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United States General Accounting Office
Washington, DC 20548

December 1, 2003

The Honorable Susan M. Collins
Chairman
Committee on Governmental Affairs
United States Senate

Subject: *Smallpox Vaccination: Review of the Implementation of the Military Program*

Dear Chairman Collins:

On December 13, 2002, in response to growing concern that a terrorist or hostile regime might have access to the smallpox virus and attempt to use it against the American people, the President announced the formation of the National Smallpox Vaccination Program. The program has two components—one responsible for vaccinating civilians and another responsible for vaccinating military personnel. The Centers for Disease Control and Prevention (CDC) is responsible for implementing the civilian component of the National Smallpox Vaccination Program. The Department of Defense (DOD) is responsible for implementing the military component of the program.

Because the National Smallpox Vaccination Program is the nation's first large-scale bioterrorism defense program, you asked us to assess the implementation of the program in order to aid the development of future programs. In April 2003, we reported on the implementation of the civilian component of the National Smallpox Vaccination Program.¹ In this report, we describe (1) how DOD implemented its smallpox vaccination program and (2) the steps DOD took to facilitate the implementation of the program.

To describe how DOD implemented its smallpox vaccination program and the steps it took to facilitate the implementation of the program, we reviewed DOD's planning guidance for the program, implementation plans related to the program, training for vaccinators, and educational materials for vaccinees. We also reviewed CDC guidelines and documents related to the civilian program that were used in the military's smallpox vaccination program. We interviewed Army, Navy, Air Force, and Marine officials and reviewed written responses to our questions provided by the

¹U.S. General Accounting Office, *Smallpox Vaccination: Implementation of the National Program Faces Challenges*, [GAO-03-578](#) (Washington, D.C.: Apr. 30, 2003).

Army National Guard and the Coast Guard. We observed the vaccination process at Andrews Air Force Base. In addition, we reviewed the Institute of Medicine's recommendations and CDC's and DOD's policies for monitoring and recording adverse health events² following the vaccinations. We obtained information about adverse health events from DOD and CDC. We performed our work from April through November 2003 in accordance with generally accepted government auditing standards.

Results in Brief

DOD implemented its smallpox vaccination program in stages and took steps to prevent and monitor adverse health events following the vaccinations. The first stage of the smallpox vaccination program consisted of a pilot program that began in December 2002, during which DOD vaccinated and monitored the health of military personnel at four sites. According to DOD officials, the intent of the pilot program was to assess DOD's procedures for administering the vaccine and monitor the frequency of adverse health reactions. After completion of the pilot program, DOD began full implementation of the smallpox vaccination program in mid-January 2003. DOD vaccinated its personnel in stages—prioritizing its personnel according to which groups would be most likely to respond first to a smallpox outbreak. As of October 2003, DOD had vaccinated more than 500,000 military personnel. In order to minimize the number of people who might have adverse reactions to the vaccine, DOD followed CDC guidelines by screening personnel for health conditions that precluded them from receiving smallpox vaccinations. To monitor adverse health events following the vaccinations, DOD used two health information tracking systems, CDC's Vaccine Adverse Event Reporting System (VAERS) and DOD's Defense Medical Surveillance System (DMSS).

To facilitate its vaccination program, DOD took steps to ensure the availability of the vaccine and educate its personnel. Specifically, DOD established practices to limit the amount of vaccine that could be wasted or contaminated. For example, to ensure the vaccine was not wasted due to a loss of potency, its temperature was monitored with a computer chip to ensure that the vaccine was maintained at the proper temperature during shipment. DOD also facilitated the implementation of its vaccination program by educating its personnel—both those who administered the vaccine and those who received it—on related issues, such as vaccination procedures and potential adverse health reactions.

In commenting on a draft of this report, DOD agreed with our findings.

²In this report we use the term “adverse health event” to refer to a health condition that occurred after vaccination and may or may not be attributable to the vaccine. When adverse health events are diagnosed as causally related to the vaccine, we use the term “adverse health reactions.”

Background

Smallpox is a contagious disease that is generally spread through prolonged face-to-face contact, but it can also be spread through direct contact with infected bodily fluids or contaminated objects. Smallpox symptoms include fever and a distinctive skin rash. There is no known cure for smallpox, and it is fatal in about 30 percent of cases. Immunity to the virus that causes smallpox—the variola virus—is conferred through inoculation with a vaccine made from the closely related vaccinia virus. After a worldwide effort of organized vaccinations, the World Health Organization declared, in May 1980, the world free of naturally occurring smallpox.

The health condition of those who receive the smallpox vaccine must be assessed before and monitored after vaccination. Before vaccination, potential recipients of the smallpox vaccine must be screened for contraindications, which are health conditions or symptoms that preclude vaccination. After vaccination, the vaccination site is monitored for a skin lesion, known as a “major reaction” or “take,” which indicates a protective immune response. If the vaccination results in a take, a red itchy bump forms over the vaccination site within 2 to 4 days. Anyone who does not experience a take has to be revaccinated.

The smallpox vaccination may create side effects known as adverse reactions. These adverse reactions include temporary symptoms such as itching, fatigue, muscle ache, and swollen lymph nodes. More serious adverse reactions include accidental inoculation (localized rash elsewhere on the body), encephalitis (inflammation of the brain), generalized vaccinia (rash spread to the entire body), myocarditis or pericarditis (inflammation in or around the heart), and death. Because the vaccine uses live virus, an inadvertent transfer of vaccinia can occur in persons exposed to the vaccination site of someone who has recently received the vaccine. There are two drugs used to treat certain adverse reactions caused by the vaccine: vaccinia immune globulin (VIG) and the antiviral drug cidofovir.

Routine smallpox vaccinations were discontinued among U.S. children in 1972, and among U.S. healthcare workers in 1976. However, in contrast with the civilian sector, DOD continued to provide smallpox vaccinations to its troops. Between 1984 and 1990, smallpox vaccinations were only provided irregularly to recruits during basic training because there were shortages of VIG.³ In 1990, DOD vaccinations were discontinued until the President announced the formation of the National Smallpox Vaccination Program in December 2002.

³In addition, smallpox vaccinations were not provided at some military facilities because some facilities lacked the ability to test for the human immunodeficiency virus (HIV), and DOD does not knowingly vaccinate personnel with HIV.

In administering the civilian component of the National Smallpox Vaccination Program, CDC updated the Smallpox Response Plan and Guidelines (CDC guidelines).⁴ These guidelines include guidelines for recognizing contraindications and vaccine takes, administering and storing the vaccine, recognizing adverse reactions, administering VIG, and monitoring and reporting adverse health events information.

DOD designated the Department of the Army as responsible for overseeing the military component of the National Smallpox Vaccination Program. The Army's Military Vaccine (MILVAX) Agency was responsible for developing clinical guidelines for DOD that are consistent with CDC guidelines for the civilian component of the National Smallpox Vaccination Program. The U.S. Army Medical Materiel Agency (USAMMA) Distribution Operations Center (DOC) was responsible for coordinating the distribution of the smallpox vaccine within DOD.

In September 2002, we reported on DOD's Anthrax Vaccine Immunization Program. Specifically, we reported on the limited availability of the vaccine and general dissatisfaction among military personnel with the completeness and accuracy of the information DOD provided about the anthrax vaccination program and the anthrax vaccine.⁵

DOD Implemented Its Smallpox Vaccination Program in Stages and Took Steps to Prevent and Monitor Adverse Reactions

DOD implemented its current smallpox vaccination program in stages and took steps to prevent and monitor adverse health events following the vaccinations. Prior to full implementation of its program in mid-January 2003, DOD conducted a pilot study during which it vaccinated and monitored the health of military personnel. DOD used CDC's clinical guidelines as a template throughout its smallpox vaccination program for establishing priorities for who would be vaccinated and for screening potential vaccinees for contraindications. DOD also monitored adverse health events following the vaccinations with information supplied by each of the services.

DOD's Smallpox Vaccination Pilot Program Preceded Wider Vaccinations

DOD initiated its smallpox vaccination program with a pilot program. In December 2002, DOD began the smallpox vaccination pilot program by vaccinating and monitoring healthcare personnel at four sites: Walter Reed Army Medical Center, Washington, D.C.; Aberdeen Proving Ground, Md.; Wilford Hall Air Force Medical Center, Lackland Air Force Base, San Antonio, Tex.; and the National Naval Medical Center, Bethesda, Md. According to DOD officials, the intent of this pilot program was to monitor vaccinee take rates and the frequency of adverse health reactions.

⁴Centers for Disease Control and Prevention, *Smallpox Response Plan and Guidelines*, Draft 3.0 (Atlanta, Ga.: Sept. 21, 2002).

⁵U.S. General Accounting Office, *Anthrax Vaccine: GAO's Survey of Guard and Reserve Pilots and Aircrew*, [GAO-02-445](#) (Washington, D.C.: Sept. 20, 2002).

In monitoring vaccinees in the pilot program, DOD found that 1,017 primary vaccinees had a take rate of 95.5 percent, and 975 revaccinees—individuals who had been vaccinated at some point in the past—had a take rate of 95.8 percent.⁶ Further, DOD surveys of about 530 health care personnel vaccinated during the pilot program found that they experienced expected temporary symptoms after vaccination, such as itching, muscle aches, and headaches. DOD also reported that there was no transmission of vaccinia from a healthcare worker to a patient among the 1,992 vaccinations DOD administered.

DOD Began Full Implementation of its Smallpox Vaccination Program in January 2003

In mid-January 2003, DOD began full implementation of its smallpox vaccination program. DOD started vaccinating in stages—prioritizing its personnel according to which groups would respond first to a smallpox outbreak. Healthcare providers were vaccinated first. To do this, DOD began Stage 1a of its smallpox vaccination program, which consisted of vaccinating Smallpox Epidemiological Response Teams who would assist with epidemic control and contact tracing in an outbreak.⁷ DOD’s smallpox vaccination program Stage 1b consisted of vaccinating medical teams and hospital clinic teams who would care for smallpox cases. In Stage 2 of the smallpox vaccination program, DOD expanded its vaccinations to critical mission and support personnel—those who were deployed or assigned overseas, those who would be expected to deploy in a contingency, and those who support contingency forces when they deploy. (For information on the number of personnel vaccinated in each stage, see table 1.)

Table 1: Number of Personnel Vaccinated by Service and Stage as of October 8, 2003

Service	Stage 1a Smallpox epidemiological response teams	Stage 1b Medical and hospital clinic teams	Stage 2 Critical mission and support personnel	Total
Army	726	4,226	220,917	225,869
Air Force	14	3,644	81,782	85,440
Navy	20	2,053	106,476	108,549
Marines	256	0	64,577	64,833
Coast Guard ^a	669	492	16,094	17,255
Total	1,685	10,415	489,846	501,946

Source: Department of the Army.

^aThe Coast Guard is an agency within the Department of Homeland Security.

⁶Primary vaccinees were those receiving the vaccine for the first time. Revaccinees had been vaccinated at some point in the past. Because immunity to the smallpox vaccine decreases over time, DOD revaccinated personnel who had been vaccinated more than 10 years earlier.

⁷Contact tracing is the identification and tracking of individuals who may have been exposed to a person with an infectious disease.

Although the stages of the vaccination program were supposed to be separated, DOD's stages of implementation overlapped because of military deployment to Iraq in early 2003. As a result, thousands of military personnel were vaccinated in a short period of time—over 450,000 were vaccinated as of May 3, 2003—with the number of vaccinations ranging from 300 to 64,000 per week. A DOD official told us that the smallpox vaccination program is currently in a maintenance phase, with the program administering approximately 1,000 to 2,000 vaccinations per week to keep hospital staffs prepared and to prepare new forces supporting U.S. Central Command.

DOD Followed CDC Guidelines in Screening Potential Vaccinees

In administering these smallpox vaccinations, DOD told us it followed CDC's guidelines that recommend screening individuals for the contraindications that preclude smallpox vaccination.⁸ According to these guidelines, DOD would not vaccinate personnel with allergies to the smallpox vaccine, those who were breast-feeding, and those who had certain cardiac conditions. In addition, DOD would not vaccinate personnel with a compromised immune system, eczema or atopic dermatitis, active skin disease such as psoriasis, or those who were pregnant—nor would DOD vaccinate personnel living with someone who had these four contraindications.⁹ DOD implemented this standard because the smallpox vaccine contains a live virus that can be spread from a vaccinee to a household member. Officials from the Navy and Marines said they did not vaccinate personnel living with a child less than 1 year old.

To screen for contraindications, DOD required its personnel to fill out a form identifying contraindications that may exempt them from receiving the smallpox vaccine. Completed forms were reviewed by clinicians to resolve questions about whether specific conditions were contraindications. All services used the same screening form. DOD officials told us that contraindications resulted in exemption rates that varied by military unit, ranging from 11 to 34 percent of eligible personnel. Among service members in deployed units, living apart from their households, the exemption rates were lower—ranging from 4.9 to 7.8 percent. Skin conditions were the primary reason for being exempted from vaccination, followed by pregnancy and immune conditions.

⁸According to DOD's policy, in the event of a smallpox outbreak, all military personnel—including those with contraindications—would be vaccinated.

⁹Despite DOD's efforts to avoid vaccinating women who were pregnant, as of May 28, 2003, 85 women were vaccinated before they knew they were pregnant. These women were offered medical counseling and enrolled in a prospective registry. Similarly, as of May 28, 2003, 10 men were vaccinated before recognition that they were infected with HIV. They did not experience any adverse health reactions at the time they received the vaccine.

DOD Used Two Tracking Systems to Monitor Adverse Health Events

To monitor adverse health events following vaccination, DOD used two health information tracking systems—one to keep CDC officials apprised of adverse events following vaccinations and one for DOD officials. CDC manages, collaboratively with the Food and Drug Administration (FDA), the first system DOD used, the national VAERS.¹⁰ VAERS serves as a national registry of individual cases of adverse events. Data submitted to this tracking system can be supplied by patients or clinicians and are completed on a VAERS form or submitted over the Internet. Although VAERS forms are typically used to record any adverse events following vaccinations, in the case of DOD's smallpox vaccinations, DOD officials said they did not expect clinicians to use VAERS forms to report the temporary symptoms expected in most smallpox vaccinees such as pustule formation, itching, or swollen lymph nodes. DOD officials told us that they decided it was more useful to record noteworthy adverse events on VAERS forms rather than more common adverse events.¹¹

DOD also used its own internal information system, the DMSS, to track adverse health events following the vaccinations. DOD officials told us that military medical units were instructed to file adverse events reports simultaneously with VAERS and with the medical authority in their respective service. Each military service was then required to forward these data to DMSS. The MILVAX Agency reviewed both VAERS and DMSS data. A DOD official told us DOD used the information in DMSS to determine whether vaccinated personnel were using more healthcare services than unvaccinated personnel in order to determine whether the vaccination could be linked to reported adverse events. This information may also be used to help identify new, unusual, or rare vaccine reactions; monitor increases in known adverse reactions; as well as determine patient risk factors for particular types of adverse reactions.

By October 13, 2003, DOD recorded 184 noteworthy adverse reactions among the 501,946 vaccinations DOD administered. Of the 184 noteworthy adverse reactions, DOD reported the following:

- 62 self inoculations (virus affected other parts of body);
- 34 mild cases of generalized vaccinias (blistery body rash);
- 58 acute myopericarditis (swelling of heart tissue or sac around heart);
- 1 encephalitis (swelling of the brain);
- 1 erythema multiforme major (serious skin reaction); and
- 28 inadvertent transfers of vaccinia.

¹⁰VAERS is a national vaccine safety surveillance system that encourages the reporting of any significant adverse reaction occurring after the administration of any vaccine licensed in the United States. Data reported to VAERS are reviewed by both CDC and FDA. FDA reviews adverse reactions reporting trends and assesses whether reported adverse reactions are adequately reflected in a product's labeling.

¹¹DOD defined noteworthy adverse events as those that were "significant, serious, or unexpected and those that the public and clinicians should know about."

Two of the 184 noteworthy adverse reactions were serious enough to require treatments with VIG. According to DOD officials, the reported rate of adverse reactions was similar to or lower than the rates associated with previous U.S. smallpox vaccination programs, which were conducted in the 1960s. However, some experts have noted that these reported rates may not be generalizable to the population as a whole because the military population is relatively young and was carefully screened before receiving vaccinations.¹² DOD officials told us that DOD continues to monitor adverse health events for which a causal association between the vaccine and the event has not been confirmed or may be unlikely. For example, DOD is monitoring the several instances where military personnel have developed a neurologic reaction that included muscle weakness after vaccination.

DOD Facilitated Its Smallpox Vaccination Program by Ensuring the Availability of the Vaccine and by Educating Its Personnel

DOD facilitated its smallpox vaccination program by ensuring the availability of the vaccine and by educating its personnel. Specifically, DOD established practices to limit the amount of vaccine that could be wasted or contaminated. DOD also facilitated its vaccination program by educating its personnel—both those who administered the vaccine and those who received it—on the vaccination process. These actions were intended to help DOD avoid problems it encountered in administering its Anthrax Vaccine Immunization Program—such as the limited availability and general dissatisfaction among military personnel with the completeness and accuracy of the information DOD provided about the Anthrax Vaccination Program and the anthrax vaccine.¹³

DOD Took Steps to Ensure the Availability of the Smallpox Vaccine

DOD took steps to ensure the availability of the smallpox vaccine by limiting the amount of vaccine that could be wasted or contaminated. Because the smallpox vaccine may lose its potency after 90 days once the vaccine vial is opened, DOD officials told us that they took steps to minimize the number of unused doses. For example, to manage requests for the vaccine and thereby minimize the number of unused doses, each vaccination clinic was required to submit requests for the number of doses it needed to the clinic's supporting Service Vaccine Control Center.¹⁴ Once the requests were reviewed by the centers, USAMMA authorized shipment of the smallpox vaccine.¹⁵ Similarly, DOD officials said in order to reduce the possibility of wasting the vaccine supply, USAMMA did not ship the smallpox vaccine to small units, but brought the units to facilities where a larger number of personnel were

¹²M. Wright and A. Fauci, "Smallpox Immunization in the 21st Century," *Journal of the American Medical Association*, vol. 289, no. 24 (2003).

¹³[GAO-02-445](#).

¹⁴These centers manage and process requests for vaccines and related supplies for clinical vaccination sites. The Service Vaccine Control Centers are Naval Medical Logistics Command (NAVMEDLOGCOM), Air Force Medical Logistics Office (AFMLO), and USAMMA for both the Army and the Coast Guard.

¹⁵DOD acquired 1.5 million doses of the smallpox vaccine from CDC's Strategic National Stockpile.

being vaccinated. Furthermore, units with leftover doses shared their supplies with other units or with other services to reduce waste. To ensure the vaccine's potency, its temperature was monitored with a computer chip to ensure that the vaccine was maintained at the proper temperature during shipment. This monitoring process was an effort to avoid DOD's previous experience delivering the anthrax vaccine, when some vaccine was wasted because the temperature under which the vaccine was stored could not be confirmed. To ensure that the smallpox vaccine was delivered without tampering, DOD was to arrange door-to-door, escorted transportation of the vaccine from the supply depot to the pharmacies and medical depots supporting the clinics. Upon receipt, shipments of the vaccine were inspected for damage or signs of contamination.

DOD Facilitated Its Smallpox Vaccination Program with Education Efforts

According to DOD officials, DOD facilitated its vaccination program by educating those who administered the vaccine and those who received it. These efforts occurred both before and during the implementation of the program. A conference in October 2002, before the DOD smallpox vaccination program was implemented, provided training across all the services. Each service sent healthcare personnel—approximately 500 in total—to learn the vaccination procedure. The conference also provided education on vaccine history and potential adverse reactions, as well as information on the logistics of receiving and storing the vaccine. The healthcare personnel who attended were responsible for training other healthcare personnel in their units. DOD videotaped the conference and required other healthcare personnel to view various segments of the training relevant to their responsibilities in administering the smallpox vaccination program.

DOD officials told us that DOD also provided educational support to potential vaccinees. To ease concerns about receiving the smallpox vaccine, commanding officers received training materials in advance and presented information to potential vaccinees before the vaccination process began. Medical personnel attended these meetings to answer questions. In addition, questions and answers about the smallpox vaccine were posted on DOD Web sites. All of the services distributed a trifold brochure to potential vaccinees that described contraindications, the appearance of the vaccination site, the expected side effects, and instructions on how to take care of the skin area where the vaccination was administered. For additional information, the brochure listed Web site addresses and contact phone numbers. In some cases, the services required military personnel to watch a videotape describing the smallpox vaccination process. DOD organized focus groups between January and March 2003 at selected Army, Navy, Marine Corps, and Air Force facilities to identify concerns among service members, clinicians, and family members and gauge the effectiveness of educational materials. Lessons learned from these sessions were incorporated into subsequent editions of the educational material. Recommendations from these focus groups included making information available to all individuals who were going to be vaccinated or those who would come into contact with them, using layperson terms, and reinforcing the difference between the smallpox disease and the smallpox vaccination.

According to DOD officials, these education efforts were key to the successful implementation of the smallpox vaccination program. DOD officials explained that these efforts were intended to avoid some of the problems DOD encountered when it began its Anthrax Vaccine Immunization Program in March 1998. For example, a survey of Guard and Reserve pilots and aircrew in 2000 reported dissatisfaction with the completeness and accuracy of the information DOD provided on the threat posed by anthrax and on the anthrax vaccine's safety risks and possible side effects.¹⁶

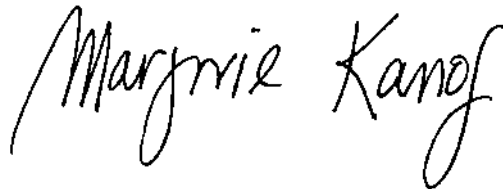
Agency Comments

In commenting on a draft of this report, DOD agreed with our findings (see enclosure). DOD also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Defense and interested congressional committees and will make copies available to others upon request. This report will also be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have questions about this report, please contact me at (202) 512-7119 or Kristi Peterson at (202) 512-7951. Gloria Taylor, Louise Duhamel, and Krister Friday made key contributions to this report.

Sincerely yours,



Marjorie E. Kanof
Director, Health Care—Clinical Health Care Issues

Enclosure

¹⁶GAO-02-445.

Comments from the Department of Defense



REPLY TO ATTENTION OF

DEPARTMENT OF THE ARMY
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MCIR

14 November 2003

MEMORANDUM THRU Assistant Secretary of the Army (Manpower and Personnel Affairs) *John P. McLaurin III*
11/14/03 **Deputy Assistant Secretary (Human Resources)**

FOR U.S. General Accounting Office, Director, Health Care – Clinical Health Care Issues, ATTN: Ms. Marjorie E. Kanof, 441 G Street, NW, Room 5104, Washington, DC 20548

SUBJECT: Reply to U.S. General Accounting Office (GAC) Draft Report GAO-04-215R, *SMALLPOX VACCINATION: Review of the Implementation of the Military Program*

1. This is the Department of Defense (DoD) response to the GAO draft report GAO-04-215R, "*Smallpox Vaccination: Review of the Implementation of the Military Program*," dated November 4, 2003. We appreciate the opportunity to comment on your report.
2. We concur with your report and its findings as written.
3. Our point of contact is COL John Grabenstein, Deputy Director for Clinical Operations, Military Vaccine Agency, (703) 681-5059. COL Grabenstein served as the primary action officer on behalf of the DoD for this GAO review.

FOR THE SURGEON GENERAL:

KENNETH L. FARMER, JR., M.D.
Major General
Deputy Surgeon General

Encl

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