

The Smallpox Vaccination Plan: Challenges and Next Steps

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Testimony:

Good morning, Mr. Chairman and members of the Committee.

I am Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR).

Thank you for the opportunity to testify today about the efforts underway to assure the nation is prepared in the event of an attack using smallpox virus as a weapon.

THE DISEASE

Smallpox is a serious, contagious, and sometimes fatal infectious disease. There is no specific treatment for smallpox disease. Prevention strategies involve vaccination of exposed or potentially exposed individuals. Smallpox outbreaks have occurred from time to time for thousands of years, but the disease was eradicated after a successful worldwide vaccination program. The last case of smallpox in the United States was in 1949. The last naturally occurring case in the world was in Somalia in 1977.

Regardless of the mode, magnitude or duration of any terrorist attack, smallpox would be expected to spread from person to person following its introduction. Much is known about the natural transmission of smallpox. Generally, direct and fairly prolonged face-to-face contact is required to spread smallpox from one person to another. Smallpox also can be spread through direct contact with infected bodily fluids or contaminated objects, such as bedding or clothing. Rarely, smallpox has been spread by virus carried in the air in enclosed settings, such as buildings, buses, and trains. Humans are the only natural hosts of variola, the virus that causes smallpox. Smallpox is not known to be transmitted by insects or animals.

THE VACCINE

The smallpox vaccine is the only way to prevent smallpox. The vaccine is made from a virus called vaccinia, which is another “pox”-type virus related to smallpox virus. The vaccine helps the body develop immunity to smallpox. It was successfully used to eradicate smallpox from the human population. We have had a lot of experience with the smallpox vaccine and know it is very effective: it was used to eradicate smallpox from the world. It is safe in most people, but in some people it is associated with life-threatening adverse events. This risk of serious adverse events has made it more difficult to find the right balance between preparedness and not placing people at risk unnecessarily.

Routine vaccination of the American public against smallpox stopped in 1972 after the disease was eliminated in the United States. Vaccination was stopped because the risk of the vaccine was felt to outweigh the risk from the disease.

Until recently, the U.S. government provided the smallpox vaccine only to a few hundred scientists and medical professionals annually who work with smallpox and similar viruses in a research setting.

The stockpiling of smallpox vaccine was an important priority before September 11, 2001, and smallpox vaccine was already in production at that time. The events of the fall of 2001 heightened concern that terrorists may have access to the virus and attempt to use it against the American public. In response to these events, the Department of Health and Human Services (HHS) increased its order for vaccine, accelerated production, and began working to develop a detailed plan for the public health response to an outbreak of smallpox. The United States currently has sufficient quantities of the vaccine for every single person in the country in an emergency situation.

SMALLPOX RESPONSE PLANNING

A single report of a smallpox case in the United States will require an aggressive outbreak control effort to contain spread of the disease. In partnership with State and Local Health authorities, DHHS/CDC is in the process of establishing a smallpox preparedness and response program that:

- Enhances community awareness and clinician expertise about smallpox disease and smallpox vaccination through education and training;
- Performs disease surveillance and laboratory analysis to rapidly detect a single case of smallpox and any subsequent cases;
- Implements public health interventions, based on careful consideration of epidemiology and mode of transmission of smallpox, in the safest possible manner;
- Provides vaccination and follow-up service, on a voluntary basis, immediately to those individuals who respond to a smallpox emergency (including, but not limited to, those who will treat the victims, provide security, vaccinate the population, and perform disease case investigations), then, based on knowledge gained, expand the program to include those responders who would be occupationally at risk during a smallpox outbreak;
- Provides for the capability to rapidly vaccinate a greater number of responders or the entire population should a case occur or threat levels of a possible smallpox terrorist attack increase.

• Response to an Attack

States need to be prepared to rapidly implement aggressive smallpox containment activities, including the ability to vaccinate their entire populations. On October 28, 2002, CDC issued post-event smallpox planning guidance to the 50 states; the District of Columbia; the commonwealths of Puerto Rico and the Northern Marianas Islands; American Samoa; Guam; the U.S. Virgin Islands; the republics of Palau and the Marshall Islands; the Federated States of Micronesia; and the nation's three largest municipalities (New York, Chicago and Los Angeles County). To date, all 62 jurisdictions have developed plans that are undergoing review by CDC.

In addition, we are also working collaboratively with other nations (Canada, France, Germany, Italy, Japan, Mexico, and the U.K.) in the Global Health Security Action Group (GHSAG) to provide a coordinated and collaborative response to a bioterror event.

In particular, we are working closely with Canada and Mexico, as a smallpox outbreak in either could necessitate a rapid response in the U.S.

INCREASING PREPAREDNESS PRIOR TO AN ATTACK

- President's Plan

On December 13, 2002, President Bush announced a plan to better protect the American people against the threat of smallpox attacks by hostile groups or governments. This announcement is a vital step in ensuring that we are prepared to respond to a single reported case of smallpox. The President's decision will provide the public health and emergency response system with a cadre of vaccinated individuals who would respond in the event of outbreak of smallpox. The President's announcement identified the need for the public health system to provide smallpox vaccine to the following:

- Smallpox Response Teams

HHS has been working with state and local governments to form volunteer state and local Smallpox Response Teams that can provide critical services to their fellow Americans in the event of a smallpox attack. To ensure that Smallpox Response Teams can mobilize immediately in an emergency, health care workers and other critical personnel are being asked to volunteer to receive the smallpox vaccine. Pre-attack vaccination of Smallpox Response Teams will allow them, in the event of a smallpox attack, to immediately administer the vaccine to others and care for victims. In the initial phase of vaccination, vaccine will be offered to core members of public health and health care response teams. Then vaccination will expand to include health care workers and others who may be first responders.

- Department of Defense and State Department Personnel

The President also announced that the Department of Defense (DOD) will vaccinate certain military and civilian personnel who are or may be deployed in high threat areas. Some United States personnel assigned to certain overseas embassies will also be offered vaccination.

- Members of the General Public

The federal government is not recommending that members of the general public be vaccinated at this time. The government has no information that a smallpox attack is imminent, and there are significant side effects and risks associated with the vaccine. HHS is in the process of establishing an orderly process to make unlicensed vaccine available to those adult members of the general public without medical contraindications who want to be vaccinated either in 2003, with an unlicensed vaccine, or in 2004, with a licensed vaccine. A member of the general public may also be eligible to volunteer for an on-going clinical trial for next generation vaccines.

IMPLEMENTATION OF SMALLPOX PREPAREDNESS PLANS

On November 22, 2002, CDC asked states how they intend to vaccinate individuals most likely to respond to a smallpox attack. CDC requested pre-attack plans that contain information on the number of people comprising each Smallpox Response Team, information on where vaccines would be administered, the number of health care facilities identified to participate, and the number of clinics needed to support this effort. States were also asked to address vaccine logistics and security, vaccine safety monitoring, training and education, data management, and communications in their plans.

- Status of State Pre-Attack Vaccination Plans

States have worked diligently to develop plans to vaccinate and have begun implementing them. My oral testimony will address the current status of their implementation.

The plans indicate that approximately 450,000 public health and healthcare personnel may be offered the smallpox vaccine. Vaccination is voluntary and eligible individuals will make their own decisions as to whether or not to receive the vaccine. There are no negative ramifications employment ramifications for anyone who chooses not to be vaccinated. About 1,500 clinics around the nation will be set up to deliver the vaccine to those who choose to receive it. In addition, state health officials have identified over 3,300 health care facilities that will participate in the program.

DISTRIBUTING VACCINE TO THE STATES

The National Pharmaceutical Stockpile (NPS) Program ensures the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents. The NPS Program stands ready for immediate deployment to any U.S. location in the event of a terrorist attack using a biological toxin, chemical or radiological agent directed against a civilian population at the request of the locality.

The week of January 20, 2003, CDC delivered kits with enough vaccine and needles for 21,600 public health and healthcare workers to Connecticut, Nebraska, Vermont and Los Angeles County. As of January 22, 2003, 20 states (including 1 county) requested nearly 100,000 doses of vaccine. These were the first shipment of vaccine to state and local governments under the President's plan to protect the American people from an intentional release of the smallpox virus. Under the program, smallpox vaccine is being offered to those most likely to respond to a potential outbreak of the disease. Each state notifies CDC when it is ready to receive its shipment of smallpox vaccine to begin pre-event vaccination of public health and healthcare workers. Once CDC receives a request for smallpox vaccine from a state, the order is forwarded to the National Pharmaceutical Stockpile for processing and shipment. CDC is providing smallpox handling instructions, cold chain management guidance, and all appropriate documentation. CDC will deliver Dryvax[®] smallpox vaccine, packaged and shipped in increments as small as one vial (100 doses). CDC will validate all delivery information prior to shipment and will release vaccine after validation of temperature monitoring information.

TRAINING AND EDUCATION

Because smallpox vaccine has not been used routinely in the United States since the

early 1970s, many of today's healthcare providers are not familiar with the disease, the vaccine, or the vaccine's potential side effects. This makes training of those administering and those receiving the vaccine necessary to ensure that this program is implemented as safely as possible. Anyone considering vaccination must receive information on conditions that are contraindications to vaccination (e.g., certain skin conditions, compromised immune systems, pregnancy, allergies to components of the vaccine, or household contacts with a condition listed above). CDC has held 19 training and education sessions on smallpox that reached an estimated 800,000 clinicians,

members of the public health workforce, and members of the general population. Training has been conducted in classrooms, via satellite, over the Internet, through videotaped sessions and CD-ROM, and over the telephone. Thirty different training products, in a wide variety of media formats, currently are available.

- Training for Response Team Members

Training and education for Smallpox Response Team members will be critical. In order to prepare for their participation in a smallpox response effort, all Smallpox Response Team vaccination candidates will be asked to watch a video distributed by CDC and will receive a packet of information describing the purpose of the national smallpox preparedness program. The response team members will receive general information about smallpox disease and the vaccine, including pre- and post-vaccination worksheets to provide instructions for anticipating and monitoring any potential side effects, as well as fact sheets on various methods of treatment for side effects resulting from vaccination. Prior to vaccination, each vaccine recipient will be required to fill out a patient medical history and consent form to confirm the absence of contraindications and to confirm the patient's consent in receiving the vaccine.

- Training for Clinicians

Clinicians must be able to detect the first symptoms of a potential case of smallpox. During vaccination of response team members, clinicians will be an important resource for volunteers who are making a decision about whether or not they want to accept the smallpox vaccine. CDC has an ongoing initiative to educate clinicians about smallpox, done in conjunction with experts from a variety of medical professional organizations, including the Infectious Disease Society of America, the American Academy of Dermatology, the American College of Emergency Medicine (within a consortium of other emergency clinician organizations), and several primary care organizations. We are planning to help these organizations repackage information from CDC, and distribute it to their constituents in the format most appropriate for their members. In addition, CDC has established ongoing communication with 66 professional organizations that represent front-line clinicians to determine the smallpox training and education needs of their members. Within the next month, CDC is planning a national mail-out of critical clinician information to the nation's hospital and clinical community through each state's licensing board. In addition, we anticipate hundreds of thousands of clinicians will participate in CDC's upcoming Public Health Training Network program on "Clinical Management of Adverse Events Following Smallpox Vaccination: A National Training Initiative" scheduled for February 4, 2003. To supplement this extensive campaign to educate clinicians, CDC is also utilizing its normal means of getting information to clinicians, including the Health Alert Network, the secure Epi-X program, and the Morbidity and Mortality Weekly Report (MMWR). CDC has also contracted to establish a 24-hour-a-day, 7-day-a-week hotline for clinicians to call with questions about smallpox vaccinations.

- Training for Laboratorians

CDC is providing smallpox training for laboratorians, including detailed instructions on the differentiation of smallpox from other rashes. On January 29, 2003, CDC will broadcast nationally a training program entitled, "Smallpox and Vaccinia Laboratory

Testing: A National Training Initiative.” The program presents detailed information, specific to those who perform testing and those who use laboratory services, such as physicians, nurses, epidemiologists, and state medical officers. They will also be given specific information on the laboratory role in diagnosing adverse events associated with smallpox vaccination. In addition, CDC has developed “Agents of Bioterrorism: A Guide for Clinical Laboratories,” which includes information for clinical laboratorians about handling specimens suspected of containing smallpox. This guide will be distributed to the state public health laboratories within the next two weeks. The state public health laboratories can customize the guide with state-specific information and deliver it to the clinical laboratories in their area.

- Education for the Public and the Media

CDC has, and will continue to use, weekly (and as warranted) media briefings, media advisories, access to smallpox vaccine experts, and public information materials to create awareness of the smallpox vaccination recommendations, the purpose of the recommendations, and the risks associated with smallpox vaccine. In addition, CDC is using its website to provide easy access to a wide range of smallpox education materials, including materials designed specifically to meet the needs of different audiences—such as members of the public, health care providers, people for whom smallpox vaccination is recommended, and state and local health departments. We have been, and will continue to work with, state and local health departments and other partners to help ensure our messages and materials are visible and readily available. CDC also operates a 24-hour-a-day, 7-day-a-week public information hotline that is accessible in English and Spanish.

PREVENTING, DIAGNOSING, TREATING, AND MONITORING ADVERSE EVENTS

Ensuring that we can implement this program as safely as possible has been central to our planning. The first part of this effort is to carefully educate and screen those considering vaccination. We have had a great deal of experience with this vaccine and have information on who is at risk of serious adverse events (e.g., those who have certain skin conditions, have compromised immune systems, are pregnant, have allergies to components of the vaccine, or have a member of their household with a condition listed above). Second, we will, with state and local health departments and the healthcare community, ensure that we diagnose, manage, and treat adverse events promptly and correctly. Third, we will very carefully monitor adverse events to ensure that we know of any unexpected patterns or types of adverse events on a real-time basis and can quickly modify the program to decrease the risk of adverse events if necessary. Included in this effort is education about what to expect after vaccination, when to be concerned about an adverse event, and where to go for help.

The Smallpox Vaccine Adverse Events Monitoring and Response System will monitor the occurrence of clinically significant, especially serious, adverse events (AEs). It will also serve to identify any unexpected adverse events. This process will help to build state capacity for assessment of adverse events.

- Diagnosing and Treating Adverse Events

CDC will provide technical assistance to state health departments, including screening to identify and exclude persons with contraindications and help in implementing proper clinical procedures. There will be a designated telephone hotline for state health

departments. CDC will monitor state tracking of clinically significant AEs. CDC will also inform states of any adverse event reports transmitted directly to CDC.

Efforts are underway to work with healthcare providers to assure they are educated about the smallpox vaccination program and smallpox vaccine AEs. This includes recognizing possible AEs and managing and treating any AEs among their patients. Standard algorithms are under development to assist physicians in proper identification and treatment of these patients.

Vaccinia Immune Globulin (VIG) is a product used to treat certain serious adverse reactions caused by smallpox vaccine. Sufficient quantities of VIG are available now to treat all anticipated adverse events resulting from the current vaccination program. New VIG is being produced and delivered to the National Pharmaceutical Stockpile for distribution, if needed, as the vaccination program expands. An effort is underway to produce new lots that will meet the standards for intravenous immune globulin. Cidofovir is a drug used to treat viral infections in persons with HIV/AIDS. It may be helpful in treating vaccinia reactions in cases where VIG does not work.

The state will inform CDC of VIG and/or Cidofovir requests. A CDC clinical team will then assess the request with the state and treating physician. CDC Drug Services and the National Pharmaceutical Stockpile will coordinate release of VIG and Cidofovir. The treating physician will then be designated as a co-investigator on the Investigational New Drug (IND) protocol.

- Reporting

CDC is working with the states to develop an active surveillance system to detect serious adverse events following smallpox vaccine. CDC intends to implement recommendations that all health care workers have their vaccination sites monitored in the hospital daily, which will contribute information on serious illnesses that occur in all vaccinees. In addition, CDC will use the Vaccine Adverse Event Reporting System (VAERS), a national surveillance system administered by CDC and the Food and Drug Administration (FDA), to monitor smallpox AEs. The data collected through VAERS will be analyzed to identify any new or rare vaccine side effects, increases in rates of known side effects, associations with specific vaccine lots, or patient risk factors.

- Post-vaccination Surveillance

Post-vaccination surveillance will be conducted for people receiving the smallpox vaccine. This surveillance will assist in determining the rates of common AEs, assessing impact on time lost from work, and evaluating vaccinee satisfaction with the immunization program. This will be done by telephone survey 10 and 21 days post-vaccination.

- Data and Safety Monitoring Board

CDC has established a Data and Safety Monitoring Board to provide advice to the CDC and program managers on selected aspects of pre-event smallpox vaccination program implementation.

The committee will review reported adverse events to determine whether rates of serious events are within expected limits; whether recommendations for screening out persons with contraindications are being properly observed; whether adverse events following vaccination are causally or only coincidentally linked to vaccination; and whether the

adverse events experienced necessitate a substantial change in the way the program is run.

IOM COMMITTEE

Through the Institute of Medicine's (IOM) Committee on Smallpox Vaccination Program Implementation, the IOM is providing advice to the CDC and program managers on selected aspects of pre-event smallpox vaccination program implementation. The IOM Committee released its first report on January 17, 2003.

The committee is making recommendations to CDC and state and local vaccine program managers to improve: CDC guidance designed to identify potential vaccine recipients at high risk of vaccine adverse events and complications; CDC measures to ensure the early recognition, evaluation, and appropriate treatment of adverse events and complications of smallpox vaccination; CDC plans for collecting and analyzing data on vaccine immunogenicity, adverse events, complications, and vaccine coverage; the informed consent process for vaccine recipients; professional education and training materials; communication plans for public health and medical professionals and the public; state smallpox vaccination implementation plans; and the achievement of overall goals of the smallpox vaccination program (e.g., vaccine coverage rate, equity of access, adverse reaction rates, etc.).

CONCLUSION

Assuring the nation is prepared in the event of an attack by a hostile group or government is one of the highest priorities for the administration. HHS and CDC are dedicated to assisting the states in increasing smallpox preparedness. We greatly appreciate all the work the states and local jurisdictions have done to develop plans and begin to implement them. We look forward to continuing to support states' efforts to protect the American people.

Thank you for the opportunity to testify before you today on this important public health issue. I would be happy to answer any of your questions.