



THE CITY OF NEW YORK
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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Preliminary Planning Guidance for the Vaccination of Health Care Response Teams Against Smallpox: Wave I

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This document is to be used by the hospital smallpox vaccination planning team as an overview and preliminary guidance in planning for the voluntary on-site vaccination of health care smallpox response teams. The Department of Health and Mental Hygiene will provide more in-depth guidance, educational materials and training at a later date.

I. Introduction

The New York City Department of Health and Mental Hygiene (DOHMH) has prepared a plan to provide smallpox vaccinations to health care, public health and other key first responder teams, to support national smallpox preparedness and response activities.

This plan is based on the following assumptions:

- The goal of this initial voluntary vaccine campaign is to ensure the city's ability to care for and initiate the public health response to the first smallpox cases.
- This initial vaccination phase is **NOT** meant to ensure preparedness for a large or overwhelming outbreak by vaccinating all health care workers, public health workers and first responders.
- Calculations were based on the possibility that New York City will need to be prepared for an initial outbreak of 5 simultaneous cases of smallpox. In addition, this initial vaccination effort should ensure the capacity to vaccinate rapidly all other health care and first responder staff in the event of a smallpox outbreak to ensure an effective emergency response.
- Potential cases of smallpox could present to any acute care facility in New York City, so all hospitals need to be prepared to recognize and care for potential smallpox cases.
- Enough hospital staff should be vaccinated to provide care for up to 5 smallpox cases for 7 to 10 days until sufficient additional hospital staff has been vaccinated.

The DOHMH's foremost priority is ensuring that vaccine is administered safely. All efforts will be made to fully educate potential vaccinees in order to prevent administering the smallpox vaccine to anyone with a contraindication or to anyone who has a household member with a contraindication.

II. Program Overview

1. Hospital Eligibility

- Seventy-four acute care hospitals are eligible to participate.
- Hospital participation is voluntary.
- With support from DOHMH, participating hospitals must be able to support the educational programs and clinic infrastructure outlined in Section 3 of this document.
- Enough volunteers must be identified to support a Health Care Smallpox Response Team (See Appendix 1).

2. Health Care Smallpox Response Teams (HCSRT)

- Appendix 1 describes the assumptions that should guide the identification of each hospital's HCSRT and provides a template for the types of staff that should be recruited. **The DOHMH recognizes the need to allow hospitals flexibility in defining their specific response teams.**
- Each hospital may expect to receive between 100 to 200 vaccinations depending upon hospital size.

3. Hospital Responsibilities

While the DOHMH will be assisting in all aspects of the vaccination activities, hospitals will have the primary responsibility to develop, implement and maintain their hospital's smallpox vaccination program. Vaccination will occur at a hospital clinic site. This will have the following advantages: 1) to minimize disruption to hospital staffing patterns and increase participation, 2) to prepare hospitals to educate, vaccinate and monitor their staff during Wave II of the smallpox vaccination program or in response to an outbreak, should this occur, 3) to utilize the hospitals' incident management system in preparation for a possible smallpox epidemic or another emergency, and 4) to ensure that they are 'covered persons' under section 304 of the Homeland Security Act.

A. Hospital Internal Planning Team

The hospital will need to form an internal planning team to oversee and support all aspects of the vaccination program. Staff from the following hospital areas is recommended:

- Hospital administration;
- Infectious diseases and infection control;
- Employee health;
- Information technology
- Mental health;
- Emergency preparedness/disaster planning;
- Legal; and
- Human resources.

B. Supervision and Communication with DOHMH

The DOHMH will assign a Hospital Liaison Team (HLT) to each hospital. The HLT will consist of a physician (Medical Doctor), a public health specialist (Administrator), one or two registered nurses (Nurse Vaccinators), and a data specialist (Data Manager). The hospitals will each be required to **designate a Smallpox Vaccine Administrative Liaison** to DOHMH who will be responsible for supervision of all hospital activities and employees, including facilitating all activities conducted by the DOHMH. **The Liaison needs to be identified as**

**soon as possible and their contact information provided to the DOHMH.
(See Appendix 2.)**

There will be two individuals at every site responsible for all clinic activities: The DOHMH HLT Team Leader (the physician or administrator) and the hospital's Smallpox Vaccine Administrative Liaison. The DOHMH HLT Team Leader will be responsible for the vaccine and all related activities. The DOHMH will also have personnel who make sure that all the necessary supplies and personnel are in place before we begin the vaccination process.

The hospital's Smallpox Vaccine Administrative Liaison to DOHMH and other key members of the hospital's HCSRT will be asked to register for the DOHMH Health Alert Network (DOHMH HAN), a new communication network linking hospitals and the DOHMH, which will be activated in the last week of December 2002. This system will allow on-line conferencing, bulletin board communication, and downloading of documents from a document library. It is anticipated that much of the communications related to this smallpox vaccination program will occur over the DOHMH HAN. The DOHMH will coordinate registration through the hospital's Smallpox Vaccine Administrative Liaison to DOHMH.

C. Facilities

The hospital is responsible for providing the following space and equipment:

- A fixed clinic for administration of vaccination, monitoring of vaccine "take", and medical care for adverse events.
- An auditorium to provide educational sessions for staff who are potential vaccinees.
- Enabled, continuous web access at the clinic is preferred.
- Digital camera to facilitate consultation on "vaccine take" and any cutaneous adverse events.

D. Personnel

The hospital is responsible for providing the following personnel:

- Security guards to maintain the safety of the clinic and clinic staff.
- Registration clerks who will register interested potential vaccinees.
- Physicians, nurses or other appropriate personnel who will review all medical contraindications with potential vaccinees and obtain their informed consent.

- Staff to vaccinate, perform required site check and dressing changes, and check for vaccine “take” after they are successfully vaccinated and trained in these responsibilities by DOHMH.
- Staff to educate vaccinees about post-vaccination site care and instruct vaccinees on the expected range of local and systemic reactions, as well as the more severe adverse events with clear instructions on how to seek care for any post-vaccination adverse event.
- Medical staff available to care for adverse reactions to vaccine.
- Patient flow monitors, if needed.

The hospital is also responsible for maintaining a clinic chart on each patient. The DOHMH HLT Administrator will bring copies of all the necessary paperwork for the entire program to each clinic on each clinic day. Hospitals will be required to provide a copy machine and copy the necessary paperwork as needed.

4. DOHMH Responsibilities

The HLTs will be trained on all aspects of smallpox vaccination and will monitor and assist hospitals in conducting the smallpox vaccination clinics.

DOHMH will maintain central control of all vaccine, and HLTs will assist hospitals with administering smallpox vaccine. The HLT will be responsible for quality control of the provider education sessions, oversight of all vaccine handling and administration, reconstitution of the vaccine, oversight of hospital staff obtaining consent, managing data and teaching hospital staff to manage data and returning the vaccine to the DOHMH each day. All vaccine administration will either be performed or supervised by DOHMH staff.

III. Vaccination Clinic Management

1. Pre-Clinic Activities

A. Employee Education and Identification of Vaccinees

It is impossible to overstate the importance to hospitals, potential vaccinees and their household members that an accurate and effective educational program is implemented in all hospitals. As education is an integral part of the consent process, participation in certain sessions will be mandatory for all those who are vaccinated.

The education program will provide hospital employees with information that includes eligibility for the program; vaccine contraindications in hospital employees and their household members; availability of free, confidential, and anonymous HIV testing and pregnancy testing; potential adverse events; and

compensation and liability. This information should be adequate to allow employees to make informed decisions regarding participation in this voluntary smallpox vaccination program. Hospitals will be asked to strongly encourage potential vaccinees to consult their providers with any questions regarding their suitability for this program, and to arrange for confidential and/or anonymous HIV counseling and testing beforehand and pregnancy testing, if indicated.

Hospitals will:

- Attend a mandatory train-the-trainer education session provided by DOHMH. During this session, hospitals will review: a) educational materials provided by DOHMH and the federal government and b) the goals and format of educational sessions that should be made available to hospital employees considering smallpox vaccination.
- Train their staff to conduct the necessary educational sessions.
- Conduct a general education session(s) that is recommended for all hospital employees considering smallpox vaccination.
- Target outreach by job title to employees who are needed for the hospital's HCSRT (See Appendix 1), which should result in the identification of a self-selected group of potential vaccinees.
- Conduct a detailed education session at least one week prior to vaccination for this selected group of potential vaccinees. **Attendance at this session will be mandatory for all persons who are vaccinated, and hospitals will need to document attendance.** The hospital will designate an appropriate staff person(s) to be available to answer questions during the period between this session and vaccination and allow for 1:1 consultation, if warranted.
- Provide a final education session at the vaccination clinic that all potential vaccinees will attend prior to vaccination (*see page 7*). **Attendance at this session will be mandatory for all persons who are vaccinated, and hospitals will need to document attendance.**

DOHMH will:

- Provide all necessary educational materials.
- Provide a train-the-trainer session, as described above.
- Be represented at a general education session(s) to assist with answering questions, as needed.
- Provide referral sites for free, confidential and anonymous HIV and pregnancy testing.

B. Scheduling

Hospitals will need to work with DOHMH to schedule clinics at which up to one-third of the facility's HCSRT will get vaccinated per week.

The vaccine clinics will operate no more than once a week per hospital, with the clinic hours on Monday-Thursday from 10:30 a.m. to 4 p.m. to allow for delivery and return of the vaccine from the DOHMH.

2. Clinic Operations

A. Screening/Informed Consent at the Vaccination Clinic:

- **Hospitals will** provide a final follow-up education session to all eligible vaccinees about the contraindications for the vaccine during the vaccination clinics. Hospitals will be responsible for obtaining informed consent.
- **DOHMH will** provide the screening and consent forms and all other required paperwork. DOHMH will assist and monitor the informed consent process.

B. Smallpox Vaccination:

- **Hospitals will** have the opportunity to train their staff physicians and nurses how to administer the vaccine.
- **DOHMH will** be responsible for overseeing and implementing the administration, storage and handling of smallpox vaccine. Once the hospital vaccinators have been successfully vaccinated as demonstrated by a “take” reaction, as well as trained and certified by DOHMH, they can begin to administer smallpox vaccine during Wave 1 of the smallpox vaccination program.

C. Paperwork

- **Hospitals will** be required to maintain a medical chart for all employees who are vaccinated. The chart will include all necessary paperwork (e.g., copies of the screening and consent forms) and progress notes documenting vaccine “take” and all phone calls or clinic visits related to suspected adverse events.

D. Discharge Planning

After vaccination and prior to discharge from the clinic, dedicated hospital staff will review the proper management of the vaccination site and all related infection control issues; daily monitoring of the vaccination site in the designated clinic location *before* work; and monitoring for and

management of potential adverse events, including dedicated on-call consultation for potential adverse events, as described below.

3. Post-Clinic Activities

A. Adverse Event Evaluation:

- **Hospitals will** be responsible for providing initial specialty consultation (e.g., dermatology, infectious disease, ophthalmology, neurology) for employees with suspected vaccine-related complications and reporting their findings as recommended by the DOHMH. Hospitals must have a digital camera on site and be able to transmit digital photos to DOHMH and CDC for consultation purposes.
- **DOHMH will** advise on how to identify and report suspected adverse events. Staff will be available for consultation through a 24-hour hotline.

B. Treatment:

- **Hospitals will** be responsible for treating or making treatment arrangements for vaccinees with complications.
- **DOHMH will** provide the treating hospital with information about how to receive VIG and/or cidofovir and will coordinate with the hospital, the CDC and the Clinical Immunization Safety Assessment (CISA) Center in New York City to assure that VIG and/or cidofovir arrives in a timely fashion.

C. Daily Vaccination Site Checks:

- **Hospitals will** be required to assign trained and vaccinated hospital staff to perform daily site checks when vaccinees report to work, and dressing changes, if needed. Hospitals will document their findings in the medical record. This will be performed by designated hospital staff who have been approved by DOHMH.
- **DOHMH will** provide didactic sessions and demonstrations about how to perform daily site checks and dressing changes.

D. Evaluation of “Takes” and Revaccination:

- **Hospitals will** provide and document “take” checks and alert DOHMH that revaccination may be necessary. For questionable “takes”, hospitals

will be required to take digital photos and transmit them to the DOHMH for consultation.

- **DOHMH will** provide detailed instruction about how to determine if scarification occurred through didactic sessions and demonstrations. DOHMH will return to provide revaccination, if needed.

4. Data Management

The HLT from the DOHMH will have a data manager who will be responsible for training equivalent hospital staff on how to use the recommended CDC Pre-event Vaccination System (PVS) to enter vaccination data. PVS is a Web-based system that is being provided by CDC to track vaccine administration in the pre-event vaccination campaign.

IT Infrastructure recommendations at vaccination clinic site:

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|-----------------------------------|---|
| 1. Hardware Processor (minimum): | Pentium II and above |
| 2. Modem Speed (minimum): | 56K and above (continuous internet access preferred) |
| 3. Web-Page Resolution (minimum): | 800 x 600 |
| 4. Web Browser (minimum): | Internet Explorer 5.0 and above
OR
Netscape 6.0 and above |
| 5. Operating Systems Supported: | Windows: 98; NT 4.0+; 2000; XP |
| 6. Web Code Support: | JSP; HTML |

Hospital staff needed:

1. IT liaison at hospital- Hospital staff will need to work with a DOHMH technical liaison to assess readiness and provide necessary support for setting up infrastructure, troubleshooting, and installing digital certificates on identified computers. **The DOHMH will need the name and contact information for this individual so that necessary preparations can begin as soon as possible (Appendix 2).**

2. Data management and entry staff – Hospital staff will be trained by the DOHMH HLT during a “train the trainer” session. Hospital staff attending this session should be able to train others at the hospital. Hospital staff will be trained on how to enter data into PVS, how to retrieve the data, how to enter “take check” and revaccination information and how to generate the available predefined reports.

Appendix 1. Identification of Hospital Health Care Smallpox Response Teams (HCSRT)

Assumptions:

- Smallpox vaccination is voluntary; however, any staff who volunteers to be vaccinated should be willing to be on the HCSRT at their hospital.
- Initial teams should be able to care for 5 patients with suspected or confirmed smallpox for 7-10 days, until the rest of the staff is vaccinated.
- Pre-vaccinated staff will need to be available on all shifts (i.e., 24 hours per day for 7-10 days).
- Employees from each title may need to work 12-hour shifts in the event that a suspected or confirmed smallpox case presents at the institution.
- Redundancy will account for staff leave and back-up.
- For certain positions (e.g., infectious disease specialist), staff would be able to care for 5 patients simultaneously.

Each hospital should plan for receiving approximately 100 to 150 vaccinations; larger hospitals may request up to 200 doses. DOHMH recognizes the need to allow some flexibility in the types of job categories that should be targeted for vaccination, as well as the total number of vaccinated personnel within each of these categories. If hospitals identify additional job categories that they want to include in their HCSRT, or if they want to increase the total number of vaccinated personnel within certain job categories (e.g., emergency department personnel), it will be incumbent upon them to justify how these suggested additions would be needed to care for suspected or confirmed smallpox cases, once an outbreak had been recognized. The following job categories should be targeted, with the minimum number of personnel in each category:

Emergency Department Staff (round-the-clock coverage)	
Security	5
Triage	5
Senior Physicians	5
Nurses	5
Infection Control and Employee Health	
Physicians	2-3
Nurses	5
Administrators	2-3
Floor Staff	
Nursing for isolation rooms (one nurse/ 2 rooms)	5
Primary Care Internists	2-3

Pediatricians	2-3
Intensive Care Unit	
Physicians	2-3
Nurses	5
Consultant Physicians	
Infectious Disease	2-3
Dermatology	2-3
Anesthesiologists	2-3
Ophthalmology	2-3
General Surgeons	2-3
Neurologists	2-3
Allied Health	
Radiology Technicians	5
Respiratory Technicians	5
Phlebotomists	5
Staff from other Hospital Departments	
Laundry Workers	2-3
Laboratory Personnel	5
Hospital Security	5
Housekeeping	5
Engineering	2-3
Maintenance	2-3
Transport	2-3
Other*	17 - 28
Total	112 - 138

*Other may include staff from family practice, obstetrics-gynecology, laboratory, private EMS providers, orderlies, licensed practical nurses, and nurse's aides.