

Introduction to Developing a Vaccination Strategy for Smallpox Preparedness

**Department of Health and Human Services
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Today, I will briefly discuss additional supplemental guidance for recipients of federal funding through the Public Health Preparedness and Response for Bioterrorism Cooperative Agreement for the purpose of supporting smallpox preparedness and response. This supplemental guidance amends the Guidance for Post-event Smallpox Planning issued by CDC on October 28, 2002, and provides additional specificity to support the vaccination of healthcare and public health smallpox response teams. CDC will provide technical assistance to cooperative agreement recipients or grantees throughout the program, for both planning and implementation, as well as smallpox vaccine, once grantee plans are approved.

Why Vaccinate Health Care Workers?

- **In Europe between 1950 and 1971, more than 50% of transmission by imported smallpox cases occurred in hospitals**
- **About 20% of secondary cases were in health care workers**

Mack J, JID 1972



In Europe, between 1950 and 1971, more than 50% of transmission by imported smallpox cases occurred in hospitals. Health care workers accounted for about 20 percent of all cases after these importations.

Why Vaccinate Health Care Workers?

- **Mathematical models suggest contagiousness of smallpox is reduced by about half if health care setting transmission is eliminated**
- **Reason: smallpox spreads from very sick persons, who are usually in hospitals**



Mathematical modeling suggests the contagiousness of smallpox is reduced by half if transmission in health care settings is stopped. The reasons for this last finding are clear: smallpox spreads from very sick patients, who are the most likely to go to hospitals for care.

Goal of Program

- **To increase the nation's smallpox preparedness capacity by offering vaccination safely to:**
 - 1. Public health teams designated for outbreak control**
 - 2. Health care workers treating and managing initial cases**



The goal of this program is to increase the nation's smallpox preparedness capacity by offering vaccination safely to two groups: First, volunteer public health teams to conduct investigations and outbreak control for the initial cases of a smallpox event. And second, to key volunteer healthcare workers who would treat and manage the initial smallpox cases and suspects.

Overview of Program Guidance

- **Guidance issued November 22**
- **Plans due to CDC December 9**
- **Will supplement plans for smallpox outbreak control submitted December 2**
- **Guidance elements to be covered throughout the broadcast in more detail**



The supplemental program guidance was issued November 22, 2002, and the plans are due to CDC on Monday, December 9. The guidance supplements earlier guidance issued for plans for smallpox outbreak control, which were to have been submitted to CDC by December 2. Throughout this broadcast, the required eleven elements have been and will be covered in much more detail than I will cover now. Immunization operations should be completed within 30 days of the program's announced start date.

Organization and Management

- **Public Health Preparedness and Response for Bioterrorism grantees in states and large cities will implement smallpox immunization programs**
- **A smallpox coordinator should be appointed in each state and city grantee, and work with the Bioterrorism Advisory Committee, and healthcare partners**



The first element is Organization and Management. Public Health Preparedness and Response for Bioterrorism state and local grantees will be responsible for implementing and managing the smallpox immunization program. Each grantee must appoint a coordinator for the smallpox immunization program. Advice on program implementation should be sought from the health department's Bioterrorism Advisory Committee and appropriate healthcare partners.

Organization and Management

- **States/local HD will identify**
 - **management personnel by title, function, contact information**
 - **timeline for implementation**
 - **structure and management (organizational chart)**



State and local grantees will identify: management personnel by title, program function, contact information; the timeline for program implementation; an organizational chart showing the structure and management of the smallpox immunization program.

State/Local Health Departments will plan and determine:

- **The estimated number of hospitals/
healthcare teams expected to participate**
- **A policy defining hospital
responsibilities**
- **Number and occupations of HC
personnel expected to be vaccinated**
- **A timeline for selection of hospitals and
vaccination dates**



State and local health departments will determine: the estimated number of hospitals and healthcare response teams expected to participate; a policy defining hospital responsibilities, including pre-program education, screening, adverse event evaluation, and treatment, daily vaccination site management, and evaluation of vaccination takes; the estimated number and occupational types of healthcare personnel expected to be vaccinated, and a timeline for selection of hospitals and individual health care workers and the vaccination of healthcare response teams.

Identification of Response Teams

- **Public Health Smallpox Response Teams**
 - **Medical expert**
 - **PHA**
 - **Epidemiologist**
 - **Nurses**
 - **Disease Investigators**
 - **Lab scientist (LRN)**
 - **Vaccinators**



Each grantee should have at least one public health smallpox response team. Each team should include a medical expert as team leader, public health advisors, medical epidemiologists, nurses, disease investigators, diagnostic laboratory scientists, including those assigned to perform vaccinia and orthopox diagnostics within the Laboratory Response Network or LRN, vaccinators, and other necessary personnel as determined by state and local officials. The Advisory Committee on Immunization Practices suggests that where possible previously vaccinated public health personnel be made part of the response teams.

Identification of Response Teams

- **Healthcare Response Teams**
 - **Hospital-based personnel to care for patient for 7-10 days in event of a case of smallpox**
 - **Hospital personnel chosen appropriate to institution (e.g., ER, ICU staff)**



Health care response teams should be selected so that each participating hospital has enough vaccinated staff to care for a smallpox patient or patients for 7-10 days. Team members should be appropriate for the institution, such as staff from emergency departments and intensive care units.

Selection of Clinic Sites and Vaccination Teams

- **Rationale:**
 - **100 dose vials**
 - **Limited supply of vaccine**
 - **Reduce wastage**
 - **Need for careful vaccine handling**
 - **Security**
 - **Screening**



In considering selection of clinic sites and vaccination teams, CDC envisions limiting the number of vaccination clinic sites in each grantee area to a few, fixed, geographically distributed sites. In addition, grantees may choose to use clinic teams or sub-teams that operate from a clinic base to perform vaccinations as required by population and hospital distributions. The rationale for this includes: the packaging of smallpox vaccine in 100 dose vials, the currently limited supply of smallpox vaccine, the need for careful vaccine handling that minimizes wastage and ensures security, and the level of supervision and expertise required to maintain the highest quality of patient screening and vaccination practices, thereby maximizing the safe use of the vaccine.

Vaccination Clinic Sites, Planning, Scheduling, Operations and Management

- **State Health Department determines:**
 - **Number/location of clinic sites, teams**
 - **Timeline**
 - **Training, supervision, management, evaluation of clinic teams**
 - **Day/hours of clinic operations**
 - **Total number of clinic personnel**



Each grantee will be responsible for determining: the number and tentative location of clinic sites; a timeline for selection of clinic sites and clinic vaccination teams; a plan for training members of the clinic teams and for providing supervision management and evaluation of the clinic and clinic team members; the intended days and hours of clinic operation; and the estimated total number of clinic personnel needed.

Vaccine Logistics and Security

- **Licensed vaccine is packaged as a 'kit'**
 - **1 vial of diluent for 100 doses**
 - **100 bifurcated needles**
 - **1 transfer syringe/needle**
 - **Package insert/lot number stickers**



In considering vaccine logistics and security, you should know that CDC is prepared to ship vaccine to all 62 grantees and will be responsible for security from the repository designated by each grantee. CDC will provide smallpox vaccine, vaccine 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, or 100 doses.

Licensed vaccine is packaged as a 'kit' made up of 1 vial smallpox vaccine, 1 vial of diluent for 100 doses, 100 bifurcated needles, one transfer syringe and needle, package insert and lot number stickers. This vaccine, reconstituted with the diluent, can be used over several clinic sessions, if handled correctly.

Clinic Operations and Management

- Adequate screening of potential vaccinees
- Clinic supplies, equipment
- Educational and screening materials
- Timelines for clinic operations



Every grantee will be responsible for: description of the process for ensuring adequate screening of potential vaccinees; plans to ensure clinics have adequate supplies and equipment and educational and screening materials and a timeline for implementing clinic operations.

Two-step Vaccination Process

- **Potential vaccinees to be selected by hospital or public health unit, then:**
 - **Step 1: pre-vaccination counseling to occur at hospital or public health unit**
 - **Step 2: vaccination to follow some time later, to permit further counseling, and laboratory testing if desired by potential vaccinees**



An important part of clinic operations is CDC's recommended two-step vaccination process. In step one, potential vaccinees will receive information about the program, including vaccine contraindications and options for screening tests, usually at their hospital or place of work. Potential vaccinees will then have time to decide about any need to consult their family members, physicians, or receive screening tests, such as those for HIV infection or pregnancy, both of which conditions are contraindications for vaccination. In step two, some days later, those agreeing to be vaccinated will go to a designated vaccination clinic, and be vaccinated.

Training and Education

- **State and local health department will provide general education and training on components of smallpox vaccination plan to hospitals, professional organizations**
- **CDC will provide training and educational materials**



State and local health departments will provide general education and training on the components of the smallpox vaccination plan for their own staff, as well as those from hospitals, professional organizations, and others. A variety of methods, venues, and materials can be used. CDC will provide and deliver training and educational materials in a variety of methods including live satellite broadcasts, webcasts, audiocasts, videotapes, CD ROMS, web-based and printed materials.

Data Management

- **Grantees may choose vaccination information system**
 - **1. Pre-Event Vaccination System (PVS) with named data**
 - **2. PVS without named data**
 - **3. Perform data exchange with CDC from certified, alternative state system**
- **Support and integrate with VAERS**



Detailed information and data will be needed on an ongoing, real-time basis to inform policy makers, health officials, clinic managers, and the public about the status of a smallpox vaccination program. Data derived from the clinics must be analyzed frequently to enable managers at all levels to identify and resolve problems, evaluate progress toward meeting objectives and redirect the activities, as necessary.

Grantees will choose from one of the three following options for providing smallpox vaccination information to the CDC: one, use the Pre-Event Vaccination System, or PVS, with named data; two, use the PVS application without named data; or three, perform data exchange with the CDC from a certified, alternative state system. Grantees are strongly encouraged to pursue option 1 or option 2 until certification of data exchange from an alternative system is established. The use of named data is solely for the support of state functionality of the PVS application. The CDC will not use named data. Grantees will also describe how the State and clinics will support and integrate with the Vaccine Adverse Events Reporting System or VAERS, and PVS.

Communication

- **Medical and public health professionals and public must realize purpose of activity to effectively manage a smallpox emergency if one were to occur**
 - **SHD should identify a point of contact responsible for communications**
 - **Address critical communication issues**



Effective communication is essential. Medical and public health professionals and the public must realize the purpose of this activity. Federal, state, and local health officials, hospitals and provider professional organizations are collaboratively responding to strengthen the nation's ability to effectively manage a smallpox emergency if one were to occur. Given the short timetable for program implementation, grantees are encouraged to use existing CDC communications materials but should develop grantee-specific communication when time allows. In addition, they should identify a point of contact responsible for communications associated with this activity, and address critical communication issues, such as the purpose of the smallpox vaccination program and vaccine safety monitoring.

Reporting Requirements

- **Submit semi-weekly status reports (Monday, Thursday)**
- **Report to Data Management Division, National Immunization Program**



The final point I will cover is that of reporting requirements. Grantees will be required to submit semi-weekly status reports on each Monday and Thursday throughout the vaccination program. These reports should be submitted to National Immunization Program's Data Management Division.

For More Information

- **CDC Smallpox website**
www.cdc.gov/smallpox
- **National Immunization Program website**
www.cdc.gov/nip

