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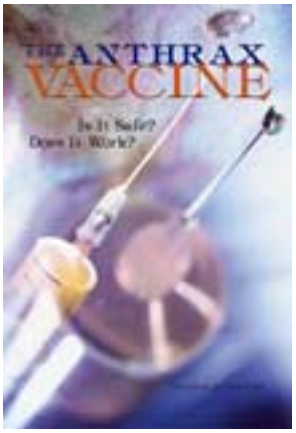
INSTITUTE OF MEDICINE

Shaping the Future for Health

THE ANTHRAX VACCINE: IS IT SAFE? DOES IT WORK?



In autumn of 2001, anthrax emerged as a national concern. Deliberate distribution through the mail of anthrax bacteria led to at least five deaths and 13 non-fatal infections. Thousands of people received treatment for known or suspected exposure to the bacteria.

An Institute of Medicine (IOM) study already under way on the vaccine now used to protect humans against anthrax, called Anthrax Vaccine Adsorbed, was accelerated in response to these events. The IOM issued its report—*The Anthrax Vaccine: Does It Work? Is It Safe?*—in March 2002.

HOW DO PEOPLE GET ANTHRAX?

Anthrax is caused by bacteria that are usually confined to animals such as cows and sheep. Historically, humans have gotten the disease through contact with animals or animal products, such as hair or hides, that are contaminated with anthrax "spores." These spores, which are dormant forms of the bacteria, can exist in the environment for years. If a person takes in spores—perhaps by breathing or through a cut in the skin—the spores can then germinate into active bacteria that produce powerful poisons.

Major concern now centers on the possibility that terrorists or a hostile nation might use "bioweapons" to expose large numbers of people—soldiers or civilians—to anthrax spores. What makes anthrax attractive for such use is that its spores can be processed into a form (such as the "white powder" circulated in ordinary envelopes sent through the mail) that can readily become airborne and spread across fairly wide areas. Anyone exposed to the spores will be at risk of developing anthrax.

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DOES THE VACCINE WORK?

The IOM report concludes that the vaccine is effective in protecting humans against anthrax. The vaccine is administered in a series of six subcutaneous (under the skin) injections. After the initial dose, shots are given at 2 weeks, 4 weeks, 6 months, 12 months, and 18 months. Annual booster shots are required.

The vaccine should protect people against all known strains of anthrax bacteria, as well as against any strains that might be created by potential terrorists or others. It may be beneficial in another way as well. For unvaccinated people who breathe in anthrax spores, administering the vaccine along with antibiotic drugs may keep them from developing the disease.

IS THE VACCINE SAFE?

The IOM report concludes that the vaccine is acceptably safe.

The IOM report concludes that the vaccine is acceptably safe. People receiving the vaccine do not face an increased risk of life-threatening or permanently disabling effects, either immediately after vaccination. There also appears to be no increased risk of experiencing serious health effects in the years following vaccination, although information on later-onset effects is limited.

It is fairly common for people to experience local reactions, such as redness and swelling at the injection site, within hours or days of vaccination. A smaller number of people experience more general reactions, such as fever and malaise. But such reactions soon go away on their own. These reactions, and the rates at which they occur, are comparable to those observed with other vaccines given to adults.

CAN IMPROVEMENTS BE MADE?

Even though the vaccine has proven acceptably safe and effective, improvements are needed. This takes on particular urgency since the military may speed up its anthrax vaccination program and the government may consider providing vaccinations for "high-risk" persons in the civilian population, such as postal investigators, FBI agents, and members of the Centers for Disease Control and Prevention (CDC) investigative teams who will be called upon to assess suspected anthrax-exposure events.

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The IOM report concludes that advances are needed in several main areas: improving the way the vaccine is now used, expanding surveillance efforts to detect side effects from its use, and developing a better vaccine. Among the actions suggested:

- ***Better ways to administer the vaccine should be developed.*** The current method of injecting the vaccine under the skin and using a series of six doses may not be ideal. Studies suggest that injecting the vaccine into the muscle (the route employed for most other vaccines) and using fewer doses will be effective while causing fewer instances of bothersome local reactions.
- ***The Department of Defense should strengthen systems for detecting health problems that might occur months or years after the receipt of any vaccine, including the anthrax vaccine.*** One approach is to use the Defense Medical Surveillance System (DMSS) to follow up on any suspicious data that emerge from other reporting systems now in use. Administered by the Army, DMSS brings together health-related information on every active service member. Since DMSS can follow service members over their entire length of service, it will provide a longer period of observation than is available for most vaccine safety studies.
- ***Future monitoring of adverse health effects should continue to include separate analyses of data for men and women.*** Women appear more likely than men to experience local reactions from the anthrax vaccine, or from other vaccines.

Why this happens is not known, but may be due to such factors as differences in body mass or care-seeking behavior.

- ***The Department of Defense should speed up its research to develop an improved vaccine.*** A new vaccine should not cause any severe local reactions, should require only two or three injections that provide protection for at least a year, and should remain potent for a long period of time so that it can be stockpiled to ensure ample supplies when needed.

WHAT PROMPTED THE IOM STUDY?

The vaccine was approved by the government in 1970. It was first used on a limited basis, primarily to protect people who might be exposed to anthrax spores where they worked, such as veterinarians and textile plant workers who process animal hair. In 1991, its use expanded greatly. The U.S. military, worried that Iraq possessed anthrax bioweapons, administered the vaccine to some 150,000 service members deployed for the Gulf War. When it later became clear that Iraq had indeed developed anthrax bioweapons, the Department of Defense announced a plan for the mandatory vaccination of all U.S. service members. The Anthrax Vaccine Immunization Program began in March 1998 with personnel sent to high-risk areas, such as South Korea and Southwest Asia.

As more service members received the vaccine, however, some of them raised concerns about how well it works and how safe it is. Some service members also suggested that the vaccine might have caused the illnesses experienced by some Gulf War veterans. In addition, problems arose with manufacture of the vaccine. In early 1998, the only company making the vaccine closed its facility for renovation. The company resumed limited production in 1999, but the Food and Drug Administration prohibited the release of any newly produced vaccine until the company demonstrated that its production process met all federal regulations. Following the halt in production, supplies of the vaccine dwindled, and by 2000 the military had extensively slowed its vaccination program.

In response to these concerns, Congress directed the Department of Defense to support an independent examination of the vaccine. In October 2000, the Institute of Medicine convened the Committee to Assess the Safety and Efficacy of the Anthrax Vaccine to carry out this study. Recognizing that it was dealing with difficult and controversial issues, the committee chose to be as open as possible, electing to hear from all groups and individuals who wished to contribute data, concerns, or complaints. The committee prepared its report after considering all available evidence.

The bottom line: the vaccine will be produced under strict controls according to current federal requirements.

IS MORE VACCINE BEING MADE?

The vaccine manufacturer received government approval of to release newly-produced vaccine in January 2002, and it plans to begin shipping new supplies in the near future.

As part of its study, the IOM committee reviewed and evaluated the steps taken by the company to gain approval. The bottom line: the vaccine will be produced under strict controls according to current federal requirements.

For More Information…

Copies of ***The Anthrax Vaccine: Is it Safe? Does it Work?*** are available for sale from the National Academy Press; call (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP home page at **www.nap.edu.** The full text of this report is available at **http://www.nap.edu**

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The Institute of Medicine is a private, nonprofit organization that provides health policy advice under a congressional charter granted to the National Academy of Sciences. For more information about the Institute of Medicine, visit the IOM home page at **www.iom.edu.**

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