9698  
<http://chppm-www.apgea.army.mil>

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