

What about long-term side effects?

✓ This vaccine has been used for over 30 years. Like other vaccines, rarely has death or serious illness been reported after vaccination. Each case is reviewed by CDC, FDA, and DoD, to make vaccinations as safe as possible.

If I have a health problem or adverse event after vaccination, what do I do?

✓ First, if a health problem occurs following any vaccine, seek medical care to take care of your immediate health problem! If your symptoms persist, you or your provider may contact the DoD Clinical Call Center at **866.210.6469**. Then follow the information below to file a report with the Vaccine Adverse Event Reporting System (VAERS). We are committed to giving you the best care, no matter what caused the problem.

When do I file a VAERS report?

✓ Adverse events after vaccination are reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS forms are available at www.vaers.org or call **800.822.7967**. Healthcare workers and vaccine recipients are encouraged to report any severe events that require medical treatment and/or interfere with work or recreation. DoD requires VAERS reporting by healthcare workers for adverse events that cause hospitalization or loss of work for 24 hours or more.

✓ You or any healthcare provider (civilian or military) treating you may contact the Vaccine Healthcare Center (VHC) for help with preparing a VAERS report or vaccine adverse event consultation.

If I started anthrax vaccinations, but had doses delayed, do I have to restart the series?

✓ No, you will not have to restart the series. You will simply pick up where you left off. This is consistent with national guidelines from the CDC's Advisory Committee on Immunization Practices (ACIP).

✓ The protection of each additional dose builds on the immune response to earlier doses. This is like climbing steps on a ladder towards full protection. Six doses are needed for full protection.

What about Reserve Component (RC) units that drill every month?

✓ Your unit commander, in coordination with the medical authority responsible for immunizations, will schedule your vaccinations in a timely manner.

I'm in the Reserves or National Guard. If I have an adverse event, can I go to a military hospital or clinic?

✓ Adverse events after military-directed vaccinations are in "line-of-duty" (LOD). Some RC members may seek medical care from their private physicians, while others may seek medical care at a local military Medical Treatment Facility (MTF).

✓ Those who seek treatment for an adverse event related to an official immunization will be treated. Any necessary line-of-duty (LOD) documents shall be completed after the person is treated. If you see a NON-military provider, be sure to notify your commander for the proper paperwork for an LOD or Notice of Eligibility determination.

✓ Evaluation or treatment will not be denied or delayed, pending a line-of-duty determination.

✓ For civilian health services outside a military Medical Treatment Facility call: **888.MHS.MMSO (888.647.6676)**.

What if I'm pregnant?

✓ Good medical practice defers vaccination during pregnancy, unless clearly needed. If you are unsure if you are pregnant, you may request a pregnancy test from your medical provider.

✓ A study at Fort Stewart found that vaccinated women get pregnant and give birth at the same rate as unvaccinated women. Outcomes of pregnancies are comparable in vaccinated and unvaccinated women.

✓ Preliminary results suggest that anthrax vaccine may be linked with birth defects if given during pregnancy. These data are unconfirmed. Pregnant women should not be vaccinated against anthrax unless the potential benefits of vaccination outweigh the potential risk to the fetus.

Anthrax Vaccine Immunization Program

- For information about vaccine or policy,
Military Vaccine (MILVAX) Agency:
Websites: www.anthrax.mil www.vaccines.mil
E-Mail: vaccines@amedd.army.mil Toll-Free: **877.GET.VACC**
- For medical advice about your vaccination,
DoD Vaccine Clinical Call Center: Toll-Free: **866.210.6469**
- For clinical consultation or exemption assistance,
DoD Vaccine Healthcare Centers: www.vhcinfo.org
E-Mail: askvhc@amedd.army.mil Phone: **202.782.0411**
- **CDC National Immunization Hotline:** **800.232.2522**

To Civilian Healthcare Providers: If a Reservist or Active Duty Service Member presents to you for a condition that may be an adverse event caused by a military vaccination, please provide appropriate care. For authorization and payment, contact the **Military Treatment Facility (MTF)** where the member is enrolled, OR contact the **Military Medical Support Office (MMSO, 888-647-6676)** if not enrolled to an MTF.

WHAT YOU NEED TO KNOW ABOUT ANTHRAX VACCINE



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EUA Edition

Update

US military forces are at risk of attack with anthrax spores. A significant potential for a military emergency exists.

The FDA Commissioner granted an Emergency Use Authorization (EUA) for anthrax vaccine to prevent inhalation anthrax.

Your military and civilian leaders strongly recommend anthrax vaccination.

For more information:

www.anthrax.mil www.vaccines.mil
vaccines@amedd.army.mil
877-GET-VACC, DSN 761-4245

- In January 2005, the Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) for anthrax vaccine to prevent inhalation anthrax. This permits vaccinations to resume.
- The FDA determined that the known and potential benefits outweigh the known and potential risks for this use.
- A study in mill workers showed that anthrax vaccine was 92.5% effective in preventing anthrax (including cutaneous [skin] and inhalation anthrax cases).
- U.S. anthrax vaccine has been FDA-licensed to prevent anthrax since 1970.



Who should not get anthrax vaccine?

- ✓ Some people should not get anthrax vaccine or should wait:
 - People who had a serious allergic reaction or other serious reaction to a prior dose
 - People who have a moderate or severe illness
 - Women who are pregnant
 - People with a possible history of latex sensitivity
 - HIV-infected and immune-suppressed people
 - People who had Guillain-Barré Syndrome (GBS)
 - People who recovered from anthrax infection
- ✓ You can request an evaluation for a medical exemption from your provider. If you or your provider need assistance with medical exemption questions, the Vaccine Healthcare Center (VHC) is available for consultation services or referral for a second opinion.

What side effects can I expect?

- ✓ A burning sensation may occur immediately after getting anthrax vaccine and can last about a minute.
- ✓ Like other vaccines, anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site.
- ✓ Up to 30% of men and 60% of women report small local reactions, but these reactions usually last only a few days. A lump at the site occurs commonly, up to 50% of the time, lasting for a few weeks.
- ✓ Larger injection-site reactions occur in about 1% to 4% of vaccinees.
- ✓ Beyond the injection site, 5% to 35% may notice such symptoms as muscle or joint aches, headaches, rashes, chills, low-grade fever or nausea. These symptoms usually go away in less than a week.
- ✓ Any vaccine, like any prescription drug, can cause serious reactions including those requiring hospitalization or medical care. Severe allergic reactions occur less than once per 100,000 doses.

How many shots will I get?

- ✓ The FDA-licensed schedule for anthrax vaccine is 6 doses given over 18 months: 0-2-4 weeks, 6-12-18 months, plus annual boosters. Six doses are needed for full protection. Do not get a dose earlier than your due date. If your risk of exposure to anthrax changes, we will reconsider the need for you to continue vaccination.

THE THREAT FROM ANTHRAX SPORES IS DEADLY AND REAL

- The most deadly form of anthrax is inhalation anthrax.
- You can be infected with anthrax and not know it, until it's too late.
- No other product is approved by FDA to prevent anthrax before exposure.



- Without vaccination, you would be more vulnerable to lethal anthrax infection.
- If you get infected with anthrax, your loss could endanger other people in your unit who depend on you.
- If you get infected with anthrax, it could endanger your mission.

- You may refuse anthrax vaccination under the EUA, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination.
- The consequences of refusing anthrax vaccine include that you will be more vulnerable to lethal anthrax infection. Your loss could threaten the lives of others in your unit who depend on you, and could jeopardize the success of the mission.
- On October 27, 2004, a Federal District Court issued an order declaring unlawful and prohibiting mandatory anthrax vaccinations to protect against inhalation anthrax, pending further FDA review. A copy of the Court's order and opinion is available at www.anthrax.mil or from the vaccination clinic.
- The issue of mandatory vaccination will be reconsidered after the FDA completes its administrative review, which DoD expects to occur later in 2005.

Information about anthrax vaccine...

- The FDA-licensed dosing schedule is 0-2-4 weeks, 6-12-18 months, plus annual boosters, given subcutaneously.
- Injection site reactions, like burning, redness and swelling are common. Local reactions occur in 30% of men and 60% of women. Anthrax vaccine can cause a lump under the skin where injected. These lumps can last a few weeks, but they go away on their own.
- Systemic reactions, such as headaches or a fever, are less common than injection-site reactions. These occur at rates similar to other vaccines: 5% to 35%.
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS). Get VAERS forms at www.vaers.org or call 800.822.7967. Healthcare workers and vaccine recipients are encouraged to report via VAERS any severe events within 30 days of vaccination, that require medical treatment and/or interfere with work or recreation. DoD requires healthcare workers report adverse events that cause hospitalization or loss of work for 24 hours or more.