

**GAO**

Report to the Chairman, Committee on  
Governmental Affairs, U.S. Senate

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April 2003

# SMALLPOX VACCINATION

## Implementation of National Program Faces Challenges





Highlights of [GAO-03-578](#), a report to the Chairman of the Committee on Governmental Affairs, U.S. Senate

## Why GAO Did This Study

Amid growing concerns about a potential smallpox attack, the Centers for Disease Control and Prevention (CDC) is working with 62 state, local, and territorial jurisdictions to implement the civilian part of the National Smallpox Vaccination Program. The goal is to increase the nation's response capacity by vaccinating health workers for Smallpox Response Teams as quickly as is safely possible. A civilian program using vaccination to bolster bioterrorism preparedness is unprecedented, the health risks are uncertain, and the public health system has had little recent experience with smallpox. Safe implementation of such a program will be complex. GAO was asked to examine implementation and its challenges. GAO reviewed program materials and data and interviewed CDC officials and representatives of organizations involved.

## What GAO Recommends

GAO recommends that the Director of CDC provide guidance to the jurisdictions for

- estimating response capacity needs and revising targets for the first stage and
- implementing the second stage, that is, vaccination of additional health workers and other emergency response personnel.

CDC concurred with these recommendations.

[www.gao.gov/cgi-bin/getrpt?GAO-03-578](http://www.gao.gov/cgi-bin/getrpt?GAO-03-578).

To view the full report, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

# SMALLPOX VACCINATION

## Implementation of National Program Faces Challenges

### What GAO Found

Implementation of the smallpox vaccination program has proceeded more slowly than CDC planned. Vaccinations are to be given to volunteers in two stages. CDC's nationwide target for the first stage was an estimated 500,000 health workers in 30 days. The number of health workers was based on the jurisdictions' combined targets for their Smallpox Response Teams. In the second stage, CDC plans to expand the program to as many as 10 million additional health workers and other emergency response personnel. On the official start date of vaccination, January 24, 2003, only one state began vaccinating. CDC reports that by week 10 (April 4, 2003) about 6 percent of the number of volunteers targeted for the first stage had been vaccinated. Eight states accounted for about half of the vaccinees. Because of the slow pace, not enough data were generated by week 10 to evaluate whether the program is proceeding as safely as possible.

Implementation of the program is facing two major challenges. The first is the program schedule, which placed heavy demands on CDC and the jurisdictions. The second is hesitation on the part of the two main groups needed to participate in the program—the state and local public health authorities and hospitals needed to implement it, and the health workers needed to volunteer to be vaccinated. Many implementers are concerned about insufficient resources to support the program and about liability protection. Many potential volunteers are concerned about health risks to themselves and their co-workers, families, and patients and about compensation for adverse events and lost income.

Program officials and Congress have been working to address some of the major challenges but it is too soon to evaluate the impact of these efforts on participation in the program. Unless these efforts succeed in overcoming the hesitancy of the participants, it may be difficult to achieve the initial targets for the first stage. CDC has reconsidered the initial targets and said that as few as 50,000 vaccinated health workers nationwide would provide sufficient response capacity. But as of late April, CDC had not set a new nationwide target or requested that the 62 jurisdictions adjust their targets for numbers and types of vaccinated health workers and distribution of response teams. CDC also has not said what the implications of this potential change in targets for the first stage would be for the second stage. In addition, although CDC announced that it would provide guidance for and request plans from the jurisdictions for the second stage, it has not yet done so.

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## **Abbreviations**

ASTHO	Association of State and Territorial Health Officials
CDC	Centers for Disease Control and Prevention
DOD	Department of Defense
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
IOM	Institute of Medicine
NACCHO	National Association of County and City Health Officials
VIG	vaccinia immune globulin
WHO	World Health Organization

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United States General Accounting Office  
Washington, DC 20548

April 30, 2003

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

Dear Chairman Collins:

On January 24, 2003, four physicians in Connecticut became the first civilians in this country to receive the smallpox vaccine—which has not been routinely administered in over 30 years—as part of the administration’s National Smallpox Vaccination Program. The program, which was announced by the President in December 2002, was developed in response to growing concern that a terrorist or hostile regime might have access to the smallpox virus and attempt to use it as an agent of bioterrorism against the American people. In 1980, after a successful eradication program, the World Health Organization (WHO) declared the world free of naturally occurring smallpox. However, concern remains that stockpiles of the virus may exist in laboratories other than the two repositories designated by WHO following eradication.<sup>1</sup> Although the administration indicated that a terrorist attack involving smallpox is not imminent, it determined that the program should proceed as quickly as is safely possible.

The Centers for Disease Control and Prevention (CDC) is charged by the Department of Health and Human Services (HHS) with implementing the civilian part of the smallpox vaccination program.<sup>2</sup> The goal of the program is to increase the nation’s smallpox preparedness capacity by offering vaccinations safely to volunteer health workers to increase their readiness to respond to a smallpox attack.<sup>3</sup> CDC planned for the

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<sup>1</sup>The two designated repositories are at the Centers for Disease Control and Prevention in Atlanta, Georgia, and at the Russian State Centre for Research on Virology and Biotechnology in Koltsovo, Russia.

<sup>2</sup>The program also includes provision for the mandatory vaccination of 500,000 Department of Defense personnel, primarily those deployed in high-threat areas, and offers vaccination on a voluntary basis to State Department personnel deployed in the Middle East.

<sup>3</sup>Centers for Disease Control and Prevention, *Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program* (Atlanta, Ga.: Nov. 22, 2002).

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vaccinations to be carried out in two stages. The first stage began on January 24, 2003, the date on which protection against liability for injury or death arising from smallpox vaccine administration became effective under the Homeland Security Act of 2002 for entities or individuals involved in implementing the program.<sup>4</sup> CDC planned that during the first stage the vaccine would be offered on a voluntary basis to an estimated 500,000 public health and health care workers, who would be formed into Smallpox Response Teams.<sup>5</sup> These teams would be responsible for investigating an outbreak following a bioterrorist attack, caring for patients, and vaccinating members of the public who may have been exposed to the virus. CDC planned to complete the first stage in 30 days. During the second stage, the program would be expanded to as many as 10 million other health care workers, police officers, firefighters, and emergency medical technicians, again on a voluntary basis.<sup>6</sup>

CDC is implementing the smallpox vaccination program in collaboration with 62 state, local, and territorial governments.<sup>7</sup> Thus the plan for the program is embodied in multiple federal guidance documents and recommendations, the individual CDC-approved plans of the 62

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<sup>4</sup>Protected entities and individuals include manufacturers and distributors of certain measures to counter bioterrorism using smallpox; hospitals, clinics, and other health care entities under whose auspices such measures are administered; and licensed health care professionals or other individuals authorized to administer the measures under state law. The Homeland Security Act of 2002, which was enacted on November 25, 2002, provides that these entities and individuals are to be treated as federal employees for purposes of liability arising from the administration of certain measures to counter smallpox under the smallpox vaccination program. Therefore the federal government would become the defendant in claims for injury or death made in this context. These provisions became effective 60 days after enactment. Homeland Security Act of 2002, Pub. L. No. 107-296, § 304, 116 Stat. 2135, 2165 (2002).

<sup>5</sup>We found in CDC files and statements of federal program officials estimates ranging from about 400,000 to about 700,000 health workers to be vaccinated in the first stage. These estimates were derived using various assumptions. We have selected the estimate of 500,000 because it was the one provided to the public in conjunction with the President's announcement of the program.

<sup>6</sup>Although HHS does not recommend vaccination for the general public, it recognized that some members of the public may want to be vaccinated and has stated its intention to work to accommodate them later in the program.

<sup>7</sup>In addition to the 50 states and the District of Columbia, the 62 jurisdictions include the nation's three largest municipalities, New York City, Chicago, and Los Angeles County, as well as the commonwealths of Puerto Rico and the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, the republics of Palau and the Marshall Islands, and the Federated States of Micronesia.

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jurisdictions, and the plans of thousands of individual hospitals involved. Each of the jurisdictions and hospitals has tailored its first-stage planning and targets for numbers and distribution of teams and numbers and types of health workers on the teams to its own particular circumstances. CDC has defined the program's targets for national preparedness as the sum of the targets set by the jurisdictions in their plans.

A large-scale public vaccination program against a disease that no longer exists as a natural threat is unprecedented and presents many challenges. The relatively small and known risks of adverse events associated with vaccines in past vaccination programs have been justified on the basis of the need to reduce a known incidence of disease in the population. For smallpox, such justification no longer exists. Both the nature and rates of adverse events to be expected in today's population<sup>8</sup> and the risk of a bioterrorist attack are uncertain, making the development and safe implementation of a program of smallpox vaccination especially challenging.

In recognition of the potential difficulties in implementation of the smallpox vaccination program, you requested that we determine (1) how implementation of the civilian part of the program is proceeding, (2) what challenges have been encountered, and (3) whether these challenges have been addressed.

In carrying out our work, we conducted a literature review and examined program-related materials and data and interviewed officials and representatives involved in the program. Specifically, we obtained program-related materials and data on plans, numbers of health workers vaccinated, shipments of vaccine, adverse events reported, and other relevant information from CDC through the first 10 weeks of vaccination. We obtained data about the jurisdictions from the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO). We reviewed relevant materials from the Department of Defense (DOD), the Institute of Medicine (IOM), WHO, the 62 jurisdictions, and 25 organizations representing state and local health authorities, hospitals, physicians,

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<sup>8</sup>Today's civilian population has a larger proportion of people with compromised immune systems due to HIV (human immunodeficiency virus), cancer treatment, and organ transplantation, as well as higher rates of some conditions that indicate against smallpox vaccination, such as eczema, than the 1960s population from which most of the data about smallpox vaccination come.

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nurses, and other health workers. In addition, we interviewed representatives from some of those organizations, including the American College of Emergency Physicians, the American Hospital Association, the American Nurses Association, ASTHO, NACCHO, and the Service Employees International Union, as well as CDC and IOM and selected jurisdictional public health officials. We did not systematically review the jurisdictional plans nor survey the jurisdictions, and thus we provide information about jurisdictions only to illustrate the range of policies and activities they encompass. We did not independently verify data provided to us by CDC and organizations involved in the program; however, we tested the data and determined that they were adequate for our purposes. We conducted our work from January 2003 through April 2003 in accordance with generally accepted government auditing standards.

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## Results in Brief

Implementation of the smallpox vaccination program has proceeded more slowly than CDC planned. On the start date of vaccination, most of the 62 jurisdictions were not prepared to begin vaccinating volunteers: More than half had not yet requested vaccine from CDC, and most of the remaining jurisdictions had requested that their vaccine not be shipped until after the start date. On the first day, only one state began vaccinating. As many jurisdictions had projected in their individual plans, the vaccination of health workers in the first stage of the program is taking longer than the 30 days set by CDC as an initial target. CDC reports that by week 10 about 6 percent of the initial target (a total of 31,297 health workers) had been vaccinated in 54 of the 62 jurisdictions. Eight states accounted for about half of the vaccinees. As of week 10, there are not enough data to precisely estimate rates of adverse events and other indicators of program safety.

Implementation of the program is facing two major challenges—the program schedule, which placed heavy demands on CDC and the jurisdictions, and hesitation on the part of the two main groups needed to participate. CDC developed extensive guidance, training and educational programs, and other materials to support implementation, but the schedule made it difficult for the agency to resolve all issues prior to the start of vaccination. For example, a CDC data system for hospitals to track adverse reactions was not available until more than 3 weeks after vaccinations had begun. The jurisdictions had less than 3 weeks to develop their plans and less than 2 months to prepare to begin vaccination. Although generally supportive of the program's goal, the two major groups of participants—the state and local public health authorities and hospitals needed to implement it, and the health workers needed to volunteer to be vaccinated—have concerns and therefore are hesitating to participate.



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Many implementers are concerned about insufficient resources to support the program and about liability protection. Many potential volunteers are concerned about safety and protection for themselves and their co-workers, families, and patients and about compensation for adverse events and lost income.

CDC and HHS have been working to address the major challenges, but to date they have not been able to overcome them. With regard to the challenging program schedule, CDC has reconsidered the initial target of vaccination of 500,000 public health and health care workers in 30 days. It has said that there is no longer a deadline for the first stage and that as few as 50,000 vaccinated health workers nationwide would provide sufficient capacity to respond to a smallpox attack. But as of late April, CDC had not set a new nationwide target or requested that the 62 jurisdictions adjust their targets for numbers and types of vaccinated health workers needed to effectively investigate an outbreak, care for patients, and vaccinate members of the public with fewer, smaller, or differently distributed Smallpox Response Teams. CDC also has not said what the implications of this potential change in targets for the first stage would be for the second stage involving police, fire, and other workers. In addition, although CDC announced that it would provide guidance for and request plans from the jurisdictions for the second stage, it has not done so. Program officials have also worked to address the concerns impeding participation by the implementers and volunteers, but many of these remain unresolved. To address the implementers' concern about resources, HHS announced in late March that up to 20 percent of 2003 bioterrorism preparedness funding would be available to the jurisdictions immediately upon approval of their applications by CDC, but HHS has not yet specified this application procedure. In addition, in mid-April Congress appropriated other funds to support implementation of the smallpox vaccination program. To address the volunteers' concern about compensation, on April 24, 2003, Congress presented legislation to the President for his signature that provides benefits to public health and health care team members participating in a smallpox emergency response plan and public safety personnel who are injured as a result of receiving the vaccine. It is too soon to evaluate the impact of these legislative efforts on participation in the program.

We are making recommendations to the Director of CDC to provide guidance to the jurisdictions for revising targets for the first stage of the smallpox vaccination program and for expansion of the program in the second stage. CDC concurred with our recommendations and provided information about guidance it is planning to issue.

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## Background

Since the terrorist attacks of September 11, 2001, and the subsequent anthrax cases, there has been heightened public awareness and fear of potential bioterrorist attacks, including an attack involving smallpox. Smallpox is a contagious disease whose symptoms include fever and a distinctive progressive skin rash. It is fatal in about 30 percent of cases and is considered by CDC to be one of the six biological agents that pose the greatest potential threat for adverse public health impact and have a moderate to high potential for large-scale dissemination.<sup>9</sup> There is no specific treatment for smallpox, but according to CDC it can be prevented or its course can be significantly modified in most people through vaccination within 3 days of exposure, and vaccination 4 to 7 days after exposure will probably offer some protection or may lessen the severity of the symptoms.<sup>10</sup>

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## Role of Vaccination in Public Health

The successful use of mass vaccinations to control deadly and debilitating diseases worldwide is one of the great public health achievements of the past century. Routine immunization programs have been built around safe and effective vaccines targeted at smallpox, poliomyelitis, measles, rubella, tetanus, diphtheria, influenza, and other infectious diseases. Although vaccination programs have provided great benefits, they also carry some risk. Most vaccines, like most medications, have a very small rate of severe adverse reactions.

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## Smallpox Vaccination

Public vaccination for smallpox began in the United States in the early 1800s, when Massachusetts began to require smallpox vaccinations for its residents. By the late 1800s, smallpox was coming under control in the United States as the practice of vaccination became more routine. By the 1960s, experience had shown that for every 1 million people vaccinated for the first time, between 14 and 52 could experience serious and potentially life-threatening adverse events and 1 to 2 could die. But these risks were deemed acceptable to control this contagious and often fatal disease. By 1972 the risk of smallpox in the United States was sufficiently remote that routine vaccinations were discontinued, 8 years before WHO's announcement that the disease had been eradicated worldwide.

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<sup>9</sup>The other agents in the group are anthrax, botulism, plague, tularemia, and viral hemorrhagic fevers.

<sup>10</sup>Centers for Disease Control and Prevention, *Smallpox Fact Sheet: Vaccine Overview* (Atlanta, Ga.: Dec. 9, 2002).

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Immunity to the virus that causes smallpox—the variola virus—is conferred through inoculation with a vaccine made from the closely related vaccinia virus. The smallpox vaccine does not contain the variola virus and cannot cause smallpox. The smallpox vaccine is a “live virus” vaccine; that is, the vaccinia virus it contains is living and may produce mild reactions, including rash, fever, and head and body aches.<sup>11</sup> In certain groups of people, including those with compromised immune systems and certain skin conditions such as eczema, adverse events associated with the vaccine can be severe. Because the virus is live, it can be transmitted to other parts of the body or to other people, who could also face potentially serious complications, and so care has to be taken to minimize the risk of spreading the vaccinia virus from the vaccination site.<sup>12</sup> Previous experience with the vaccine has shown that it spreads to other parts of the vaccinee’s body at a rate of 25 to 532 per million individuals vaccinated and spreads from the vaccinee to others at a rate of 20 to 60 per million.

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## The National Smallpox Vaccination Program

The National Smallpox Vaccination Program is unique in the history of civilian immunization programs in that it is not a public health program in the traditional sense but rather a program of bioterrorism preparedness. The population to be vaccinated in the first and second stages of the civilian part of the program is not the general public as in traditional programs, but key public health, health care, and emergency response workers. Smallpox Response Teams vaccinated in the first stage would receive vaccine not solely to protect their own health but primarily to increase the nation’s capacity to respond to a smallpox attack by investigating an outbreak, caring for patients, and vaccinating members of the public who may have been exposed. Because vaccination soon after exposure can prevent or reduce the severity of the disease, planners project that there will be sufficient time for these key workers to vaccinate members of the public as needed to contain a smallpox outbreak after it has been recognized.

CDC’s guidance allows the 62 jurisdictions some flexibility in forming their Smallpox Response Teams. For example, it provides recommendations for

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<sup>11</sup>Live virus vaccines, like all other licensed vaccines, are considered safe and effective for most people with healthy immune systems. Other live virus vaccines include those for measles, mumps, rubella, and chickenpox.

<sup>12</sup>For more information on smallpox and the smallpox vaccine, see CDC’s smallpox fact sheets at <http://www.cdc.gov/smallpox>.

the types of workers to be included in the two types of Smallpox Response Teams—the Public Health Smallpox Response Teams and the Healthcare Smallpox Response Teams—but leaves the numbers of workers and exact composition of teams to the jurisdictions to decide on the basis of their particular needs. For the public health teams, which are based at state and local public health agencies, the guidance states that each team should have a medical expert as team leader and should include public health advisors, medical epidemiologists, disease investigators, laboratory workers, nurses, and vaccinators. For the health care teams, which are based at hospitals, the criteria for choosing which health care workers to include are to be developed locally. Each jurisdiction was to have formed at least one public health team and as many other public health and health care teams as it deemed necessary by 30 days from the announced start date of vaccination. The jurisdictions' plans vary widely in terms of the time line for the first stage of vaccination and their targets for the numbers of teams and workers to be vaccinated (see table 1). The jurisdictions with CDC-approved plans proposed to vaccinate 1,101 public health teams and 4,532 health care teams, for a total of 415,691 vaccinated volunteers nationwide.<sup>13</sup> Although CDC had called for the first stage of vaccinations to be completed in 30 days, many jurisdictions expected vaccinations to take longer than that to complete.

**Table 1: Targets for the First Stage of the Program, as Initially Proposed by the 54 Jurisdictions with CDC-Approved Plans**

	Targets		
	Average	Minimum	Maximum
Planned duration of first stage (in days)	55	7	126
Planned number of Public Health Smallpox Response Teams	21	1	107
Planned number of Healthcare Smallpox Response Teams	92	2	375
Planned number of volunteers to be vaccinated	7,997	323	40,000
Planned number of volunteers to be vaccinated per million population	1,903	81	8,772

Source: GAO analysis of CDC data.

Note: The plans for the territories had not been approved as of January 2003.

<sup>13</sup>The plans for the territories were not yet approved when CDC derived these figures, which therefore represent the totals from the plans for the 50 states, the District of Columbia, New York City, Chicago, and Los Angeles County.

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CDC has said that safety is the top priority in implementing this program. To enable jurisdictions to implement this program in the safest manner possible, the agency has provided guidance and materials for critical elements of the program, including

- education and training of health workers who will be administering the vaccinations;
- education and screening of volunteers to rule out those who may be at greater risk for severe reactions;
- care of the site of vaccination on the vaccinee’s body to prevent secondary infection or transmission to others;
- monitoring of adverse events;
- distribution of the two investigational drugs used in treating certain adverse reactions caused by the vaccine, vaccinia immune globulin (VIG) and cidofovir<sup>14</sup>; and
- systems for ongoing collection, management, and analysis of program data—including adverse events,<sup>15</sup> transmissions of the vaccinia virus to individuals the vaccinee was in contact with following the vaccination (or “secondary transmission”), requests for VIG or cidofovir, needlestick injuries to vaccinators,<sup>16</sup> and vaccine wastage—to evaluate the program and make adjustments as necessary.

In addition, CDC is sponsoring an advisory group, the IOM Committee on Smallpox Vaccination Program Implementation, to provide advice to program officials at CDC on selected aspects of program implementation, including guidelines and instruments for screening; measures to ensure the early recognition, evaluation, and appropriate treatment of adverse events; plans for collecting and analyzing data; and the achievement of

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<sup>14</sup>VIG, which is recommended as the first line of therapy, and cidofovir are available for civilians only through CDC following consultation with CDC staff.

<sup>15</sup>Most of these systems are passive surveillance systems, which rely on patients or staff involved in their care to take the initiative to provide data. Adverse events that require hospitalization or outpatient care (such as encephalitis, eczema vaccinatum, progressive vaccinia, and inadvertent inoculation) are being tracked by CDC and state health departments primarily using the Vaccine Adverse Events Reporting System, which is a passive system. CDC expects adverse events of this kind to be well captured by a passive system, but less severe adverse events that do not require treatment (such as low-grade fever, headache, mild skin rash, and nausea) to be underreported.

<sup>16</sup>Procedures involving needles pose the risk that either the person using the needle or someone involved in its disposal will be unintentionally stuck, thereby potentially coming in contact with whatever substance the needle delivered and the blood of the person on whom it was used.

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overall goals of the smallpox vaccination program. This committee has issued two of a planned series of reports.

Originally, the program had no provisions to compensate anyone for lost time from work, health care costs, disability, or death due to adverse events. Instead, it was expected that workers would be covered by existing mechanisms such as workers' compensation and insurance.

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## Initial Federal Funding for the Smallpox Vaccination Program

The initial federal funding for the smallpox vaccination program came from CDC's bioterrorism preparedness funding. Since fiscal year 1999, HHS has distributed funding for bioterrorism preparedness to state and local health departments in the 62 jurisdictions primarily through CDC's Bioterrorism Preparedness and Response Program.<sup>17</sup> In January 2002, HHS announced the availability of supplemental funding through the CDC program and a Health Resources and Services Administration (HRSA) program. Under the CDC program, \$918 million in supplemental funding was made available to jurisdictions for general bioterrorism preparedness.<sup>18</sup> HHS required jurisdictions to submit their applications for these funds by April 15, 2002. Each jurisdiction was to develop a plan during 2002 to improve general bioterrorism preparedness within six categories: preparedness planning and readiness assessment, surveillance and epidemiology capacity, laboratory capacity for biological agents, communications and information technology, risk communication and health information dissemination, and education and training. At the same time, under the Bioterrorism Hospital Preparedness Program, HRSA made \$125 million available through cooperative agreements to the jurisdictions to enhance the capacity of hospitals and associated health care entities to respond to bioterrorist attacks, as well as other public health emergencies.

In March 2002, CDC announced the extension of its Bioterrorism Preparedness and Response Program through August 2005, without indicating whether additional funds would be available. On November 22,

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<sup>17</sup>U.S. General Accounting Office, *Bioterrorism: Federal Research and Preparedness Activities*, GAO-01-915 (Washington, D.C.: Sept. 28, 2001). Also see the "Related GAO Products" section at the end of this report.

<sup>18</sup>The funds were appropriated by the Department of Defense and Emergency Supplemental Appropriations for Recovery from and Response to Terrorist Attacks on the United States Act, Pub. L. No. 107-117, 115 Stat. 2230, 2314 (2002), and the Department of Health and Human Services and Education, and Related Agencies Appropriations Act for Fiscal Year 2002, Pub. L. No. 107-116, 115 Stat. 2186, 2198 (2002).

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2002, CDC notified the jurisdictions that they were to plan and implement the National Smallpox Vaccination Program by utilizing and redirecting the monies previously disbursed under the Bioterrorism Preparedness and Response Program. These plans for the first stage of smallpox vaccination were due to CDC on December 9, 2002.

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## Implementation Is Slower Than CDC Planned

Implementation of the smallpox vaccination program has proceeded more slowly than CDC planned. Because of the slow pace, not enough data have been generated to determine whether implementation is proceeding as safely as possible according to the program's goal.

Specifically, vaccination of health workers in the first stage has proceeded slowly. CDC's initial target date for completion of the first stage has passed. As of the start date for vaccination, January 24, 2003, most of the jurisdictions were not ready to begin vaccinating: More than half of the jurisdictions had not yet requested vaccine from CDC, and most of the remaining jurisdictions had requested that their vaccine not be shipped until after the start date. (See table 2.) On the first day, four health care workers in one jurisdiction—Connecticut—were vaccinated. As many jurisdictions had projected in their individual plans, the vaccination of health workers in the first stage of the program is taking longer than the 30 days set by CDC as an initial target. By the end of the tenth week, April 4, 2003, 7 jurisdictions had yet to request vaccine, but the rest had requested and received their shipments. Although CDC reported that a total of 31,297 health workers (about 6 percent of the initial target) had been vaccinated in 54 of the 62 jurisdictions by week 10, about half of those vaccinated were distributed across eight states: Florida, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Tennessee, and Texas. Sixty-two percent of those vaccinated were Healthcare Smallpox Response Team members, and 33 percent were Public Health Smallpox Response Team members; the remaining 4 percent were "other," which includes public officials who are not part of a Smallpox Response Team.<sup>19</sup> As of late April, CDC did not have information about the number of complete response teams formed. As of week 10, CDC reported that roughly one-third of an estimated 5,000 acute care hospitals in the jurisdictions began vaccinations. Almost half of these hospitals are in seven jurisdictions: Florida, Louisiana, Missouri, Nebraska, Ohio, Tennessee, and Texas.

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<sup>19</sup>Due to rounding, the percents do not total to 100.

**Table 2: Status of National Smallpox Vaccination Program Implementation, Day 1 through Week 10**

	As of day 1 (January 24, 2003)	As of week 4 (February 21, 2003)	As of week 10 (April 4, 2003)
Number (percent) of jurisdictions that had requested vaccine <sup>a</sup>	27 (44%)	52 (84%)	55 (89%)
Number (percent) of jurisdictions that had received vaccine <sup>a</sup>	8 (13%)	52 (84%)	55 (89%)
Number (percent) of jurisdictions that had initiated vaccinations <sup>a</sup>	1 (2%)	40 (65%)	54 (87%)
Number (percent) of volunteers vaccinated <sup>b</sup>	4 (<1%)	7,354 (<2%)	31,297 (6%)

Source: CDC.

<sup>a</sup>Percent of total of 62 jurisdictions.

<sup>b</sup>Percent of initial estimated target of 500,000.

Because progress has been slow, to date there are not enough data to precisely gauge indicators of the safety of implementation. For example, too few health care workers have been vaccinated and too little time has passed since their vaccination to precisely estimate rates of adverse events. Therefore it cannot yet be determined whether the rates are the same as would have been anticipated on the basis of historical data or different enough to trigger reconsideration of how the program should proceed. As of April 4, 2003, CDC had received reports of 68 moderate to severe adverse events<sup>20</sup> and 250 less severe adverse events, such as fever and rash, potentially related to smallpox vaccination. In addition, CDC had received reports that two volunteers who had been vaccinated died of heart attack, but CDC has not yet determined whether the deaths were

<sup>20</sup>These reports include cases of generalized vaccinia, inadvertent inoculation, myocarditis, pericarditis, and ocular vaccinia, but no reports of other severe adverse events, such as progressive vaccinia, eczema vaccinatum, encephalitis, encephalomyelitis, or vaccinia transmission.



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related to the smallpox vaccine.<sup>21</sup> CDC officials maintain that the low number of severe adverse events associated historically with smallpox vaccination strongly suggests that screening efforts and measures to prevent transmission of vaccinia virus to contacts have been effective. However, the experience of more vaccinees would have to be examined in order to derive precise rates of how often the rare but most severe adverse events occur.<sup>22</sup> Further, because more than half of the individuals were vaccinated during weeks 6 through 10, some of the adverse events that can occur weeks after vaccination would not yet have been detected. Moreover, not all planned vaccination monitoring systems were in place until more than 3 weeks after vaccination began, and some jurisdictions report ongoing difficulties in using the systems required by CDC.<sup>23</sup> Therefore some of the experience to date may not have been captured by these systems.

The data obtained as of week 10 are also insufficient to answer other important safety questions. For example, although CDC had reported no needlestick injuries as of late April, too few vaccinations have been given

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<sup>21</sup>CDC announced on March 25, 2003, that volunteers with heart disease should not be vaccinated until further notice. CDC also issued modified smallpox vaccination program implementation materials that reflected this new exclusion. Nine states announced that they were temporarily suspending their vaccination programs until the new guidance was released. As of late April, all but two of these states had resumed vaccinations.

<sup>22</sup>DOD has reported on experience with vaccinating over 350,000 personnel as of March 31, 2003, more than 8,000 of which were health care workers. As of that date, DOD reports 82 adverse events and that 3 percent of vaccinees took an average of 1.5 days of sick leave. DOD also reports that one vaccinee died of heart attack but states that smallpox vaccination was unlikely to be the cause of death. Although the DOD experience is informative and DOD is sharing information with HHS, the military program differs from the civilian one in several respects that limit the ability to generalize results from one program to the other. For example, the DOD program is not voluntary, the military setting provides more options for keeping vaccinated personnel separated from others, and the military population is on average younger than the general population. Thus, for example, data from the DOD program could contribute to understanding the rates of adverse events in properly screened vaccinees, but would have less relevance for determining the effectiveness of the educational and screening process for volunteers in the civilian program.

<sup>23</sup>CDC developed the voluntary, Web-based Hospital Smallpox Vaccination Monitoring System for hospitals to track such indicators as workdays lost and symptoms reported by vaccinees (ranging from mild to severe), but that system was not available until February 18, 2003. Because this system is designed to be used by hospitals to track vaccinees in real-time, it could be part of an active surveillance system. In contrast to a passive system, an active surveillance system would seek out the vaccinees to collect data on them.

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to precisely estimate the rate of such injuries. Similarly, there are not enough data to evaluate the effectiveness of the screening process, the effectiveness of measures to prevent the spread of vaccinia virus, the safety and effectiveness of VIG and cidofovir, and the effectiveness of CDC's distribution system for these investigational drugs.<sup>24</sup>

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## Major Challenges Are Program Schedule and Hesitancy on Part of the Two Main Groups Involved in Program

Implementation of the smallpox vaccination program is facing two major challenges. One is the program schedule, and the other is hesitancy on the part of the two main groups involved in the program—those needed to implement it and those needed to volunteer to be vaccinated. Although these two groups have generally expressed support for the goals of the program, they have concerns regarding the availability of resources to implement the program, liability protection, safety, and workers' compensation.

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## Program Schedule Has Challenged CDC and the Jurisdictions

The program schedule is challenging and has placed heavy demands on CDC and the jurisdictions (see table 3). CDC has developed a wide range of implementation materials, which it has distributed through multiple channels. These materials include guidance documents and educational and training programs. The effort to produce materials quickly has led to difficulties. Some of the materials that were distributed needed to be revised, and some were inconsistent or untested. Some key materials were not available until after the start of vaccination. For example, the package of materials to be used to obtain informed consent for vaccination from volunteers was first made available 8 days before the start of vaccination, and the revised version was issued the day before vaccination was to start. The delayed availability of these materials created difficulties for those trying to implement the program. In addition, CDC has provided conflicting information about the precise method for administering the vaccine. Further, the materials used to educate and screen volunteers were not tested for comprehensibility to ensure that the screening process would function as intended. Moreover, while CDC provided preliminary guidance for adverse event monitoring in November, it hosted training on this issue 2 days before the program began and did not issue detailed guidance about the adverse event monitoring system until 2 weeks after vaccination had begun.

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<sup>24</sup>CDC reports that it shipped VIG to two states and made no shipments of cidofovir.

**Table 3: Key Events in National Smallpox Vaccination Program Time Line as of April 2003**

<b>Date</b>	<b>Event</b>
November 22, 2002	<ul style="list-style-type: none"> <li>• CDC issued guidance to jurisdictions for developing plans for first stage of vaccination.</li> </ul>
November 25, 2002	<ul style="list-style-type: none"> <li>• Homeland Security Act of 2002 enacted.</li> </ul>
December 9, 2002	<ul style="list-style-type: none"> <li>• Jurisdictional plans for first stage were due to CDC.</li> </ul>
December 12, 2002	<ul style="list-style-type: none"> <li>• CDC completed initial review of jurisdictional plans for first stage.</li> </ul>
December 13, 2002	<ul style="list-style-type: none"> <li>• President announced National Smallpox Vaccination Program.</li> </ul>
December 18-20, 2002	<ul style="list-style-type: none"> <li>• CDC-sponsored IOM Committee on Smallpox Vaccination Program Implementation held first meeting.</li> </ul>
January 16, 2003	<ul style="list-style-type: none"> <li>• CDC-sponsored IOM Committee on Smallpox Vaccination Program Implementation issued first report.</li> </ul>
January 21, 2003	<ul style="list-style-type: none"> <li>• Jurisdictions that requested vaccine began receiving smallpox vaccine from CDC.</li> </ul>
January 24, 2003	<ul style="list-style-type: none"> <li>• Liability provisions of Homeland Security Act of 2002 went into effect.</li> <li>• HHS authorized start of vaccination program.</li> <li>• First stage of vaccination began.</li> </ul>
February 13-14, 2003	<ul style="list-style-type: none"> <li>• CDC-sponsored IOM Committee on Smallpox Vaccination Program Implementation held second meeting.</li> </ul>
February 22, 2003	<ul style="list-style-type: none"> <li>• CDC's original target date for completion of first stage of vaccination.</li> </ul>
March 21, 2003	<ul style="list-style-type: none"> <li>• CDC-sponsored IOM Committee on Smallpox Vaccination Program Implementation issued second report.</li> </ul>
April 16, 2003	<ul style="list-style-type: none"> <li>• President signed Emergency Wartime Supplemental Appropriations Act, 2003, which includes additional funding that can be used for smallpox vaccination program.</li> </ul>
April 24, 2003	<ul style="list-style-type: none"> <li>• Congress presented H.R. 1770, Smallpox Emergency Personnel Protection Act of 2003, to President for his signature.</li> </ul>

Source: HHS, IOM, and the Library of Congress.

The program schedule has pressured the advisory process that CDC has set up through IOM to help ensure that the program achieves its goals safely, and the advisory committee has been concerned that the schedule might not allow for a thorough evaluation of the program. Little time was available for IOM's Committee on Smallpox Vaccination Program Implementation to undertake its first review and for CDC to respond to the committee's first report, which was issued 8 days before the start of the

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vaccination effort.<sup>25</sup> Consequently, many of the IOM recommendations that relate to ensuring the safety of the program and facilitating implementation had not been addressed at the start of vaccination. For example, the IOM committee recommended that the materials to be used to screen volunteers be pretested for comprehensibility before vaccination started, but CDC responded that the schedule of the program precluded such testing and initiated vaccination with the untested screening materials. To ensure that the program proceeds safely, IOM also called for a thorough evaluation by IOM and others following the first stage, prior to beginning the second stage, as one of its key recommendations. CDC has said that because of the need to implement the program rapidly there is no distinction between the first and second stages and it does not expect to identify a formal end to the first stage. Instead, CDC expects that evaluation will be ongoing. In its second report, IOM reiterated its concern that a too rapid expansion of the program could preclude the opportunity to learn from the first stage before proceeding, and it again urged CDC to comprehensively evaluate the smallpox vaccination program and its outcomes in order to improve its implementation and to protect the vaccinees and the public.<sup>26</sup>

The program schedule has also placed heavy demands on the jurisdictions. CDC required the jurisdictions to develop plans and targets for the first stage of vaccination in less than 3 weeks. It provided some guidance on the types of workers to be vaccinated on each type of team, but no guidance for estimating the number of workers on teams or the number and distribution of teams within a jurisdiction needed to provide sufficient smallpox response capacity.<sup>27</sup> CDC expected the jurisdictions to be ready to begin vaccinating less than 2 months after it approved their plans. The jurisdictions are dependent on the guidance, educational and training programs, and other materials produced by CDC, but these materials have been changing since the program started. In accord with IOM's recommendation, some jurisdictions have also indicated that they would

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<sup>25</sup>Institute of Medicine, Committee on Smallpox Vaccination Program Implementation, *Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation: Letter Report #1* (Washington, D.C.: Jan. 16, 2003).

<sup>26</sup>Institute of Medicine, Committee on Smallpox Vaccination Program Implementation, *Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation: Letter Report #2* (Washington, D.C.: Mar. 21, 2003).

<sup>27</sup>CDC's guidance on the types of workers to be vaccinated for health care teams was not formalized until February 26, 2003.

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benefit from an evaluation of the first stage of the program before proceeding to the second. CDC has indicated that the jurisdictions are to proceed to the second stage as they determine they are ready to do so. However, CDC has not provided guidance to help them plan and implement the second stage of the program.

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**Implementers and Organizations That Represent Them Are Hesitating to Participate Because of Concerns about Adequacy of Resources and Liability Protection**

The smallpox vaccination program is to be implemented in the jurisdictions by state and local public health authorities and individual hospitals. But these implementers are hesitating to participate in the program because of concerns about adequacy of resources and liability protection.

State and local health officials have stated that they are committed to the safe and timely implementation of the smallpox vaccination program; however, some have expressed concerns about the availability of resources to implement this program. CDC initially provided no cost estimates, but in testimony given in late January the Director estimated the basic cost of administering the vaccine at \$13 per vaccinee.<sup>28</sup> State and local health officials assert that CDC has underestimated the cost of planning and implementing the program. According to recent ASTHO and NACCHO surveys, estimates of the cost of the whole first-stage vaccination process—from planning through follow-up—range from \$79 to \$1,784 per vaccinee.<sup>29</sup> ASTHO and NACCHO estimate that the average cost per vaccinee is \$265 and \$204, respectively. CDC expects jurisdictions to redirect funds made available through bioterrorism cooperative agreements to pay for the smallpox vaccination program. However, state and local health officials report that as of March 2003 most of these funds were already committed to other bioterrorism activities; on average only 7 percent of these funds remain available. Thus in order to meet the

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<sup>28</sup>Statement of Director, Centers for Disease Control and Prevention, Department of Health and Human Services, before the Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, *Hearing on Implementation of Smallpox Vaccination Plan*, 108th Cong., 1st sess. (Jan. 29, 2003), and Statement of Director, Centers for Disease Control and Prevention, Department of Health and Human Services, before the Senate Committee on Health, Education, Labor, and Pensions, *Hearing on the Administration's Smallpox Vaccination Plan: Challenges and Next Steps*, 108th Cong., 1st sess. (Jan. 30, 2003).

<sup>29</sup>In addition to the costs for administration of the vaccine, these estimates include costs such as planning, education, training, screening, communication, data management, vaccine clinic implementation, monitoring of the vaccination site, surveillance, and treatment of adverse events.

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demands of the smallpox vaccination program, they would need to divert funds supporting other bioterrorism preparedness efforts and other public health services. According to a recent NACCHO survey, about 79 percent of local public health agency respondents reported that smallpox work is adversely affecting their other bioterrorism preparedness efforts. About 53 percent reported that resources for other public health services such as childhood immunization have been diverted to smallpox and other bioterrorism efforts. ASTHO and some of the jurisdictions have told us that although they are working to manage the first stage of smallpox vaccination by diverting resources from other efforts, they anticipate that it will be difficult if not impossible to find resources to implement the second stage.

Organizations representing hospitals have indicated that hospitals are generally committed to participating in the program, but many have concerns about inadequate resources and about the balance between the risks and benefits of vaccination. Hospitals are concerned that they may have to assume the costs of implementing the program and note that they lack adequate resources to do so. Hospitals include in their cost calculations staff time to receive, administer, and follow up on vaccinations; materials (e.g., forms) and supplies (e.g., bandages); treatment for adverse events; and sick leave. Hospitals contend that the \$125 million previously provided by HRSA to states for use on the creation of regional hospital response plans has proved insufficient for that purpose and cannot cover the additional costs of the smallpox vaccination program. However, resources are not the primary concern for all hospitals. Hundreds of hospitals have opted not to participate in the smallpox vaccination program at this time, contending that the risks outweigh the benefits. Because the administration has characterized the threat of a smallpox attack as being low, some hospitals estimate that the countervailing risks to their patients of vaccinating hospital staff are too great. These hospitals have indicated that they would reconsider their decisions regarding participation should the risk of an attack increase or cases of smallpox appear.

State and local health officials and hospital representatives are also concerned about the scope of liability protection provided by the Homeland Security Act of 2002 and have requested clarification. These officials are requesting amendments to the act that would provide explicit liability protection to vaccination program participants not specifically protected by the act, such as public health departments and public health workers. In addition, since the act provides no apparent protection for entities that do not participate in the smallpox vaccination program,

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hospital representatives are concerned that a nonparticipating hospital, for example, may not be protected if one of its health care workers who was vaccinated elsewhere transmits vaccinia virus to one of its patients.<sup>30</sup>

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**Volunteers and Organizations That Represent Them Are Primarily Concerned about Safety and Compensation for Injury**

Many of the organizations that represent the public health and health care workers who are needed to volunteer to be vaccinated have expressed their willingness to participate in the smallpox vaccination program. However, they have concerns about the possibility of experiencing adverse reactions to the vaccine, ranging from fatigue to death, and the possibility of transmitting the vaccinia virus to coworkers, family members, or patients who could also face mild to severe complications. They also have concerns about compensation for such injuries.

Volunteers are concerned about the adequacy of CDC's screening process for ruling out volunteers with conditions that may put them at greater risk for severe reactions. For example, CDC recommends screening volunteers for pregnancy or HIV, either of which can put a volunteer at greater risk. However, volunteers do not believe they should have to undertake the effort and expense to independently be tested for these conditions. The provision of free testing for these risk factors as part of the screening process is left to the discretion of the individual participating jurisdictions and institutions. Volunteers are concerned that the lack of free, routine testing could hinder identification of potential vaccinees who may not be aware that they are pregnant or have HIV.

Volunteers who work in hospitals are concerned about the possibility of transmission of vaccinia virus to their patients. CDC asserts that following optimal infection control practices, such as using special bandages and checking them daily, wearing clothing that covers the vaccination site, and hand washing, should essentially eliminate the risk of vaccinated health care workers transmitting vaccinia virus to patients. Therefore, CDC guidance does not require that vaccinated workers be kept separate from patients until they can no longer transmit vaccinia virus. Volunteers are uncertain whether the practices that CDC recommends will be sufficient. Moreover, it is left to the individual participating jurisdictions and

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<sup>30</sup>Although the Secretary of HHS issued a letter implying protection for such a hospital, the Secretary's *Declaration Regarding Administration of Smallpox Countermeasures* indicates that hospitals would receive protection from liability under the act if they designate employees to receive the vaccine. It is unclear whether nonparticipating hospitals are in a position to make such designations. 68 Fed. Reg. 4212, 4213 (2003).

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hospitals to determine whether any leave taken to avoid contact with patients will be paid for by the institution or the health care worker. Thus, workers are concerned that they may lose income if they choose or are required to be kept separate from patients.

Nursing associations and unions representing health care workers are concerned about the two-pronged needle that CDC provides for use with the smallpox vaccine, noting that it lacks safety features such as a protective sheath available with other needles.<sup>31</sup> Health care workers assert that the needles being used in the program may increase the risk of needlesticks and exposure to the blood of vaccinees, both for those administering the vaccine and for those along the path of needle disposal.<sup>32</sup> They have recommended that an alternative needle with safety features be used instead. CDC has stated that it does not provide these alternative needles because it has determined that no commercially available safety-engineered two-pronged needle is an appropriate replacement for the one included in the prepackaged kit it is distributing for the smallpox vaccination program.

Many of the organizations representing health care workers have expressed support for the goal of the program. However, in the literature some individual physicians have questioned the program and raised concerns that the risks of smallpox vaccination to workers, their families, and patients may outweigh the benefits to society of preparedness for a smallpox attack. Like some hospital administrators, these physicians are recommending against vaccination at this time because program officials have characterized the risk of an attack with smallpox as very low and because there is a window in which vaccination is effective even after exposure. They too have indicated that they would reconsider their decision should the risk of smallpox increase.

The decision that health care workers face about whether to be vaccinated is further complicated by potentially confusing educational and screening

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<sup>31</sup>The Dryvax vaccine kit approved for use by the Food and Drug Administration (FDA) in the current smallpox vaccination program includes 100 two-pronged needles produced by the original manufacturer of the two-pronged needle. A different manufacturer produces an FDA-approved two-pronged safety needle, which has a plastic sheath that slides forward after use to cover the tip of the needle and prevent injury.

<sup>32</sup>See also U.S. General Accounting Office, *Occupational Safety: Selected Cost and Benefit Implications of Needlestick Prevention Devices for Hospitals*, GAO-01-60R (Washington, D.C.: Nov. 17, 2000).



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materials for volunteers. For example, some CDC materials specifically mention that certain asthma patients who are taking immune-suppressing drugs should be excluded. Other CDC materials screen out asthma patients for different reasons, and still others do not mention asthma patients at all. The differences in these materials may create confusion for individuals with asthma who are trying to determine if they should be excluded from vaccination. Also, because each jurisdiction can tailor some of the guidance and materials provided by CDC according to its own judgment, health care workers who live and work in separate jurisdictions could receive inconsistent materials. For example, CDC does not recommend against vaccinating individuals with an infant at home, but some jurisdictions have decided to exclude such volunteers from vaccination because of the seriousness of vaccinia virus in infants.

Organizations representing health workers are further concerned about whether the costs to volunteers and their families would be covered should they experience an adverse event and require time off from work,<sup>33</sup> need medical treatment, become disabled, or die. HHS officials have stated that they expect costs due to adverse events to be covered by sick leave, workers' compensation, or individual, institutional, or jurisdictional insurance policies. However, sick leave benefits vary from institution to institution, and thus some workers may lose income. Health care coverage also varies by institution and by policy, and thus not all volunteers are guaranteed to have coverage for the costs of treating their adverse reactions. For example, sick volunteers may have to pay co-payments for medical care. In addition, ASTHO has surveyed states and found wide variation in workers' compensation programs. Some states anticipate that vaccinated volunteers will be covered under their workers' compensation programs. However, given that workers' compensation eligibility is determined on a case-by-case basis, many states refrain from generalizing about such coverage. Even when applicable, workers' compensation may provide only a percentage of salary and may not provide coverage for individuals who received vaccinia virus from a vaccinated volunteer.

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<sup>33</sup>Based on available data, CDC estimates that, among properly screened volunteers, one-third of vaccinees will experience mild to moderate reactions that may cause them to miss at least 1 day of work.

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## Major Challenges Have Not Been Overcome and Continue to Affect Implementation

CDC and HHS have been working to address the major challenges of program schedule and hesitancy of participants, but to date they have not been able to overcome them. With regard to the challenging program schedule, CDC has reconsidered whether the initial targets for time for completion and the total number of vaccinated health care workers are required to achieve the goal of preparedness. Although CDC has said that it expected the first stage to take more than 30 days, it has not set a new target for completion of the first stage. The Director of CDC has stated, however, that it may not be necessary to vaccinate 500,000 health care workers to achieve the goal of preparedness. She has indicated that as few as 50,000 would suffice but has not explained how CDC arrived at that number. CDC has not said how these workers should be organized and distributed within the Smallpox Response Teams and across the nation. As of late April, CDC had yet to set new targets for the first stage or to request that the jurisdictions reconsider their plans to meet new targets. Most of the jurisdictions have initiated the first stage of vaccination as they had originally planned, although many have started later and have vaccinated fewer workers than they anticipated. Some jurisdictions have indicated that they are attempting to follow their original plans while awaiting resolution of the liability and compensation issues, and others have said that they have begun to revise their targets downward for the first stage without waiting for a request from CDC.

CDC has not said what the implications of this potential change in targets for the first stage would be for the second stage. In addition, although CDC announced that it would provide guidance for and request plans from the jurisdictions for the second stage, it has not done so. Thus the jurisdictions cannot determine how the workers to be vaccinated in the second stage will be used to expand response capacity. Specifically, they do not have guidance for how they should estimate their targets for the types, number, and distribution of the additional workers to be vaccinated.

CDC and HHS have made some progress in addressing the two major concerns regarding resources and liability that are contributing to the hesitancy of the implementers to participate in the program. CDC has indicated that it is developing cost estimates and working to identify additional resources to support implementation. In late March, HHS announced that jurisdictions would be allowed to obtain up to 20 percent of their 2003 federal bioterrorism preparedness funding immediately upon approval of their application by CDC. One of the activities that this funding may be requested for is smallpox vaccination. As of late April, the application procedure for obtaining these funds had not been specified. With regard to the liability concerns, CDC officials reported that they have

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worked with HHS to clarify the scope of the protection provided by the Homeland Security Act of 2002. HHS issued a letter and a declaration from the Secretary, and CDC published guidance and question-and-answer documents. Nonetheless, implementers continue to have questions and say they would prefer changes in the act itself to be assured of liability protection.

In addition, Congress has taken steps to address implementers' concerns about resources. On April 16, 2003, legislation was enacted appropriating \$100 million to the Public Health and Social Services Emergency Fund intended to support implementation of the smallpox vaccination program.<sup>34</sup> However, because CDC still has not estimated costs, it is unclear whether these funds will be sufficient to address the resource concerns of the implementers. Furthermore, details on how funds will be made available to jurisdictions have yet to be outlined.

Although CDC is working to address the volunteers' safety concerns that are leading to their hesitancy to participate, some concerns have not been resolved to the volunteers' satisfaction. CDC has decided not to change its guidance on several safety issues important to volunteers but has agreed to study some of these issues further. For example, it has not changed its recommendation that health care workers do not need to be routinely separated from patients while they are capable of transmitting vaccinia virus because it maintains that if the recommended safety measures, such as special bandaging, are followed they will provide sufficient protection. Further, CDC said that in making its decision about whether to change the needles provided with the vaccine kits, it reviewed an HHS evaluation of the alternative needle and concluded it was not safer. It does not intend to change the needles at this time, but it does intend to study the issue further and in the meantime to monitor unintentional needlesticks. Finally, CDC has not changed its recommendations regarding the provision of testing for pregnancy and HIV as part of the screening process. Thus, it is still at the discretion of jurisdictions to provide such testing routinely and free of charge. CDC plans to maintain a registry of pregnant women who may have been exposed to smallpox vaccine. Volunteers are, however, still concerned about these safety issues.

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<sup>34</sup>Emergency Wartime Supplemental Appropriations Act, 2003, Pub. L. No. 108-11, 117 Stat. 559, 586 (2003). The Conference Committee Report states that this amount is to assist state and local health authorities with costs associated with the smallpox vaccination program. H.R. Conf. Rep. No. 108-76, at 86 (2003).

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Congress has taken steps to address volunteers' compensation concerns. On April 24, 2003, it presented legislation to the President for his signature to create a smallpox vaccination compensation program. This program would provide benefits to public health and health care response team members participating in a smallpox emergency response plan and public safety personnel who are injured as a result of receiving the smallpox vaccine.<sup>35</sup> Organizations representing public health and health care workers have reacted positively to the new legislation. Other legislation that addresses challenges facing the smallpox vaccination program in addition to compensation, such as the safety concerns raised by volunteers, has been introduced in the House of Representatives.<sup>36</sup>

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## Conclusions

We recognize that CDC and the jurisdictions have been trying to mount a large effort in a short time. The National Smallpox Vaccination Program is unprecedented and complex. Our public health system has not had experience with either smallpox or smallpox vaccination in over 30 years. Further, the context for the program is one of great uncertainty about both the risk of a smallpox attack and the individual health risks involved in vaccination.

As might be expected with such a complex program, challenges have been encountered. Implementers and volunteers have indicated that they are unlikely to participate in the smallpox vaccination program in the numbers needed to achieve the initial targets unless their major concerns have been addressed. Because many concerns remain unresolved, it may be difficult to achieve the initial targets for the first stage. It is also too soon to evaluate the impact on participation in the program of steps that have been taken to provide additional resources and compensation for injuries.

However, CDC and some of the jurisdictions have indicated that as the program unfolds and they learn more, they are less concerned about achieving their initial targets and are considering revising them. However, if the estimates are reduced for the numbers and types of vaccinated health workers in Smallpox Response Teams, CDC would need to provide guidance to ensure that smaller or fewer teams are organized and

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<sup>35</sup>Smallpox Emergency Personnel Protection Act of 2003, H.R. 1770, 108th Cong. (2003) (enrolled).

<sup>36</sup>Smallpox Vaccine Compensation and Safety Act of 2003, H.R. 865, 108th Cong. (2003) (introduced).

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distributed in a manner that will provide adequate response capacity—that is, the capacity to effectively investigate an outbreak, care for patients, and vaccinate members of the public. Setting revised targets for the total number of vaccinations necessary would also provide a basis for more accurately estimating what is needed to address the major concerns of implementers and volunteers regarding resources, liability, and compensation for adverse events.

A change in targets for the first stage would likely have implications for the second stage. CDC has not provided guidance for determining how the workers to be vaccinated in the second stage will be used to expand response capacity. Thus it may be difficult for the jurisdictions to estimate targets and plan implementation of the second stage.

With regard to the top priority for implementation—safety—the important questions cannot yet be answered. To answer these questions and ensure that program implementation proceeds through the first stage as safely as possible, CDC and the jurisdictions need to collect and analyze data on an ongoing basis. To date, not enough data have been collected to provide the needed information. Answers to these questions are also important for ensuring safe expansion to as many as 10 million additional volunteers in the second stage of the program.

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## Recommendations

To ensure that the National Smallpox Vaccination Program successfully develops adequate response capacity for a potential terrorist attack involving smallpox, we recommend that the Director of CDC

- provide guidance and specific parameters to the jurisdictions for estimating response capacity needs and work with the jurisdictions to revise local and national targets for the first stage and
- provide guidance to the jurisdictions for implementing the second stage of the program.

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## Agency Comments

In its comments on a draft of this report, CDC concurred with our recommendations, and indicated that it will issue guidance to assist jurisdictions in their efforts to identify, train, and vaccinate appropriate responders (see appendix I). CDC also provided technical comments, which we incorporated as appropriate.

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We are sending copies of this report to the Director of CDC and other interested officials. We will also provide copies to others upon request. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>. If you or your staff have any questions about this report, please call me at (202) 512-7119. Another contact and key contributors are listed in appendix II.

Sincerely yours,

A handwritten signature in black ink that reads "Marcia Crosse". The signature is written in a cursive style with a long horizontal flourish at the end.

Marcia Crosse  
Acting Director, Health Care—Public  
Health and Science Issues

# Appendix I: Comments from the Centers for Disease Control and Prevention



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

APR 24 2003

Marcia G. Crosse, Ph.D.  
Acting Director  
Health Care – Public Health and Science Issues  
U.S. General Accounting Office  
441 G. Street, N.W., Room 5A14  
Washington, D.C. 20548

Dear Dr. Crosse:

The Centers for Disease Control and Prevention (CDC) is the lead agency for the national public health response to biological terrorism. Although a number of biological agents could be used to attack civilians, only a few, such as smallpox virus, have the potential to cause illness or panic which could overwhelm our present medical and public health systems.

Although smallpox was declared globally eradicated in 1980, there is concern that stores of smallpox virus may exist outside the two World Health Organization (WHO-) designated repository laboratories, which could be used as bioweapons. The emergence of a single case of smallpox (existing outside the two WHO- designated laboratories) would likely represent a bioterrorism release and would require an immediate and coordinated public health, medical, and law enforcement response to control the outbreak and to protect the public from any additional release.

In an effort to prepare the United States for a possible terrorist attack using smallpox virus, President Bush announced the smallpox program in December 2002. Since CDC initiated the smallpox vaccination program in January 2003, the vaccine has been administered to 32,644 civilian healthcare and public health workers through April 13, 2003.

CDC appreciates the efforts by the General Accounting Office (GAO) to review the implementation of the smallpox vaccine program and elucidate the challenges facing the program. We have reviewed your draft report entitled, *Smallpox Vaccination: Implementation of National Program Faces Challenges* (GAO-03-578), and concur that CDC should provide further guidance on implementing smallpox preparedness activities within state and local health departments.

Page 2 - Marcia G. Crosse, Ph.D.

CDC previously provided states a template for mass vaccination to assist them in determining the numbers and types of staff needed to vaccinate their entire populations rapidly. In addition, the Advisory Committee on Immunization Practices (ACIP) provided guidance to states on the type of personnel needed to staff smallpox response teams and listed specific categories of personnel for healthcare response teams. ACIP believes hospitals are in the best position to determine the actual number of their staff needed to care for smallpox patients until additional vaccinated staff become available.

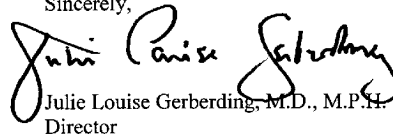
CDC will issue the "FY 2003 Continuation Guidance for the Bioterrorism Cooperative Agreement" to 62 state and local recipients. This document should help state and local jurisdictions complete efforts to identify, train, and vaccinate appropriate responders to ensure they are fully prepared to respond to a smallpox outbreak. The new guidance contains a summary of smallpox recipient activities and asks each grantee to determine the number of response personnel required to: (1) receive the smallpox vaccination before any smallpox outbreak occurs and (2) receive the vaccination in case there is an outbreak.

Additionally, the guidance requires state and local jurisdictions to enumerate:

- the number of laboratories that have the capacity for (CDC) Laboratory Response Network (LRN)-validated testing and reporting of *Variola major*, *Vaccinia*, and *Varicella zoster*;
- The percentage of identified mass vaccination clinic staff and volunteers trained;
- Percentage of participants reached in tests of public information systems.

We appreciated the opportunity to collaborate with your staff to produce the report, and we are grateful for the opportunity to contribute data, information, and technical comments. If you have any questions, please contact Michael Sage, Deputy Director, Office of Terrorism Preparedness and Emergency Response, at (404) 639-7405.

Sincerely,

  
Julie Louise Gerberding, M.D., M.P.H.  
Director



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# Appendix II: GAO Contact and Staff Acknowledgments

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## GAO Contact

Michele Orza, (202) 512-6970

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## Acknowledgments

Other key contributors to this report are George Bogart, Barbara Chapman, Angela Choy, Chad Davenport, Nkeruka Okonmah, and Roseanne Price.

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# Related GAO Products

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*Bioterrorism: Preparedness Varied across State and Local Jurisdictions.* [GAO-03-373](#). Washington, D.C.: April 7, 2003.

*Homeland Security: Voluntary Initiatives Are Under Way at Chemical Facilities, but the Extent of Security Preparedness Is Unknown.* [GAO-03-439](#). Washington, D.C.: March 14, 2003.

*Weapons of Mass Destruction: Observations on U.S. Threat Reduction and Nonproliferation Programs in Russia.* [GAO-03-526T](#). Washington, D.C.: March 5, 2003.

*Food-Processing Security: Voluntary Efforts Are Under Way, but Federal Agencies Cannot Fully Assess Their Implementation.* [GAO-03-342](#). Washington, D.C.: February 14, 2003.

*Chemical and Biological Defense: Observations on DOD's Risk Assessment of Defense Capabilities.* [GAO-03-137T](#). Washington, D.C.: October 1, 2002.

*Anthrax Vaccine: GAO's Survey of Guard and Reserve Pilots and Aircrew.* [GAO-02-445](#). Washington, D.C.: September 20, 2002.

*Bioterrorism: The Centers for Disease Control and Prevention's Role in Public Health Protection.* [GAO-02-235T](#). Washington, D.C.: November 15, 2001.

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*Food Safety: Agencies Should Further Test Plans for Responding to Deliberate Contamination.* [GAO/RCED-00-3](#). Washington D.C.: October 27, 1999.

*Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks.* [GAO/NSIAD-99-163](#). Washington, D.C.: September 14, 1999.

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*Combating Terrorism: Observations on Biological Terrorism and Public Health Initiatives.* [GAO/T-NSIAD-99-112](#). Washington, D.C.: March 16, 1999.

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