

29 years of use prove anthrax vaccine safe, effective

Partial truths, misinformation and misinterpretation about anthrax immunization are driving some people to make career-altering decisions based on fear, rather than fact. People need the facts on this critical force protection issue, and the facts are:

- Anthrax is the most likely biological weapon and poses a threat to our forces, especially in high-risk theaters of operation.

- Anthrax, as a biological weapon, is nearly 100 percent lethal.

- The vaccine is safe and effective.

- Given these facts, failure to immunize our troops would be unconscionable.

How do you know this vaccine is safe?

Anthrax vaccine has been proven safe during more than 29 years of use. The Food and Drug Administration, which has the strictest quality criteria of any industrialized country, has repeatedly verified anthrax vaccine is safe and effective. They test every vaccine lot for sterility, safety, purity and potency before distribution.

In her written congressional testimony on Oct. 12, Dr. Kathryn Zoon, director of the FDA's Center for Biologics Evaluation and Research stated, "We believe anthrax vaccine is a safe and effective vaccine for the prevention of anthrax disease - an often-fatal disease. Our confidence in this vaccine, like all vaccines, is based upon four components: first, the clinical trials and subsequent clinical laboratory experience with the vaccine; second, ongoing inspections of the manufacturing facility; third, our lot release requirements; and fourth, our ongoing collection of adverse event reports."

Rumors say the vaccine stockpile is contaminated; how do you know this isn't true?

No valid scientific or even circumstantial evidence exists to support those rumors. Every lot is inspected and evaluated for sterility, safety, purity and potency.

Testing is done at the manufacturer and sometimes the FDA as well. At DoD's request, additional testing with independent verification started in January 1998 on all stockpiled vaccine lots. Any questionable lots are quarantined until testing verifies safety and efficacy.

Is it true no long-term studies of the vaccine have been conducted?

The FDA hasn't routinely recommended, required or conducted long-term studies for vaccines (including influenza, tetanus, diphtheria, typhoid, polio, and yellow fever, to name a few) because neither cancer nor fertility problems are known to be associated with vaccines.

Since 1970, the Michigan Department of Public Health has kept long-term data on anthrax vaccine. About 1,000 doses a year are given to veterinarians, laboratory workers and livestock handlers; MDPH reports no significant adverse effects and no known long-term side effects. In 1985, the FDA re-evaluated the product and did not recommend any long-term studies.

Aren't a lot of people having serious adverse reactions to the vaccine?

Although one Air Force base is reporting a larger number of possible reactions than expected, across DoD, the number of side

effects is very small, and mostly minor. The intense focus and increased media coverage makes the number seem much higher than it is.

Any vaccine can cause some people to have adverse reactions. This vaccine is no different, but the numbers are smaller than most other vaccines and few serious reactions have occurred.

The FDA has a reporting system to track unexpected adverse reactions and rapidly recall vaccines. This Vaccine Adverse Event Reporting System is a nationwide system, not a military one. Providers or patients may access this system to report reactions directly to the FDA. Although never intended to report all reactions, it works as an early warning system. A team of civilian medical experts review these reports every four to six weeks, looking for trends or any indication that a vaccine may be causing an unexpected or severe reaction.

As of Oct. 20, 362 adverse reactions reports have been filed on 1.2 million shots given to more than 350,000 people. Of the 98 serious reactions (loss of duty greater than 24 hours or hospitalizations), 64 have been judged by the expert panel to most probably be due to the vaccine. This is a rate of less than .1 percent!

What about the "mystery" illness we hear is occurring?

Most individuals with "unexplained" illnesses are located at one base. Many of the illnesses they're demonstrating are rarely, if ever, associated with vaccines. If the vaccine were the cause, one would expect to find the same type of illnesses occurring wherever people are being immunized.

Epidemiological examinations of data from this one base, including an analysis conducted by the Mayo Clinic, found there was no consistent pattern of symptoms, lot contamination was not suspected, and a cause could not be determined.

How do we know this vaccine will be effective against inhalation anthrax?

Although the vaccine was formulated to protect individuals exposed to anthrax through skin contact, the bacteria is the same, regardless of the way it gains access to the body.

A scientific study of the vaccine's ability to protect people against inhalation anthrax would require exposing both immunized and non-immunized groups to anthrax to ensure the immunized people were protected and the non-immunized people got the disease. Obviously this is not ethical. However, Rhesus monkeys, which have immune systems similar to humans, were used to test the effectiveness of the vaccine and produced compelling evidence that the vaccine series will be effective at preventing disease after someone is exposed to airborne spores (inhalation anthrax). No vaccine is 100 percent effective, but this disease is very near 100 percent fatal if you are not immunized.

Is it true the FDA has shut down the anthrax vaccine manufacturing facility?

In 1994, 1995 and 1996, BIOPORT received rigorous inspections of their plasma

Misinformation puts airmen at risk

by Staff Sgt. Cynthia Miller
Air Force Print News

Since the Department of Defense made vaccination mandatory, anthrax has become a hot topic of conversation.

Many service members—active, Guard and Reserve—may have jeopardized their military careers due to information gained from potentially unreliable sources. Pilots, lately the most visible challengers of the anthrax vaccination program, stand to risk the most. Or do they?

"Much of our earning capacity as airline pilots occurs in the final years that we serve with the airline," said Brig. Gen. Myron Ashcraft, chief of staff, Ohio Air National Guard and a United Airlines pilot. "For that reason, it is imperative that we reach age 60, mandatory retirement age, still able to pass a physical examination every six months."

In recent testimony before the House Armed Services Committee, Rep. Benjamin Gilman, R-N.Y., said, "25 of the 48 pilots at Stewart Air National Guard Base, N.Y., have submitted resignations to be held in the event mandatory anthrax vaccination goes forward. Most of them happen to be airline pilots, very much concerned about their physical conditions following vaccination."

This speaks to a rumor in the flying world that civilian airlines won't hire military pilots who've had the anthrax vaccine.

"I have been a commercial airline pilot since 1978 and can assure you that any-

thing that might jeopardize my career has my full attention," Ashcraft said.

But according to the general, the anthrax vaccination is a non-issue for commercial airlines and the Federal Aviation Administration's Aeromedical Certification Division.

Taking the anthrax shot has no effect on airline hiring and no effect on being granted a civilian medical certificate, according to Ashcraft. "United (Airlines) does not even ask if you have had the shots," he said.

"No one has refused the shots here," said Tech. Sgt. Mark R. Mellinger, public health flight NCO. "We brought in some individuals with questions about the vaccine and briefed them. So far we have given over 8000 shots to 1700 personnel."

Charleston AFB is still in Phase One of the vaccination process.

"We are currently vaccinating all members being sent to Southwest Asia or Korea," said Mellinger. "Air Mobility Command has added all flyers and the Phoenix Ravens to Phase One. Charleston, with AMC approval, has also added Combat Camera personnel and a few individuals from finance."

One place to find factual information is the Anthrax Tool Kit.

This site is currently restricted to ".mil" hits only, and must be accessed from a computer authorized for access to .mil sites. However, officials are working to release the site into the public domain. Until then, the tool kit is available at sgwww.satx.disa.mil/moasgop/restricted/ccaindex.cfm.

derivatives and rabies vaccine manufacturing operations that included several deviations from FDA standards. In March 1997, the FDA issued a "Notice of Intent to Revoke" (NOIR) letter—threatening to initiate proceedings to revoke their license for not correcting these discrepancies. None of these problems were associated with the production of anthrax vaccine. The facility was never shut down, their license was never revoked and no product was ever seized by the FDA.

MBPI developed a strategic plan, including production renovation to correct the problems noted in the plant. Bioport is following that plan. In all, the FDA and its predecessor, National Institutes of Health have inspected the labs 48 times since 1969. All vaccines used by DoD have undergone FDA and independently verified supplemental testing to ensure sterility, safety, purity and potency.

Will this vaccine be effective against newly developed or altered strains of anthrax?

The current vaccine has been tested against many strains and has been found effective. It would be difficult to develop and weaponize a form of anthrax to defeat the vaccine, which works at the fundamental molecular level common to all kinds of anthrax.

It's effective against naturally occurring anthrax strains, and protection is based on a protein found in all known strains of the organism. It would be a formidable task to alter this protein, which is central to the mechanism of the disease, and still retain the effectiveness of the modified organism as a weapon.

Why isn't this a voluntary vaccine?

Anthrax poses a real threat to the military and immunization is the single most effective way to protect the troops.

"We have a vaccine that can protect our troops from this deadly weapon. It would be irresponsible for us to deploy our servicemen and women without using this safe and efficacious vaccine," said Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, in her congressional testimony.

Summary

Fear is causing people to make career-altering decisions based on half-truths and misunderstandings. The facts speak for themselves.

Anthrax is a vaccine, just like other vaccines. It protects against a bacteria just like typhoid, tetanus, diphtheria, and many other vaccines. It just happens to be a bacteria that not only occurs naturally but also can be concentrated and used as a biological warfare agent. (AFPN)