Anthrax vaccine was administered to personnel deployed in the Gulf War. Has the anthrax vaccine been linked to illnesses among Gulf War veterans?

No. Several renowned scientific groups, including the National Academy of Sciences, have addressed this issue and found no evidence to link the FDA-licensed anthrax vaccine with illnesses among Gulf War veterans. What other medical conditions should I inform the medical staff about?

If you have an active illness, a chronic illness under medical treatment or are taking prescription medication, inform the medical staff before taking any vaccine.

#### If I feel I'm having a health problem related to vaccination. what should I do?

If an adverse event occurs, seek medical care as appropriate. At a minimum, any adverse event that results in 24 hours or more time lost from duty, or hospitalization, must be reported by your healthcare provider using the Health and Human Services Vaccine Adverse Events Reporting System (VAERS). Anyone may report a vaccine-associated adverse event of any severity or any length of time through VAERS to the FDA. To obtain blank forms. go to www.anthrax.osd.mil/vaers/vaers.htm or contact the FDA by calling 1-800-822-7967. Please see a health-care provider for help with filling out the form. I'm a reservist/Coast Guard member. If I have a reaction to the vaccine, can I go to a DoD or Coast Guard hospital or clinic?

Adverse events due to DoD or USCG-directed vaccinations are line-of-duty illnesses. Therefore, a member of the reserve component may present him/herself for initial treatment and evaluation at any military treatment facility after vaccination during a period of duty. The member will be examined and provided necessary medical care. Once treatment is rendered or the individual's emergent condition is stabilized, a Line of Duty and/or Notice of Eligibility status will be determined by the member's unit, as required. No treatment beyond that justified to

stabilize the condition or emergency is authorized until service connection is validated. Evaluation does not require being in a duty status, nor DEERS enrollment. For more information. contact your unit representative.

#### How many shots will I have to take?

Six. The first three will be given one every other week. The remaining three will be given at 6, 12 and 18 months later. An annual booster does is required to maintain ongoing immunity.

## Am I required to take the vaccine?

Yes. This vaccine, like every other required vaccination, is necessary to prepare you for deployment. Medical exemptions can be granted, if appropriate.

> Anthrax is a highly lethal biological warfare agent.

The anthrax vaccine is an effective and safe vaccine.

The anthrax vaccine does not contain squalene and has never contained squalene.

The threat of anthrax is a clear and present danger.

Dr. Sue Bailey Assistant Secretary of Defense for Health Affairs & the Service Surgeons General

For more information on the Anthrax Vaccine Immunization Program, call toll free 1-877-GFT VACC (1-877-438-8222)or visit http://www.anthrax.osd.mil

# what everyone needs to know about the anthrax vaccine

Feb1, 2000

#### What is the threat?

Biological weapons are maintained by several countries around the world, including some of our potential adversaries. Use of these weapons could cause widespread illness among unprotected U.S. forces. Anthrax is the biological weapon most likely to be encountered because it is:

- highly lethal
- easy to produce in large quantities
- relatively easy to develop as a weapon
- easily spread over a large area
- easily stored
- dangerous for a long time

What is anthrax?

Anthrax is a disease normally associated with plant-eating animals (sheep, goats, cattle and, to a lesser degree, swine). It is caused by the bacteria *Bacillus anthracis*. Once common where livestock was raised, it is now controlled through animal vaccination programs. Anthrax still occurs in countries where animals are not vaccinated, mainly in Africa and Asia. It occurs infrequently in many countries, including the United States. Human infection with anthrax usually results from direct contact with infected animals or animal products such as wool, meat or hides. However, when anthrax is used as a biological weapon, people become infected by breathing anthrax that is released into the air. Inhalation anthrax is the disease that results from breathing in anthrax spores. Under expected battlefield conditions, experts believe you can inhale

enough anthrax spores in one deep breath to kill you. Symptoms of inhalation anthrax can begin as early as 24 hours after breathing the spores. Initial symptoms include fever, cough and weakness. These ultimately progress to breathing problems, shock and death.

#### Why vaccinate?

Vaccines prevent illness by stimulating the body's natural disease-fighting abilities. They are among the most powerful tools developed by modern medicine to keep people healthy. Vaccines are used routinely in the United States to protect against diseases like tetanus, mumps, measles, whooping cough and polio. Vaccines also help protect against biological weapons like anthrax. As part of Force Health Protection, Department of Defense and Coast Guard personnel are given additional vaccines to provide maximum protection against naturally occurring diseases encountered when deploying overseas, such as typhoid, hepatitis A and vellow fever. The DoD has established a vaccination program to protect DoD and Coast Guard personnel against anthrax. What is the anthrax vaccine?

The anthrax vaccine is a sterile product made from a strain (type) of the anthrax organism that does not cause disease. The vaccine contains no living or dead anthrax organisms. Vaccination produces antibodies that neutralize the disease-causing protein common to every strain of anthrax.

The anthrax vaccine is not new. Human anthrax vaccines were developed in England and the United States in the 1950s and early 1960s. The anthrax vaccine you will receive was licensed in 1970 by the Food and Drug Administration and is manufactured by BioPort Corporation (Lansing, Mich.) under License No. 1290, formerly the Michigan Biologic Products Institute, under License No. 99.

It has been safely and routinely administered in the United States to atrisk veterinarians, laboratory workers and livestock handlers since 1970.

# Commonly asked questions & answers

## Why are we getting this vaccine?

Anthrax is a lethal biological weapon we may encounter. Vaccination before exposure is a critical part of our protection against this weapon. Is the vaccine all I need to protect against inhalation anthrax?

Vaccination is a vital component of Force Health Protection. Being fully vaccinated greatly increases your chances of surviving an exposure to anthrax. Force Health Protection is further enhanced through sophisticated early warning and detection systems, health surveillance measures and the proper wear of protective masks and overgarments. Antibiotics play a limited role, but vaccination is essential.

#### Is this an experimental vaccine?

No. The anthrax vaccine has been FDAlicensed since 1970.

#### Is this vaccine safe?

Yes. The vaccine has been safely administered in the United States since 1970. However, as with other vaccines, minor reactions are common. Serious adverse events occur rarely after any vaccination.

# What are the side effects?

Like all vaccines, anthrax vaccine may cause soreness, redness, itching and swelling at the injection site. Up to 30 percent of men and 60 percent of women report mild local reactions, but these reactions usually last only a few days.

For both genders, between 1 percent and 5 percent report reactions of 1 to 5 inches in diameter. Larger reactions occur about once per hundred vaccinees or less. A lump at the site occurs commonly, usually lasting for a few weeks before going away on its own, if left alone.

Beyond the injection site, from 5 percent to 35 percent will notice muscle aches, joint aches, headaches, malaise, rashes, chills, low-grade fever, nausea or related symptoms. These symptoms usually go away in less than a week..

Serious events, such as those requiring

hospitalization, are rare for any vaccine. For anthrax vaccine, they happen about once per 50,000 doses. Severe allergic reactions occur less than once per 100,000 doses.

Discuss with your health-care provider whether over-the-counter antihistamines or pain relievers before or after vaccination can help reduce bothersome symptoms. Report adverse events after vaccination to your healthcare provider promptly, before receiving additional vaccinations.

## What about long-term side effects?

At Fort Detrick, 1,500 lab workers have been tracked for 10 to 20 years or more after anthrax vaccination. These employees have been monitored annually. None developed unexplained symptoms due to repeated doses of this or other vaccines they received. From this and other monitoring, no patterns of delayed side effects to anthrax vaccines have been found. Monitoring continues.

## What if I'm pregnant or breastfeeding?

Anthrax vaccination, like other non-living vaccines, is not expected to cause fetal harm. No evidence exists to indicate that adverse reproductive effects occur after vaccination, including infertility. Prudent medical practice is to defer vaccination during pregnancy unless clearly needed. Therefore, pregnant women should not receive the anthrax vaccine unless anthrax exposure occurs or is imminent.

Women who believe they may be pregnant should inform their health-care provider before vaccination. If pregnancy is confirmed, anthrax vaccinations will be deferred until the woman is no longer pregnant. The Centers for Disease Control and Prevention report that vaccines are safe for breastfeeding women, causing no harm to children who are breastfed.

# What if I'm planning to have children?

The vaccine contains no infectious substance. Therefore, there is no reason to delay childbearing. This applies to both men and women who are vaccinated.