



Centers for Disease Control
and Prevention (CDC)
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Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program (NSVP)

**Public Health Preparedness and Response for Bioterrorism Cooperative Agreement
Centers for Disease Control and Prevention**

Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program (NSVP)

A. Background

This document provides additional supplemental guidance for recipients of federal funding through the Public Health Preparedness and Response for Bioterrorism (PHPRB) Cooperative Agreement (Announcement Number 99051) for the purpose of supporting smallpox preparedness and response. This supplemental guidance (amending the Guidance for Post-event Smallpox Planning issued by CDC on October 28, 2002) provides additional specificity to support the vaccination of healthcare and public health smallpox response teams.

B. Goal of this Activity

To increase the nation's smallpox preparedness capacity by: (1) offering vaccination safely to volunteer public health teams (including vaccinators) to conduct investigations and outbreak control for the initial cases of a smallpox event; and (2) offering vaccinations safely to key volunteer healthcare workers who would treat and manage the initial smallpox cases and suspects.

C. Funding

The activities necessary to plan and implement this initiative involve the critical and enhanced capacities in the 7 Focus Areas for which funding was provided through the supplemental PHPRB Cooperative Agreement funds in February 2002. Recipients are encouraged to utilize these funds to plan and implement this initiative and should redirect funds, as necessary, in accordance with the PHS Grants Policy Statement and guidance documents previously issued by CDC for this cooperative agreement.

D. Timeline

Immunization operations should be completed within 30 days of the program's announced start date.

E. Plan Format and Content

PHPRB grantees are requested to develop a plan that addresses the how they will satisfy the goal of this activity. The implementation plans must include, at minimum, the plan requirements listed below:

1. Organization and Management

PHPRB grantees will be responsible for implementing and managing the smallpox immunization program. Each grantee must appoint a coordinator for the smallpox immunization program. Plans should include a description of the program operation and management. Advice on program implementation should be sought from the health department Bioterrorism Advisory Committee and appropriate healthcare partners.

Plan Requirements:

- Identification of management personnel by position title, program function, contact information and name (if possible.)
- A timeline for program implementation
- An organizational chart showing the structure and management of the smallpox immunization program.

2. Identification of public health smallpox response teams

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, disease investigators, diagnostic laboratory scientists, laboratory response network (laboratorians assigned to perform vaccinia and othropox diagnostics within LRN laboratory network) nurses, vaccinators, and other necessary personnel as determined by state and local officials. ACIP suggests that where possible previously vaccinated public health personnel be made part of the response teams. (**Annex 1**)

Plan Requirements:

- The number of teams needed.
- The proposed composition of teams by position, title, role and agency affiliation
- A timeline for selection and vaccination of individual team members.

3. Identification of Healthcare Smallpox Response Teams

Grantees will need to collaborate with appropriate local health agencies, medical and hospital organizations and individual hospitals to develop the criteria for and numbers of hospitals to be involved and in identifying individual health care workers to be offered vaccine.

Plan Requirements:

- 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
- A timeline for selection of hospitals and individual health care workers and the vaccination of healthcare response teams

4. Selection of Clinic Sites and Vaccination Teams

The NSVP 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.

Each grantee will be responsible for determining the number, staffing needs and location of clinic sites for smallpox vaccination operations.

Plan Requirements:

- 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
- The estimated total number of clinic personnel needed

5. Scheduling

State and local health departments, selected hospitals, public response health teams, and the vaccination clinics will collaborate on the clinic site and scheduling for hospital medical team and public health team volunteers for screening and vaccination. Care should be taken to schedule vaccinations to minimize vaccine wastage and work disruption among vaccinees of participating hospitals and public health teams.

Plan Requirements:

- An estimate of the total number of persons who will be vaccinated each week
- A strategy for scheduling vaccinations of hospital and public health smallpox response teams

6. Vaccine Logistics and Security

CDC is prepared to ship vaccine to 62 grantees and will be responsible for security from the repository designated by each grantee. CDC will provide smallpox handling instructions, cold chain management guidance, handling instructions, 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 release vaccine after validation of temperature monitoring information.

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. Storage requirements are described in detail in the **Annex 2**.

Plan requirements:

- Provide primary and alternate point of contact, alternate phone numbers, fax numbers, and a designated ship-to address.
- Number of required doses
- A strategy for managing and safeguarding the vaccine and related supplies

For questions on logistics and security, please call the NPS program # 404-639-0459. Please reference smallpox vaccine when talking to the operator.

7. Clinic Operations and Management

Every grantee will be responsible for establishing an integrated clinic strategy and flow that will maximize the efficiency of the fixed clinics and/or sub teams operating outside of fixed clinics and the utilization of the vaccine. Clinic staff must be responsible for essential clinic functions including establishing patient flow, record keeping, educating and screening potential vaccinees; clinic security; ensuring adequate educational materials, forms, and other supplies, stocking of medical supplies, worker safety, obtaining consent, vaccine handling, vaccination, acute medical reaction management, data collection/entry into the information system, vaccine accountability, post vaccination wound management, waste disposal, advice on adverse events and reporting, completing the vaccinee's vaccination card, and evaluating for vaccine take for personnel referred back to the clinic for take documentation (e.g. those not affiliated with specific hospital/clinic that will evaluate their own staff takes). **Annex 3** provides detailed information on clinic operations, including forms, suggested supplies, and check lists.

Plan Requirements:

- 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.
- A timeline for implementing clinic operations

8. Vaccine Safety Monitoring, Reporting, Treatment and Patient Referral

Grantee's plans must describe how they will interface with the Smallpox Immunization Safety System (SISS) provided in **Annex 4**. General information on smallpox, smallpox vaccine and vaccination, contraindications and adverse events is available through the CDC Smallpox web-site www.bt.cdc.gov/agent/smallpox.

Plan Requirements

- The name and position of the individual(s) responsible for coordinating vaccine safety monitoring, reporting, treatment and patient referral
- A plan that describes how the grantee will provide for vaccine safety monitoring, reporting, treatment and patient referral (**see Annex 4**)

9. Training and Education

State and local health departments, hospitals, professional organizations, and others will require general education and training on the components of the smallpox vaccination plan. 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. A list of training materials under development by the CDC is provided in CDC's Smallpox Vaccine Program Training and Education Plan (**Annex 5**).

Plan requirements:

- A plan for conducting training of vaccination clinic staff on critical components of the plan including, venues for training, specific personnel to be trained, and a timeline for implementation

10. Data Management

Detailed information 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: (1) use the Pre-Event Vaccination System (PVS) described in the **Annex 8** with named data; (2) use the (PVS) application without named data; or 3) 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.

All grantee systems will be expected to meet the functional systems requirements identified in the **Annex 6**, which provides the minimum functional requirements that a vaccination record system must provide related to the support of a smallpox vaccination program.

Systems developed or purchased by grantees (option #3 above) must also meet the data exchange requirements outlined in **Annex 7**. Detailed formats of required and optional data that will be reported to the CDC to support monitoring efforts of the vaccination program are also provided.

Plan requirements:

- The name, position, and contact numbers of the individuals designated to oversee, coordinate and collaborate with state, local, clinic and CDC data management and information experts to facilitate full knowledge, understanding, acceptance and support of the system, its implementation and maintenance, and its evaluation.

- Description of how the State and clinics will support and integrate with VAERS and CDC's web-based information system (PVS) in identified clinic settings

11. Communications

Medical and public health professionals and the public must realize the purpose of this activity and that 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. Additional reference information concerning helpful URLs and key facts can be found in **Annex 9** and **Annex 10**.

Plan Requirements:

- Identify a point of contact responsible for communications associated with this activity
- Address critical communication issues

F. 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, Data Management Division. A reporting form with required data elements is provided in **Annex 11**.

G. Approval

Plans will be evaluated against the requirements stated in the Plan Format and Content section. Project officers will contact and work with grantees as necessary to obtain critical information not included in the plan as submitted. Upon the approval of CDC, (and a federal decision allowing the use of vaccine) vaccine will be released to the grantees in accordance with protocols of the National Pharmaceutical Stockpile at CDC.

H. Plan Submission and Deadline

Please submit supplemental plans via email as Microsoft Word™ attachments by COB on December 9, 2002 to:

Glen Koops
 Director, State and Local Preparedness Program
 Officer of Terrorism Preparedness and Response
 Centers for Disease Control and Prevention
gak3@cdc.gov

I. Where to Obtain Additional Information

For additional programmatic information concerning planning and implementation of the NSVP, please contact:

Tom Hicks
Program Operations Branch
Immunization Services Division
National Immunization Program
Centers for Disease Control and Prevention
404-639-8215
twh1@cdc.gov

For information concerning the use of funds provided through the PHSRB Cooperative Agreement for this project, please contact your designated BT project officer or PGO grants specialist.

Table of Annexes

- Annex 1 - Summary of October 2002 ACIP Vaccination Recommendations (Updated October 21, 2002)
- Annex 2 - Vaccine Logistics & Security Guide Supporting Documents (A-F) (Draft)
- Annex 3 - Clinic Operations Guide (Draft)
- Annex 4 - Smallpox Immunization Safety System (SISS) Overview (Draft)
- Annex 5 - Training and Education Plan (Draft)
- Annex 6 - Vaccine Application Functional Requirements & Process Flows (Draft)
- Annex 7 - Data Exchange Requirements for Vaccination Administration Systems (Draft)
- Annex 8 - Vaccine System Overview (Draft)
- Annex 9 - Communications, Training, & Education URL List (Draft)
- Annex 10 - Communications, Training, & Education Key Facts (Draft)
- § Annex 11 – Reporting Requirements