

**WEBCAST TRANSCRIPT****Transcript of "Introduction to Developing a Vaccination Strategy for Smallpox Preparedness"**

Presented by Dr. Walter Orenstein, 6 December 2002, on the satellite broadcast of "CDC Bioterrorism Update: Smallpox Preparedness"

(Associated graphics can be found at

www.bt.cdc.gov/agent/smallpox/training/webcast/dec2002/files/develop-vac-strat.ppt and www.bt.cdc.gov/agent/smallpox/training/webcast/dec2002/files/develop-vac-strat.pdf.)

Walt Orenstein, MD, Director, National Immunization Program, CDC

ORENSTEIN:

Hello, I'm Walt Orenstein, Director of the National Immunization Program at CDC. 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.

Slide 2

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.

Slide 3

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.

Slide 4

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.

Slide 5

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.

Transcript of "Introduction to Developing a Vaccination Strategy for Smallpox Preparedness"

(continued from previous page)

Slide 6

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.

Slide 7

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.

Slide 8

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.

Slide 9

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.

Slide 10

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.

Slide 11

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.

Slide 12

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.

Transcript of "Introduction to Developing a Vaccination Strategy for Smallpox Preparedness"

(continued from previous page)

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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.

Slide 13

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.

Slide 14

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.

Slide 15

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.

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Vaccine safety monitoring, reporting, treatment and patient referral is essential to the success of this vaccination program. Grantees' plans must describe how they will interface with a Smallpox Immunization Safety System that will be described elsewhere in this broadcast.

Slide 16

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.

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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.

Slide 17

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,

Transcript of “Introduction to Developing a Vaccination Strategy for Smallpox Preparedness”

(continued from previous page)

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.

Slide 18

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.

Slide 19

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. [PAUSE]

ORENSTEIN:

The implementation of a vaccination program for smallpox preparedness and response will be a challenge for all of us. We look forward to working with you to accomplish this important public health effort.

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For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

December 6, 2002

Page 4 of 4