United States General Accounting Office

GAO

Testimony

Before the Committee on Armed Services, U.S. Senate

MEDICAL READINESS

DOD Continues to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program

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GAO/T-NSIAD-00-157

Mr. Chairman and Members of the Committee:

We are pleased to be here today to discuss our past work on the Department of Defense's (DOD) anthrax vaccine immunization program. As you know, DOD regards the biological agent anthrax, an infectious disease that is 99-percent lethal if inhaled by unprotected humans, as the single greatest biological weapon threat to U.S. military forces. DOD considers vaccination one of the measures critical to protecting U.S. forces against such weapons. In December 1997, the Secretary of Defense announced a plan to immunize all active and reserve military personnel with a licensed anthrax vaccine. In August 1998, DOD began immunizing all 2.4 million U.S. military personnel—including all active and reserve personnel—against anthrax.

Today we would like to provide a brief update on three key findings of our October 1999 report. The findings relate to vaccine supply, medical records, and efforts to educate servicemembers about the program.[1] We have also reviewed other aspects of the anthrax vaccine immunization program, including the safety and efficacy of the vaccine and the contracts with the manufacturer. Our related reports are listed in an attachment to this statement.

Summary

In October 1999, we reported on challenges to implementing DOD's anthrax immunization program. First, we noted that supply problems caused by the manufacturer's inability to obtain Food and Drug Administration (FDA) approval to distribute vaccine manufactured at its renovated facility and problems testing previously stockpiled vaccine jeopardized DOD's schedule for vaccinating all 2.4 million servicemembers. Today, this fundamental requirement of the program—maintaining an adequate supply of vaccine—has not yet been met. The manufacturer has not yet obtained FDA approval to distribute vaccine produced at its renovated facility, and this approval is not expected until late 2000. Program officials expect the current supply to last until July 2000. Although program officials expect FDA to approve the release of previously stockpiled vaccine before the available supply is depleted, this expectation may be optimistic given past testing problems. DOD is vaccinating only personnel who are being deployed to high-threat areas and has delayed vaccinations of personnel in units scheduled for early deployment. If the manufacturer does not obtain FDA approvals as expected, DOD may be forced to halt vaccinations, at least temporarily. Moreover, DOD still lacks a contingency plan in the event supply problems are not resolved in time.

Second, we reported that DOD's recording and tracking system of servicemembers who receive vaccinations is an improvement over the system used during the Gulf War and in Bosnia but that DOD was not meeting its requirement to record vaccination data consistently both in paper records and in its central database. DOD reported that it planned to take further steps to improve its central database. Also, we recommended that DOD collect data on the number of servicemembers refusing the vaccine so that it can better understand servicemembers' concerns. To date, the Army has drafted a policy to collect data every 3 months. The other services are not planning to require periodic reporting but will provide data on vaccine refusals when requested.

[1] *Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program* (*GAO/NSIAD-00-36*, Oct. 22, 1999).

Finally, we reported on the results of our survey, which showed that servicemembers wanted more information on long-term side effects and procedures for reporting possible side effects from the vaccine. DOD has taken initiatives to carry out a high-visibility education campaign to inform servicemembers about the vaccine program. For example, it has implemented a speakers' bureau, has updated its Internet site, and is sponsoring studies of health effects related to the vaccine.

Supply Problems Jeopardize Vaccination Program

As of March 2000, DOD had administered at least 1.6 million anthrax vaccinations to about 419,000 servicemembers, but supply problems jeopardize its schedule for vaccinating all 2.4 million servicemembers.[2] As of April 10, 2000, DOD had approximately 273,000 doses of vaccine tested and available for use. Assuming the program continues to administer vaccines at its current rate of about 75,000 doses per month, DOD officials estimate that the supply will be depleted by July 2000 unless more lots[3] of vaccine are made available. The supply can only be increased if FDA grants permission for the sole manufacturer to release vaccine produced at its renovated facility or the vaccines stockpiled before the renovation are successfully tested and released by FDA. There are problems in both areas.

First, the manufacturer, BioPort Corporation,[4] Lansing, Michigan, has yet to receive FDA approval of its manufacturing processes following a 17-month shutdown of the facility for renovation. Until BioPort obtains this approval and additional approvals for the release of each lot, it cannot release lots produced after the renovation.[5] According to a DOD contractor's assessment of a November 1999 FDA inspection report, the FDA identified 30 deficiencies, largely dealing with BioPort not fully complying with FDA Good Manufacturing Practice regulations. The assessment noted that there may be at least two significant issues BioPort must address, namely implementing a program to validate vaccine manufacturing and testing processes and systems to ensure product quality. DOD has taken several initiatives to support and oversee BioPort's efforts to obtain FDA approval. According to a contracting official, DOD intends to order BioPort to stop production of the vaccine and focus efforts on measures to validate the manufacturing process. DOD also plans to assist BioPort by funding consultants to help BioPort obtain FDA approval and to keep the facility operating at a low level. DOD officials estimate BioPort will not obtain FDA approval of its manufacturing processes until late 2000.

[2] The vaccination program is scheduled to be implemented in three phases. Phase 1—begun in 1998—includes vaccinations of servicemembers assigned or rotating to high-threat areas. Phase 2—originally scheduled to begin in January 2000 but not yet begun—includes vaccinations for early deploying units. Phase 3 includes vaccinations for the remainder of the force. The regimen for the vaccine is an initial series of three vaccinations at 2-week intervals, followed by a series of three vaccinations at 6-month intervals, with annual boosters thereafter.

[3] A lot contains approximately 200,000 doses, but at the start of the program some lots contained fewer doses because of previous commercial sales and military use.

[4] In 1998, the facility was sold and the manufacturer's name was changed from Michigan Biologic Products Institute to BioPort Corporation. Plans for renovation began under the former name.

[5] According to a program official, the lots tested to obtain FDA approval of the new facility's manufacturing processes will also be tested for release and should therefore be immediately available. FDA will have to approve future lots produced after the renovation individually.

BioPort's inability to obtain FDA approval of its anthrax production processes has led to serious cash flow problems. Further delays will only exacerbate these problems.

Second, unless the currently available 273,000 doses are augmented with additional approved vaccine from the stockpile, the program will be without vaccine from July through late 2000 (or whenever BioPort obtains FDA approval) if it continues administering vaccinations at its current rate. When the manufacturer suspended production in January 1998 to undertake renovations, it still had 40 lots of anthrax vaccine stockpiled at its plant. Of these, 31 had passed all the tests and had received FDA approval for release. To ensure that no changes had taken place in the approved vaccine since FDA granted approval, DOD decided to subject the 31 approved lots to a series of supplemental tests for purity, potency, sterility, and safety. Since supplemental testing began in January 1998, 11 of the 31 lots have been made available for use; but 20 lots are still unavailable due to test failures or problems with the tests themselves. For example, some vaccine lots did not contain sufficient levels of a required preservative (test failure), while testing of other lots may have been invalidated because underweight guinea pigs were used as test subjects (test problems). For the remaining nine lots produced just before the renovation shutdown, BioPort needed only to obtain the normal FDA approval for release. As of April 10, 2000, five of these nine lots had been approved for release. In sum, only 16 of the 40 vaccine lots in the stockpile have been released, and according to program officials, almost all have already been used by the program.

Program officials plan to conduct tests on and obtain FDA approval for release of a limited number of stockpiled lots, thus augmenting the currently available doses before they are depleted. They estimate that this will provide sufficient vaccine to continue the program until FDA grants permission to release lots produced after BioPort's renovation, possibly by late 2000. Our analysis shows that DOD's time frames for testing and gaining FDA approval of these stockpiled lots may be optimistic. For example, it assumes that FDA will expedite approval of a revised testing protocol and final test results and that BioPort will not encounter testing problems as it has in the past.

Because of the limited vaccine supply, DOD is vaccinating only personnel who have deployed to high-threat areas and has delayed vaccinations of personnel in units scheduled for early deployment. The original date to begin vaccinating this latter population was January 2000. In response to our recommendation, DOD drafted a contingency plan to ensure the continued, measured implementation of the program, but the Office of the Secretary of Defense has not yet approved this plan.

Recording and Tracking of Vaccinations Have Improved, but Further Improvements Are Possible

In October 1999, we reported that DOD's recording and tracking system for the anthrax vaccination program is an improvement over the system used during the Gulf War and in Bosnia. However, DOD was not meeting its requirement to record vaccination data consistently both in paper records maintained at its installations and in electronic records in its central database. We compared servicemembers' vaccination records from DOD's central database with paper records at four military installations.[6] At three sites, we found that between 85 and 97 percent of paper and electronic records agreed on the number of anthrax vaccinations that had been administered. At two sites, however, matches were lower (between 17 and 69 percent) for the date of the vaccination and the vaccine's lot number. Matches in all categories were much lower at the fourth installation, with match rates of 22 percent for the number of vaccinations, 17 percent for the vaccination date, and 8 percent for the lot number.

These problems were caused in part by delays in updating data on information in the central database. For example, delays in updating data on individuals' duty stations impeded DOD's ability to use its central database to manage vaccination schedules and assess unit readiness. Commanders need updated duty station information to ensure that their personnel receive vaccinations on time and are ready for deployment. An accurate centralized database is also important for tracking which vaccine lots are administered, should health concerns about a specific lot emerge. In its response to our report, DOD said it would take aggressive steps to ensure the timely and accurate updating of personnel data in the database.

In addition, at the time of our review, DOD had not collected data on personnel who refused vaccination or left the service to avoid vaccination. DOD thus did not have an important tool to gauge the extent of resistance to the program and target training resources to give servicemembers needed and wanted information. In its response to our report, DOD said that it was reviewing a draft policy memorandum on reporting servicemembers' refusals to be vaccinated. In April 2000, a program official told us that this policy will apply only to the Army and will require major commands to provide quarterly reports on soldiers who refuse the vaccine. The other services are not planning to require periodic reporting but will provide data on vaccine refusals when requested. According to the program official, a servicemember is considered to have refused the vaccine only after he or she initially declines the vaccine, receives education and counseling (either verbally or in writing), and then disobeys a direct order to take the vaccine.

[6] We visited one location per service where a large number (more than 1,000) of vaccinations had been given: Fort Stewart, Hinesville, Georgia, for the Army; the *USS Eisenhower*, Norfolk Navy Shipyard, Portsmouth, Virginia, for the Navy; Langley Air Force Base, Hampton, Virginia, for the Air Force; and Camp Lejuene, Jacksonville, North Carolina, for the Marine Corps.

DOD Has an Extensive Education Campaign and Has Begun to Monitor Its Effectiveness

DOD and the services have used a variety of measures to educate servicemembers about the program and have taken steps to address controversy surrounding the program. However, our survey of 249 servicemembers at the four military installations between December 1998 and March 1999 indicated that many of them wanted more information on the program. More than two-thirds of survey respondents reported that the information they received on the reasons for the program, vaccination requirements and schedules, and consequences of refusing the vaccination was at least moderately helpful. However, over half said they either received no information on possible long-term side effects and procedures for reporting side effects or found the information less than moderately helpful. Although many respondents wanted more information on long-term side effects, data on this topic is limited because no long-term studies have been carried out.

At the time of our survey, DOD had not monitored the effectiveness of its educational campaign. But after our survey, DOD initiated several steps to improve its educational campaign. It established a communications division to focus on servicemembers' information needs. The division updated the program's Internet site and set up a toll-free information line and a traveling speakers' bureau of experts on anthrax and the vaccine. DOD has also begun monitoring its educational efforts. Specifically, the program now surveys servicemembers who have begun or are scheduled to begin the series of anthrax vaccinations. The survey collects information on the availability, timeliness, and effectiveness of the program's educational materials.

In its comments to our October report, DOD stated that it had taken several actions to improve guidance and training on reporting adverse events associated with the vaccine.[7] These actions included updating or developing briefings and fact sheets required to be given to servicemembers and clinicians and providing links to adverse event reporting forms through DOD's anthrax vaccine Internet site. We have not assessed these actions or evaluated their impact on the reporting of adverse health events.

To address questions regarding the safety of the anthrax vaccine, DOD established a Longitudinal Studies Concept Committee to define research needs and identify subsequent research designs. The Committee, which includes members from DOD, FDA, the Centers for Disease Control and Prevention, and the Armed Forces Epidemiological Board, met in August and September 1999 and recommended some research designs. One of the studies being planned is a prospective study of servicemembers that will follow the health effects over multiple years of vaccine and non-vaccine recipients. This study is scheduled to begin in 2001.

[7] Adverse events are outcomes for which a cause-and-effect relationship with an exposure (to a vaccine or a medication) has not yet objectively been determined. An adverse event becomes an adverse reaction once objective evidence is available to establish a cause-and-effect link between an exposure and an adverse outcome.

Mr. Chairman and Members of the Committee, this concludes our formal statement. We would be happy to answer any questions you may have.

Contact and Acknowledgments

For future contacts regarding this testimony, please contact Carol Schuster at (202) 512-5140. Individuals making key contributions to this testimony included Christine Fossett, Margaret Best, and Howard Deshong.

Related GAO Products

Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/NSIAD-00-36, Oct. 22, 1999).

Anthrax Vaccine: Safety and Efficacy Issues (GAO/T-NSIAD-00-48, Oct. 12, 1999).

Medical Readiness: Issues Concerning the Anthrax Vaccine (GAO/T-NSIAD-99-226, July 21, 1999).

Contract Management: Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer (GAO/T-NSIAD-99-214, June 30, 1999).

Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Chemical and Biological Defense: Observations on DOD's Plans To Protect U.S. Forces (GAO/T-NSIAD-98-83, Mar. 17, 1998).

Defense Health Care: Medical Surveillance Improved Since Gulf War, But Mixed Results in Bosnia (GAO/NSIAD-97-136, May 13, 1997).

Chemical and Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems (GAO/NSIAD-96-103, Mar. 29, 1996).

Chemical and Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems (GAO/T-NSIAD-96-123, Mar. 12, 1996).

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