Smallpox Vaccination Clinic Planning Manual

New Jersey Department of Health and Senior Services
Communicable Disease Service
Bioterrorism Unit
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Purpose of the Manual

The New Jersey Department of Health and Senior Services (NJDHSS) has developed this manual, based on guidelines from the Centers for Disease Control and Prevention (CDC), to define the roles, resources, and materials needed to plan and conduct a smallpox vaccination clinic. This manual identifies logistical and staffing issues for the clinic planner to consider when planning a pre-event clinic. In addition, principles outlined here may be used to plan clinics for mass vaccination, should this be required in a post-event situation or other public health emergency.

Certain assumptions were made in the writing of this manual. They are:

1. Smallpox vaccination is voluntary and available only to individuals who will serve on a Public Health Response Team (PHRT) or a Hospital Response Team (HRT).
2. **All** members of the response teams must be vaccinated.
3. Smallpox vaccination will continue to be offered so that healthcare and other workers will be prepared to serve on a hospital or public health response team.
4. The vaccination clinic will serve fewer than 100 vaccinees per session.
5. Clinical accuracy (i.e. appropriate medical screening for contraindications) is the paramount requirement of the clinic, not patient throughput.
6. Sufficient lead-time will precede the clinic to allow for pre-planning and coordination.
7. A complete description of the other duties and responsibilities of response team members will be addressed in a separate manual.

The NJDHSS should be informed of all smallpox clinic planning, as it is the liaison for hospitals, LINCS agencies, and local health departments to acquire the smallpox vaccine, be assisted with planning and be provided with technical support. Information about training for vaccinators, take readers and other clinic personnel is also available. Clinic planners should notify the NJDHSS as soon as a clinic date has been established, but at least one month in advance. Contact can be made through the Communicable Disease Program's Bioterrorism (BT) Unit at (609) 588-7500.

Smallpox Vaccination Clinic Planning Manual

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Acknowledgements

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1. Introduction

In response to the potential use of biological agents against civilians, the federal government has committed to upgrading public health preparedness and other national defenses against bioterrorism. The CDC has been designated as the lead federal agency for upgrading national public health capabilities for responding to biological terrorism.

Many biological agents could be used to attack civilians. However only a few, such as smallpox (variola) virus, are able to cause illness or panic to the extent that existing medical and public health systems would be overwhelmed. Naturally occurring smallpox disease was globally eradicated by the late 1970s, but stores of smallpox virus are held in two laboratories officially recognized by the World Health Organization. There is concern, however, that virus samples may have fallen into the hands of groups that could use smallpox as a weapon of bioterrorism.

The last case of naturally occurring smallpox in the United States was in 1947, and the last case in the world was in Somalia in 1977. If an outbreak of smallpox were to occur now, several factors could contribute to a more rapid spread than was routinely seen before this disease was eradicated. These factors include:

- Virtually nonexistent immunity to smallpox in the absence of naturally occurring disease and the discontinuation of routine vaccination in the United States in the early 1970s,
- Potentially delayed recognition of smallpox by healthcare personnel who are unfamiliar with the disease presentation, and
- Increased mobility and crowding of the population.

Because of these factors, a single case-patient of smallpox anywhere in the world would be considered a public health emergency requiring an immediate and coordinated response to contain the outbreak, prevent further infection, and control panic.

Smallpox vaccine is a highly effective immunizing agent. It is a live-virus vaccine composed of vaccinia virus, an orthopoxvirus closely related to variola virus that induces antibodies that also protect against smallpox. While there are side effects associated with smallpox vaccination, most vaccinees have no, or mild reactions such as a soreness/swelling at the site, fever, body aches, or swollen glands. Some individuals who have received the vaccine have experienced reactions ranging from serious to life threatening. It is estimated from prior experience with the vaccine that approximately 52 individuals per million vaccinated will experience life threatening adverse effects like encephalitis, and that one or two per million will die as a result of vaccination.

Education plays a key role in helping prospective vaccinees not only to understand the benefits and risks of vaccination, but also in putting the chance of experiencing an adverse event into perspective. In New Jersey's 2003 vaccination campaign, Adverse Events were reported in nine of the 671 individuals who were vaccinated. They were:

- 3 non-specific rashes; likely allergic reactions; generalized vaccinia ruled out in 2 cases, vaccinia polymerase chain reaction (PCR) tests negative by the CDC and the NJDHSS Public Health and Environmental Laboratories (PHEL)
- 2 non-specific neurological symptoms (temporary paresthesias in arm of vaccination sites)
- 1 non-specific chest pain symptoms
- 1 myocarditis
- 1 non-specific eye symptom (ocular vaccinia ruled out; vaccinia PCR tests negative by PHEL)
- 1 inadvertent auto-inoculation
- No hospitalizations, fatalities or life-threatening Adverse Events were experienced among the 671 people vaccinated.

In the United States, 38, 908 civilians and 526, 677 military personnel received the smallpox vaccine. Adverse Events associated with vaccination among these individuals are listed in the table below.

Adverse Events Associated with Smallpox Vaccination among Civilians and Military, United States (as of November 30, 2003)

Adverse Event	Military	Civilian
Eczema vaccinatum	0	0
Erythema multiforme major/Stevens-Johnson syndrome	0	0
Fetal vaccinia	0	0
Generalized vaccinina	35	3
Inadvertent inoculation, non-ocular	28	20
Myocarditis/pericarditis	69	22
Ocular vaccinia	0	3
Postvaccinial encephalitis	1	1
Progressive vaccinia	0	0
Pyogenic infection of vaccination site	0	0
Other serious adverse events	not reported	90
Other non-serious adverse events	not reported	707

2. Overview of Smallpox Vaccination Clinic Events

This manual is written to facilitate the planning and implementing of a clinic session to vaccinate persons who will serve on a Public Health Response Team or a Hospital Response Team. It offers a plan to be followed in a pre-event scenario, and assumes ample lead-time. In a post-event scenario, the same principles can be followed, with modifications to allow for large numbers of participants and condensed pre-vaccination education.

When planning the clinic, it is important to understand the special circumstances involved in providing smallpox vaccine. Routine smallpox vaccination among the American public stopped in 1972, after the disease was eradicated in the United States. Today, it is given only as part of the National Preparedness Program to protect Americans against smallpox as a biological weapon.

Because the vaccine is used solely in this setting, guidelines established by the CDC must be followed exactly. This applies to all aspects of vaccine provision, but especially to pre-vaccination education and post-vaccination surveillance. The following overviews are presented to give a quick picture of the sequence of events for both clinic planners and vaccinees.

Clinic Planner:

3 months prior to Clinic Day:

- Planning
- Staffing
- Obtaining supplies
- Training
- Publicizing

1-2 weeks prior to Clinic Day:

- Educational session(s) for staff and potential vaccinees

1-5 days prior to Clinic Day:

- Equipment/supplies inventoried
- Staff oriented

Clinic Day:

- Staff assigned
- Vaccine delivered
- Vaccinations done
- Unused vaccine returned

1-5 Days Post Clinic:

- Evaluations processed
- Core staff debriefed
- Adverse Events followed up

6-8 days post Clinic Day:

- Vaccination “takes” evaluated
- Adverse Events followed up

8-10 days post Clinic Day:

- Follow-up on broken appointments for “take” evaluation
- Adverse Events followed up

21-28 days post Clinic Day:

- Active surveillance
- Adverse Events followed up

Participant (Vaccinee):

1-2 weeks pre Clinic Day:

- Attend educational session
- Self-screen
- Make decision to be vaccinated
- Make vaccination appointment

Clinic Day:

- Check-in at clinic site
- Register
- Attend review educational session
- Confirm decision to be vaccinated
- Be screened for contraindications
- Receive medical consultation if needed
- Get vaccinated and receive vaccination card

- Be observed for 20 minutes for untoward reactions
- Receive aftercare instructions including appointment for “take” reading
- Check out

Days 1–28 post Clinic Day:

- Self-care for vaccination site, keeping of diary for Adverse Events

6-8 days post Clinic Day:

- Have “take” read, diary reviewed and vaccination card completed

21 – 28 post Clinic Day:

- Interviewed for active surveillance, vaccination site heals, diary submitted

3. Staffing, Equipment and Supplies

Personnel

The personnel needed to staff a smallpox vaccination clinic fall into two basic categories, clinical and non-clinical. Clinical staff is made up of registered nurses, physicians, paramedics/EMTs, and mental health counselors. Non-clinical staff includes health educators, greeters, registrars, monitors, security, and information technology support. If the clinic is to run smoothly and efficiently, it is vital that lines of responsibility be well defined. The clinic planner should direct the overall operation of the vaccination event, and a public health nurse or physician should supervise the clinical aspects. In cases where the clinic planner is a nurse or physician, it is recommended that an additional nurse or physician be named to manage clinical functions. This will assure adequate time for attention to all aspects of clinic operations. Training must be provided for all staff prior to the start of the clinic, and guidance should be ongoing throughout the event.

While workstations and job responsibilities are detailed in chapters eight and nine, the following lists summarize the types of personnel needed to accomplish the work of the vaccination clinic.

Registered Nurses to provide:

- Clinical supervision
- Medical supplies and inventory
- Vaccine reception, reconstitution and storage
- Patient education
- Medical screening
- Vaccine administration
- Instruction in post-vaccination care
- Take readings (6-8 day follow-up)

Physician(s) to provide any of the above nursing functions, plus:

- Standing orders to vaccinate
- Medical consultation/evaluation
- Mental health assessment/referral

Paramedics or EMTs to provide:

- First aid and transportation
- Assistance with observation in After Care

Health Educators to provide:

- Development and distribution of informational materials
- Development and analysis of evaluation instruments
- Patient education

Mental Health Counselors to provide:

- Crisis counseling
- Mental health assessment/referral

Information Technology Staff to provide:

- Set up of temporary computer network
- Training in Preparedness Vaccination System (PVS) use
- Troubleshooting/consultation for IT matters
- Assistance with video equipment

Security/Law Enforcement Agents to provide:

- Security/transportation for vaccine
- Crowd control

Administrative Staff to provide:

- Check-in and identification verification for all workers and vaccinees
- Registration of participants
- Assistance with traffic flow
- Assistance with food and drink areas
- Assistance with waiting and break areas
- Courier and communication services
- Check out for vaccinees

Equipment, Supplies and Waste Disposal

The clinic planner and clincal manager should assemble and inventory all equipment and supplies several days prior to the clinic day. Arrangements for delivery and pick-up from the clinic site should be detailed, and must include arrangements for disposal of medical waste. Bifurcated needles used to administer vaccine and used vaccine vials must be placed in a sharps container; all other materials from the vaccination station (gloves, gauze, table protectors, etc.) must be placed in biohazard bags and disposed of properly. The following checklists are provided for guidance; much will depend on the actual layout and floor plan of the facility to be used.

Equipment:

- Computers with Internet access to supply the number of stations planned
- Computer networking device(s)
- VCR with TV or projector for education video
- Extension cords and duct tape to secure/prevent tripping
- Signage
- Tables and chairs
- Vests/smocks/security badges to identify workers easily
- Screens or other barriers to demarcate workstations and provide privacy
- Refrigeration or cold storage for vaccine

Non-Clinical Supplies:

- Disposable paper ware/cutlery for refreshments or meals
- Paper towels and tissues
- Receptacles for regular paper and food waste
- Pre-assembled participant packets including screening/consent forms
- Pens/pencils and paper
- Tape for posting signs, securing wiring, etc.

Clinical Supplies:

- Strips of Preparedness Vaccine Number (PVN) stickers
- Vaccine stabilizing holder
- 25 gauge needles to vent vaccine vials
- Eye protection glasses
- Sterile and non-sterile gauze (2x2)
- Skin tape
- Disposable gloves
- Waterproof table coverings for each vaccination station
- Duct tape to secure table coverings and vaccine stabilizer
- 10:1 bleach solution in spray bottles
- Hand sanitizer
- Alcohol wipes
- Emergency/first aid kit
- Sandwich-size baggies
- Labeled pre-assembled After Care packets with dressing supplies

Waste Disposal:

- Biohazard bags
- Sharps containers

Clinic Staff Sign-Up

Name: _____

Title: _____

Organization: _____

Telephone: _____

E-mail: _____

Your job classification/skills:

- ❒ Nurse (RN)
- ❒ Pharmacist (PharmD)
- ❒ Health Educator
- ❒ Clerical/Support Staff
- ❒ Mental Health Professional
- ❒ Physician (MD/DO)
- ❒ EMS/Paramedic
- ❒ Other clinical _____
- ❒ Security
- ❒ Information Technology (IT)

Translation (specify language) _____

Station preference:

- ❒ Check-in
- ❒ Education
- ❒ Medical Consult
- ❒ Aftercare/Observation
- ❒ Registration
- ❒ Medical Screening
- ❒ Vaccination*
- ❒ Check-out

** Must be a vaccinated clinical professional to work this station*

----------***For Office Use Only***----------

Date received/confirmed: _____

Station assigned: _____

Notes: _____

_____

New Jersey Public Health Response Team
Smallpox Vaccination Clinic Staff Training
July 31, 2003

Agenda

Welcome

The Basics

- Anticipated Schedule
  - Orientation – 9am
  - Clinic – Ten to Noon
- Clinic Design & Flow -- Handout
- Jobs & Responsibilities – Handout
  - Vests – Monitors & Support Staff
- Assignments -- Handouts
- Arrival Time – 8:30AM (unless instructed otherwise)
  - Personal belongings, rest rooms, food and drink . . .
- Anticipated Work Hours – 8:30 to 1:00

Issues/Questions

- Support Staff
- Logistics, Relief, . . .

PVS Computer System Training

4. Selecting a Site for the Vaccination Clinic

Facility Specifications

When selecting a vaccination clinic site, the clinic planner should work closely with the clincal manager to evaluate the site's logistical and clinical capacities. Clinic sites should be large enough to accommodate the vaccinees, staff at workstations, and staff at monitor and security zones. Privacy must be assured in all areas of patient care. Separate rooms for medical screening, medical consultation and vaccination are preferable. The education video session should be held in a separate room to prevent noise and other distractions from interfering with hearing the video or answers to questions. Waiting areas for vaccinees and break areas for staff must be allowed for as well. It is recommended that all stations be located on one floor.

During the vaccination event, each vaccinee passes through 7-9 workstations, taking approximately 1½ hours. Functions of the individual workstations are detailed in Chapter 8. The clinic planner will need to calculate the number of each type of workstation needed to accommodate the number of vaccinees expected. Each vaccinator can handle about 4-5 patients per hour. The floor space needed is equivalent to that of a medium gymnasium or large community center. Special consideration should be given to urban and rural areas, in that the site should be near major highways and/or mass transit. The site should have:

- Sufficient parking
- Adequate lighting
- Working air conditioning and/or heating systems
- Sufficient restrooms
- Handicapped accessible accommodations (ramps, elevator, etc.)
- Access to the Internet for computer workstations
- Ample electrical outlets for computer workstations and video area
- A secure area for vaccine storage
- Refrigeration or cold storage for vaccine
- Ample tables and chairs available and/or accessible
- Screens or other barriers to demarcate workstations and provide privacy

Clinic Facility Checklist

Agency:_____ **Date:** _____

Name/Address of site:_____

(Street Address) **(Town)** **(County)**

Facility size:_____ **# of Rooms:**_____ **# of Stories:**_____
(Estimated Sq. Ft.)

		YES	NO	N/A	NOTES
1.	If site is more than one-level, are there steps between floors?				
2.	If site is more than one-level, are there elevators between floors or other means of access for handicapped individuals?				
3.	Proposed site has plan for obtaining or has refrigerator capable of maintaining temperature between 35-45° F?				
4.	Parking appears adequate; what is estimated number of vehicles that could be accommodated?				
5.	Site is available for use 24/7?				
6.	Roads leading to site allow for easy access?				
7.	Is public transportation to site available?				
8.	Directions to proposed site, from various locations are available for immediate distribution?				
9.	Site has adequate restroom facilities for public/staff?				
10.	Site has handicapped accessible restroom facilities for public/staff?				

		YES	NO	N/A	NOTES
11.	**Site is handicapped accessible?**				
12.	**Building "flow" appears to be acceptable for a clinic operation?**				
13.	**Site has area for video operation for 75 persons? Or has capability for partitioning area.**				
14.	**Site has working audio-visual equipment available for video operation or arrangements have been made to acquire audio-visual equipment needs 24/7**				
15.	**Site has working heating system?**				
16.	**Site has working air conditioning system?**				
17.	**Site has sufficient lighting throughout building?**				
18.	**Site has sufficient electric outlets located throughout building?**				
19.	**Site has activated telephone service?**				
20.	**Site has internet capability?**				
21.	**Site has high-speed internet capability?**				
22.	**Site has adequate tables, chairs, partitions available on-site?**				
23.	**If no or insufficient numbers of tables, chairs and partitions are available at site, plans have been made for 24/7 delivery?**				
24.	**Building entrances/exits are clearly marked?**				
25.	**External traffic congestion issues**				

Technology Requirements

The state of New Jersey uses the Preparedness Vaccination System (PVS) to enter vaccinee information into a web-based database and to track vaccination response. Computer access to the PVS via the Internet is needed at five of the clinic workstations. Workstation functions will be discussed in detail in Chapter 8. Prior to start of the clinic, staff at stations with computers must be trained in using PVS, and receive a user name and password. Clinic Planners should contact the NJDHSS at (609) 588-7500 to gain authorization to use the PVS at least one month prior to the clinic date so that adequate time can be allotted to grant access and provide technical assistance. On the day of the clinic, staff at computer workstations will need to log on to the PVS website: http://njiis.doh.state.nj.us/njiis/index.htm and enter each patient's information into the fields required by the station.

Vaccination clinics also require appropriate equipment to show the **mandatory** educational video entitled "Decision Point for the Smallpox Vaccine Candidate." The video is available through the CDC in VHS format, requiring a TV/VCR unit. Alternately, it can be accessed through the CDC website for viewing/projecting through a computer. This format requires high speed Internet access, and does not offer as sharp a picture, however. Use of the VHS format is preferred. The web address is: http://www.bt.cdc.gov/agent/smallpox/vaccination/decisionpoint.asp. The video is available in both English and Spanish.

5. Smallpox Vaccine

Obtaining and Storing Smallpox Vaccine

The smallpox vaccine currently licensed in the United States is Dryvax, manufactured by Wyeth Laboratories Inc. Dryvax is a preparation of live vaccinia virus grown on the skin of calves. It comes in a kit that includes a 100-dose vial of vaccine, a supply of diluent (one prefilled diluent syringe), one transfer needle, and 100 individually wrapped bifurcated needles. Dryvax has full approval for use as a licensed product. Dryvax vaccine is available for civilian use only through the CDC via the NJDHSS.

The clinic manager should contact the NJDHSS BT Unit at (609) 588-7500 to secure vaccine. The BT Unit will work with the NJDHSS Office of Health Emergency Planning and Operations to coordinate vaccine acquisition and security. Law enforcement personnel must keep the vaccine under guard at all times.

Both un-reconstituted and reconstituted vaccine must be stored at 36 to 46 degrees Fahrenheit when not in use. It may be kept at normal room temperature during the course of a clinic session and then placed back into refrigeration. Once a vial of Dryvax has been reconstituted, it has a shelf life of 90 days if maintained at 36 to 46 degrees Fahrenheit. The vial and any vaccine unused after this 90 day time period, or improperly stored, must be disposed of using proper biological waste disposal techniques. The date of reconstitution should be recorded directly on the vaccine vial in the space provided. Refer to vaccine package insert at the back of this chapter for more details.

Vaccine Administration

Smallpox vaccine may be administered only by physicians and registered nurses licensed to practice in New Jersey who are vaccinated and have been trained in the administration of smallpox vaccine. A sample standing order to vaccinate, information

about vaccination technique, and patient care immediately following vaccination may be found in the manual entitled “NJDHSS Smallpox Clinic Standing Orders and Nursing Guidelines,” available through the BT Unit by calling (609) 588-7500.

Vaccination Follow-Up

The inoculated site will need to be “read” 6-8 days following vaccination. The clinic manager will need to set-up one or more places where vaccinees can go for this reading. The persons doing the readings must have received training and must have access to the PVS so that the readings can be entered. In addition, the clinic manager will need to alert hospitals designated to assess/treat Adverse Events so that those hospitals can be prepared to receive any patients who should experience serious problems.

Smallpox Vaccine
Dried, Calf Lymph Type

Dryvax®

Dried Smallpox Vaccine

℞ only

DO NOT INJECT INTRAMUSCULARLY (IM), INTRAVENOUSLY (IV), OR SUBCUTANEOUSLY (SC). FOR CONVENTIONAL SMALLPOX VACCINATION (SCARIFICATION) ONLY.

DESCRIPTION

Smallpox Vaccine, Dried, Calf Lymph Type, Dryvax®, is a live-virus preparation of vaccinia virus prepared from calf lymph. The calf lymph is purified, concentrated, and dried by lyophilization. During processing, polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate are added, and trace amounts of these antibiotics may be present in the final product. The reconstituted vaccine has been shown by appropriate test methods to contain not more than 200 viable bacterial organisms per mL.

The diluent for Dryvax® contains 50% glycerin, and 0.25% phenol in Sterile Water for Injection, USP.

The reconstituted vaccine, which contains approximately 100 million infectious vaccinia viruses per mL, is intended only for multiple-puncture use, ie, administration of the vaccine into the superficial layers of the skin using a bifurcated needle.

CLINICAL PHARMACOLOGY

Introduction of potent smallpox vaccine containing infectious vaccinia viruses into the superficial layers of the skin results in viral multiplication, immunity, and cellular hypersensitivity. With the primary vaccination, a papule appears at the site of vaccination on about the 2nd to 5th day. This becomes a vesicle on the 5th or 6th day, which becomes pustular, umbilicated, and surrounded by erythema and induration. The maximal area of erythema is attained between the 8th and 12th day following vaccination (usually the 10th). The erythema and swelling then subside, and a crust forms which comes off about the 14th to 21st day. At the height of the primary reaction known as the Jennerian response, there is usually regional lymphadenopathy and there may be systemic manifestations of fever and malaise.

Primary vaccination with product at a potency of 100 million pock-forming units (pfu)/mL elicits a 97% response rate by both major reaction (see **DOSAGE AND ADMINISTRATION, Interpretation of Responses:** *Major Reaction*) and neutralizing antibody response in children.[1,2] Immunity wanes after several years, and an allergic sensitization to viral proteins can persist. This allergy is manifested by the appearance of a papule and a small area of redness appearing within the first 24 hours after revaccination; this may be the maximum reaction but not infrequently vesicles appear in 24 to 48 hours with ultimate scabbing. The peak of this type of

PRECAUTIONS

General

The vial stopper contains dry natural rubber that may cause hypersensitivity reactions when handled by, or when the product is administered to, persons with known or possible latex sensitivity.

After completion of the multiple-puncture vaccination, blot off any vaccine remaining on skin at vaccination site with clean, dry gauze or cotton.

The vaccine vial, its stopper, the needle to release the vacuum, the diluent syringe, the vented needle used for reconstitution, the bifurcated needle used for administration, and any gauze or cotton that came in contact with the vaccine should be burned, boiled, or autoclaved before disposal.

Individuals susceptible to adverse effects of vaccinia virus, eg, those with eczema, immunodeficiency states, including HIV infection, should be identified and measures taken to avoid contact with persons with active vaccination lesions. Contact spread of vaccinia from recently vaccinated military personnel has been reported[7,8] (see **ADVERSE REACTIONS**).

Prevention of contact transmission of vaccinia

Vaccinia virus may be cultured from the site of primary vaccination beginning at the time of development of a papule (2 to 5 days after vaccination) until the scab separates from the skin lesion (14 to 21 days after vaccination). During this time, care must be taken to prevent spread of the virus to another area of the body or to another person. The vaccination site may be left uncovered or can be covered with a porous bandage, such as gauze, until the scab has separated and the underlying skin has healed. An occlusive bandage should not be routinely used. If a bandage is used to cover the vaccination site, it should be changed frequently (ie, every 1-2 days) to prevent maceration of the vaccination site secondary to fluid accumulation. No salves or ointments should be used on the vaccination site. Contaminated bandages should be placed in sealed plastic bags before disposal in the trash. Clothing or other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water with bleach.[2] The vaccination site should be kept dry, although normal bathing can continue.[2]

Recently vaccinated healthcare workers should avoid contact with patients, particularly those with immunodeficiencies, until the scab has separated from the skin at the vaccination site. However, if continued contact with patients is essential and unavoidable, they may continue to have contact with patients, including those with immunodeficiencies, as long as the vaccination site is well covered and good hand-washing technique is maintained by the vaccinee. In this setting, a more occlusive dressing may be required. Semipermeable polyurethane dressings (eg, Opsite®) are effective barriers to vaccinia and recombinant vaccinia viruses. However, exudate may accumulate beneath the dressing, and care must be taken to prevent viral contamination when the dressing is removed. In addition, accumulation of fluid beneath the dressing may increase the maceration of the vaccination site. Accumulation of exudate may be decreased by first covering the vaccination with dry gauze, then applying the dressing over the gauze. The dressing should also be changed at least once a day.

The most important measure to prevent inadvertent implantation and contact transmission from vaccinia vaccination is thorough hand washing after changing the bandage or after any other contact with the vaccination site.

Simultaneous administration with other live-virus vaccines
There are no data evaluating the simultaneous administration of smallpox vaccine with other live-virus vaccines.

PREGNANCY

Pregnancy Category C

Animal reproduction studies have not been conducted with smallpox vaccine. Smallpox vaccine should not be given to pregnant women in routine, non-emergency conditions. For emergency conditions, see **CONTRAINDICATIONS – Contraindications for Smallpox Emergency** and **INDICATIONS AND USAGE – Use of Smallpox Vaccine in Response to Bioterrorism.** On rare occasions, almost always after primary vaccination, vaccinia virus has been reported to cause fetal infection. Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. Vaccinia vaccine is not known to cause congenital malformations.[2]

Healthcare providers, state health departments, and other public health staff are encouraged to report all exposed pregnant women to the National Smallpox Vaccine in Pregnancy Registry.[9] Civilian women should contact their healthcare provider or state health department for help enrolling in the registry. Clinicians or public health staff should report civilian cases through their state health department or to CDC, telephone 404-639-8253 or 877-554-4625. Military cases should be reported to the DoD, telephone 619-553-9255, Defense Switched Network (DSN) 553-9255, fax 619-553-7601 or e-mail code 25@nhrc.navy.mil.

Nursing Mothers

It is not known whether vaccine antigens or antibodies are excreted in human milk. This vaccine is not recommended for use in a nursing mother in non-emergency conditions. For use in emergency conditions, see **CONTRAINDICATIONS – Contraindications for Smallpox Emergency.**

Pediatric Use

Before the eradication of smallpox disease, smallpox vaccination was administered routinely during childhood. The vaccine is considered safe and effective in children. However, smallpox vaccine is not recommended for use in non-emergency situations and is contraindicated for infants <12 months in non-emergency situations.

Geriatric Use

There are no published data to support the use of this vaccine in geriatric populations. This vaccine is not recommended for use in geriatric populations in non-emergency conditions. For use in emergency conditions, see **CONTRAINDICATIONS – Contraindications for Smallpox Emergency.**

ADVERSE REACTIONS

A fever is common after vaccinia vaccination is administered. Up to 70% of children have one or more days of temperature ≥100°F from 4 to 14 days after primary vaccination, and 15% to 20% have temperatures of ≥102°F. After revaccination, 35% of children develop temperatures of ≥100°F, and 5% have temperatures of ≥102°F. Fever is less common in adults than children after vaccination or revaccination.[2]

Generalized rashes (erythematous, urticarial, nonspecific) and secondary pyogenic infections at the site of vaccine applications may occur. Rarely bullous erythema multiforme (Stevens-Johnson syndrome) occurs.[2]

Inadvertent inoculation at other sites is the most frequent complication of vaccinia vaccination, usually resulting from autoinoculation of the vaccine virus transferred from the site of vaccination. The most common sites involved are the face, eyelid, nose, mouth, genitalia, and rectum. Accidental infection (autoinoculation) of the eye may result in blindness.

Generalized vaccinia among persons without underlying illnesses is characterized by a vesicular rash of varying extent. The rash is generally self-limited and requires little or no therapy except among patients whose conditions appear to be toxic or who have serious underlying illnesses.[2] Contact spread of vaccinia from recently vaccinated military personnel has been reported (see **CONTRAINDICATIONS**).[7,8,10]

More severe complications that may follow either primary vaccination or revaccination include: postvaccinial encephalitis, encephalomyelitis, encephalopathy, myopericarditis,[11] progressive vaccinia (vaccinia necrosum), and eczema vaccinatum. Such complications may result in severe disability, permanent neurological sequelae, and/or death.[12,13] Although a rare event, approximately 1 death per million primary vaccinations and 1 death per 4 million revaccinations have occurred after vaccinia vaccination. Death is most often the result of postvaccinial encephalitis or progressive vaccinia.[2,14] Death has also been reported in unvaccinated contacts of individuals who have been vaccinated.[14]

Ischemic cardiac events, including fatalities, may follow vaccine use; the relationship of these events to smallpox vaccination is unknown, see **CONTRAINDICATIONS – Contraindications for Routine Non-Emergency Vaccine Use**.

Estimates of the risks of occurrence of complications after primary vaccination and revaccination are as follows[15]:

Rates of reported complications* associated with vaccinia vaccinations (cases/million vaccinations) †

Age (yrs) and status	Inadvertent inoculation§	Generalized vaccinia	Eczema vaccinatum	Progressive vaccinia¶	Postvaccinial encephalitis	Death[12,#]	Total**
Primary vaccination							
<1	507.0	394.4	14.1	--††	42.3	5	**1549.3**
1-4	577.3	233.4	44.2	3.2	9.5	0.5	**1261.8**
5-19	371.2	139.7	34.9	--††	8.7	0.5	**855.9**
≥ 20	606.1	212.1	30.3	--††	--††	unknown	**1515.2**
Overall rates†	**529.2**	**241.5**	**38.5**	**1.5**	**12.3**	--	**1253.8**
Revaccination							
<1	--††	--††	--††	--††	--††	--	--††
1-4	109.1	--††	--††	--††	--††	--	**200.0**
5-19	47.7	9.9	2.0	--††	--††	--	**85.5**
≥ 20	25.0	9.1	4.5	6.8	4.5	--	**113.6**
Overall rates§§	**42.1**	**9.0**	**3.0**	**3.0**	**2.0**	--	**108.2**

† Adapted from Lane JM, Ruber FL, Neff JM, Millar JD. Complication of smallpox vaccination, 1968: results of ten statewide surveys. J Infect Dis. 1970;122:303-309.

* See text for descriptions of complications.

§ Referenced as accidental implantation.

¶ Referenced as vaccinia necrosum.

\# Death from all complications.[12]

** Rates of overall complications by age group include complications not provided in this table, including severe local reactions, bacterial superinfection of the vaccination site, and erythema multiforme.

†† No instances of this complication were identified during the 1968 10-state survey.

§§ Overall rates for each complication include persons of unknown age.

The risk of complications associated with revaccination is low. Complications have occurred, especially in patients with underlying diseases or in patients receiving therapy which impairs immunologic competence, or in subjects who have not been vaccinated for many years. Subjects who have not been vaccinated for many years may respond as primary vaccinees as regards both the local and systemic reaction to vaccine administration and risk of occurrence of the above-mentioned serious complications.[2]

The Centers for Disease Control and Prevention (CDC) can assist physicians in the diagnosis and management of patients with suspected complications of vaccinia (smallpox) vaccination. Vaccinia Immune Globulin (VIG) is indicated for certain complications of smallpox vaccination. Several antiviral compounds have been shown to have activity against vaccinia virus or other orthopoxviruses in vitro and in animal models. However, insufficient information exists on which to base recommendations for any antiviral compound to treat postvaccination complications or Orthopoxvirus infections, including smallpox.[2] If VIG is needed or additional information is required, physicians should contact the CDC at (404) 639-3670, Monday through Friday 8AM to 4:30 PM Eastern Standard Time; at other times call (404) 639-2888.

The United States Department of Health and Human Services (DHHS) has established the Vaccine Adverse Event Reporting System (VAERS) to accept all reports of suspected adverse events of any vaccine. The VAERS toll-free number for VAERS forms and information is (800-822-7967).

DOSAGE AND ADMINISTRATION

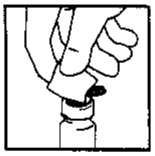
READ ALL DIRECTIONS COMPLETELY BEFORE BEGINNING RECONSTITUTION AND ADMINISTRATION. WHEN RECONSTITUTING AND ADMINISTERING THE VACCINE, USE PROTECTIVE GLOVES AND ASEPTIC TECHNIQUE.

Directions for Reconstitution:

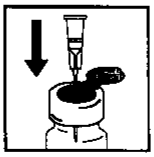
Note: The healthcare provider must have available a sterile 21 gauge or smaller needle to release the vacuum in the vials prior to adding diluent. This needle must only be used to release the vacuum. The needle to release the vacuum is NOT included in the kit.

1. Lift up tab of aluminum seal on vaccine vial. DO NOT BREAK OFF OR TEAR DOWN TAB.

2. Wipe off vial stopper with an alcohol sponge and allow to dry.



3. Place vaccine vial upright on a hard, flat surface. Insert a sterile 21 gauge or smaller needle into the rubber stopper to release the vacuum from the vaccine vial. Discard the needle in biohazard waste container.



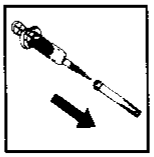
4. To reduce viscosity of cold diluent, warm by holding diluent-cartridge in palm of hand for a minute or so.

5. Peel open the vented needle package (provided with the kit) and aseptically remove the vented needle.

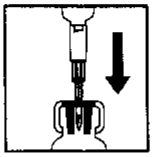
6. Remove rubber cover from end of the diluent syringe.

7. With a twisting motion, aseptically attach the vented needle to the hub of the diluent syringe.

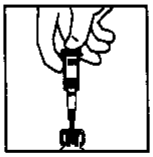
8. Remove protective cover from the vented needle and expel the air from the diluent syringe.



9. Aseptically insert the needle through the rubber stopper into the vaccine vial up to the first hub.



10. Depress the plunger to ensure the entire volume of diluent is delivered into the vial.



11. Withdraw diluent syringe/vented needle and discard in biohazard waste container.

12. Allow vaccine vial to stand undisturbed for 3 to 5 minutes. Then if necessary, swirl vial gently to effect complete reconstitution.

13. Record date of reconstitution.

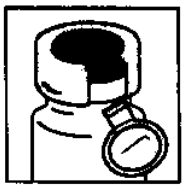
14. Store reconstituted vaccine at 2° to 8°C (36° to 46°F) when not in actual use. The vaccine may be stored for no more than 90 days after reconstitution based on viral potency testing.

Sites of Vaccination:
The skin over the insertion of the deltoid muscle or the posterior aspect of the arm over the triceps muscle is the preferred site for smallpox vaccination.

Method of Vaccination:
USE 2 OR 3 NEEDLE PUNCTURES FOR PRIMARY VACCINATION; 15 FOR REVACCINATION.

Reconstituted vials should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use vaccine if particulate matter or discoloration is present.

1. First pull down the "tear off" tab from the aluminum seal of the vaccine vial.

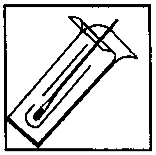


2. Remove entire aluminum seal from the vaccine vial. Then remove rubber stopper from vaccine vial and aseptically retain stopper (set aside inverted) for subsequent reuse.

3. The skin over the insertion of the deltoid muscle or the posterior aspect of the arm over the triceps muscle is the preferred site for smallpox vaccination. If alcohol is used to clean the site, the skin must be allowed to dry thoroughly to prevent inactivation of the vaccine by the alcohol.

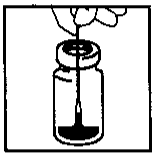
4. Tear off a packette containing a single, sterile bifurcated vaccinating needle.

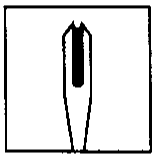
5. Peel back the packaging approximately halfway exposing the butt-end of needle.



6. Hold butt-end of needle and gently pull bifurcated point end free of packaging.

7. Carefully dip bifurcated end of needle into vaccine. Visually confirm that the needle picks up a drop of vaccine in the space between the two tips.





8. Deposit the drop of vaccine onto clean, DRY site previously prepared for vaccination. ***Do not redip needle into vaccine if needle has touched skin.***

9. With the same needle, and using multiple-puncture technique, vaccinate through drop of vaccine. Holding the bifurcated needle perpendicular to the skin, punctures are rapidly made with strokes vigorous enough to allow a trace of blood to appear after 15-20 seconds. Two or 3 punctures are recommended for primary vaccination; 15 punctures for revaccination.

   Any remaining vaccine should be wiped off with dry sterile gauze and the gauze disposed of in a biohazard waste container.

10. Discard needle in a biohazard waste container.

11. Repeat Steps 3 through 10 for each individual to be vaccinated utilizing a new bifurcated needle for each individual vaccinated.

12. If vaccine is to be stored for subsequent use, re-stopper the vial with the rubber stopper and store at 2° to 8°C (36° to 46°F). The vaccine may be stored for no more than 90 days after reconstitution based on viral potency testing.

13. When next needed, remove vial from refrigerator, gently swirl suspension to ensure resuspension, and then carefully take off stopper-cap.

14. Repeat Steps 3 through 10.

15. If vaccine is to be restored for subsequent use, replace stopper-cap and store at 2° to 8°C (36° to 46°F). The vaccine may be stored for no more than 90 days after reconstitution based on viral potency testing.

Interpretation of Responses:

The vaccination site should be inspected 6 to 8 days after vaccination. Two types of responses have been defined by the World Health Organization (WHO) Expert Committee on Smallpox.[3] They are: 1) major reaction, indicating that virus replication has taken place and vaccination was successful; or 2) equivocal reaction, indicating a possible consequence of immunity capable of suppressing viral multiplication or allergic reactions to an inactive vaccine with production of immunity.

Major Reaction

Major reaction is defined as a vesicular or pustular lesion or an area of definite palpable induration or congestion surrounding a central lesion that might be a crust or an ulcer. The inoculation site becomes reddened and pruritic 3-4 days after vaccination. A vesicle surrounded by a red areola then forms, which becomes umbilicated and then pustular the 7th to 11th day after vaccination, and the pustule begins to dry, the redness subsides, and the lesion usually becomes crusted between the 14th and 21st days. By the end of approximately the third week, the scab falls off, leaving a permanent scar, which at first is pink in color but eventually becomes flesh-colored (see **CLINICAL PHARMACOLOGY**).[2]

Primary vaccination may be accompanied by fever, regional lymphadenopathy, and malaise persisting for a few days.

Revaccination is considered successful if a vesicular or pustular lesion is present or an area of definite palpable induration or congestion surrounding a central lesion, which may be a scar or ulcer, is present on examination 6-8 days after revaccination.[3] Major reactions, especially when there has been an interval of many years since the last successful vaccination, may be accompanied by fever, regional lymphadenopathy, and malaise persisting for a few days.

Equivocal Reaction

Equivocal reactions are defined as all responses other than major reactions.[3] If an equivocal reaction is observed, vaccination procedures should be checked and vaccination repeated with vaccine from another vial or vaccine lot, if available. If a repeat vaccination by using vaccine from another vial or vaccine lot fails to produce a major reaction, healthcare providers should consult CDC or their state or local health department before giving another vaccination.[2]

HOW SUPPLIED

Combination package of 1 vial of Dried Smallpox Vaccine, 1 Diluent syringe (0.25 mL), 1 vented needle, 100 individually wrapped bifurcated needles (20 strips, 5 needles per strip). Note: The healthcare provider must have available a sterile 21 gauge or smaller needle to release the vacuum in the vials prior to adding diluent. The needle to release the vacuum is NOT included in the kit.

NDC# 0008-0348-08

STORAGE

Store un-reconstituted Smallpox Vaccine, Dried, Calf Lymph Type, Dryvax® in the refrigerator (2° to 8°C, 36° to 46°F). DO NOT FREEZE. RECONSTITUTED Dryvax® may be used for 90 days if stored at 2° to 8°C (36° to 46°F), based on viral potency testing, when not in actual use. At time of reconstitution, record date. Dryvax® should not be used after the expiration date regardless of whether it is in the dry or reconstituted form.

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15. Lane J, Ruben F, Neff J, Millar J. Complications of smallpox vaccination, 1968: results of ten statewide surveys. *J Infect Dis.* 1970;122 (4):303-309.

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Marietta, PA 17547 USA

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6. The Pre-Vaccination Education Session

Purpose of Education

Individuals considering smallpox vaccination must be well informed about the vaccine, its normal response, possible side effects and potential contraindications. In addition, prospective vaccinees must understand liability and compensation issues. Therefore, the clinic manager must offer an education session to support decision-making at least one week prior to the vaccination clinic. This will allow sufficient time for the participant to consider the information, discuss with family and close contacts, and come to a decision. The education session may be given in a group setting or one-on-one. There must be opportunity for participants to have questions answered, not only at the session, but also between the session and clinic day. Nurses, physicians or health educators may present this session, but at least one registered nurse or physician must be available to address clinical questions.

If mass vaccination is called for following a smallpox event, it is likely that the pre-vaccination education session will be deleted. All education will be done at the clinic site on the day of vaccination.

Materials Available

The content of the pre-vaccination education session has been designed by the CDC to help the individual make an informed decision about whether to be vaccinated. A packet of materials can be accessed on the web at http://www.bt.cdc.gov/agent/smallpox/vaccination/infopacket.asp. This package of materials is to be used to help ensure that potential vaccinees are adequately informed of the benefits and risks of smallpox vaccination, to assist in screening out individuals who should not receive the vaccine, and to obtain signed consent from those individuals who receive smallpox vaccine. In particular circumstances, the federal government will assume liability for injury or death attributable to a smallpox vaccination. These packet materials fulfill federal obligations to inform vaccinees about the risks and benefits of the

smallpox vaccine. **Use of the items in the packet in the manner stated on the website is mandatory. The clinic manager must NOT alter the materials or replace them with alternative documents.** Complete information about federal assumption of liability under Section 304 of the Homeland Security Act, and compensation under the Smallpox Emergency Personnel Protection Act of 2003 is also available on the CDC website.

Since the education materials are periodically updated, clinic planners should consult the CDC website before holding an education session to ensure that the most recent version of education materials is distributed to participants. In addition to checking the CDC website for smallpox vaccination updates, it is recommended that clinic planners regularly visit the CDC website and consult with the NJDHSS to keep abreast of updated information relating to smallpox and the vaccination initiative.

Education materials must be distributed to participants as a "packet" in a folder or binder at the beginning of the pre-vaccination education session and again at registration on the day of the clinic. Clinic planners should allow adequate time for duplication and collation of materials. Pre-Vaccination Education materials from the CDC may be accessed and downloaded from their website; the link to this information is provided on the preceding page. Please note that the pre-education packet from the CDC is current as of November 15, 2003.

7. Planning and Follow-Up Stages

The clinic planner must pay scrupulous attention to detail when preparing to implement a smallpox vaccination clinic, because so many different resources will be called into play. The following outline is meant to serve as a guide and checklist for the clinic planner/clinical manager to use in working through the process. It is recommended that a tabletop exercise be conducted well in advance of the actual vaccination event. This "dry run" will not only identify problems to be overcome, but also point out ideas for improved efficiency.

Of course, lead-time of three months or more will not be available in a post-event scenario. A confirmed or highly suspect case of smallpox may make it necessary to mount a mass vaccination clinic in a very short period of time. In this case, the plans in this manual will need modification, but should still provide a basis for action.

3 months prior to clinic

- Determine Director/Supervisor of overall clinic operations
- Determine Director/Supervisor of clinical operations (clincal manager)
- Determine Medical Director to sign standing orders and provide consultation
- Notify the NJDHSS of proposed date/time/location of smallpox vaccination clinic
- Identify and contact staff to work various stations (**NOTE**: staff working as vaccinators and/or at the vaccination station **MUST** be vaccinated)
- Determine approximate number of vaccinees to be seen
- Identify possible clinic location(s)

1 month prior to clinic

- Confirm clinic location
- Determine floor plan and equipment needs (tables/chairs/screens/etc.)
- Determine staffing needs and assign clinic workers
- Publicize clinic to potential vaccinees
- Set appointment schedule for clinic participants
- Identify location(s) for "take" reads

2-3 weeks prior to clinic

- Follow-up and confirm details of vaccine delivery with the NJDHSS
- Gain clearance from the NJDHSS to use PVS system; enter user names

- Make appointments for clinic participants
- Confirm all staff for clinic
- Order/confirm availability of equipment (computers, VCR, screens, etc.)
- Order medical supplies (gauze, gloves, tape, red medical waste bags, etc.)
- Identify/notify hospital(s) for treatment of Adverse Events
- Obtain and copy materials for Participant, After Care, and Staff Training packets
- Obtain and copy participant and staff evaluation forms
- Order food/refreshments for staff and participants

7 days – 1 day prior to clinic

- Assemble Participant and After Care packets*
- Obtain PVN stickers from NJDHSS for all prospective vaccinees
- Obtain Office of Emergency Management (OEM) Volunteer Registry Book from the NJDHSS (sign-in for individuals not employed by hospitals or health departments)
- Secure staff-identification vests for non-clinical workers
- Develop map of clinic lay-out
- Create signage
- Prepare staff training agenda and Staff Training Packet
- Confirm participant appointments
- Confirm food/refreshments for staff
- Confirm delivery of equipment and supplies
- Establish floor plan and equip workstations (when possible)
- Provide staff training (when possible)

Day of Clinic

- Establish floor plan and equip workstations (if not done 1 day prior)
- Provide staff training (if not done 1 day prior)
- Hang signage to identify workstations and direct traffic flow
- Distribute staff-identification vests; collect after clinic
- Receive/reconstitute vaccine
- Set up vaccination station(s) and open vaccine batch(es) in PVS
- Educate, screen and vaccinate participants
- Make appointments for “take” readings
- Close vaccine batch(es) in PVS and return unused vaccine
- Collect participant and staff evaluation forms
- Notify “take” reading locations of names of vaccinees to expect
- Debrief core staff

1-4 Weeks after clinic

- Process participant and staff evaluations
- Follow-up on any Adverse Events in collaboration with the NJDHSS

- Follow-up on vaccination “take” readings and broken appointments
- Perform active surveillance in collaboration with the NJDHSS
- Assure medical clearance and respirator fitting for response team members

*Clinical manager(s) should determine appropriate contents for the After Care packet. At a **minimum**, materials should include:

- A listing of hospitals designated to assess/treat Adverse Events
- Smallpox Vaccination After Care Instructions
- Information about “take” reading
- Vaccination dressing supplies

Samples of these materials are included.

Smallpox Vaccine –NJ Regional Hospitals Designated to Assess/Treat Adverse Events

Trenton and NJDHSS Employees:

St. Francis Medical Center
601 Hamilton Avenue
Trenton, NJ 08629

Northeast Region (Serving Bergen, Essex, and Hudson Counties)

University of Medicine and Dentistry of NJ
150 Bergen Street, Room D-215
Newark, NJ 07103

Northwest Region (Serving Sussex, Warren, Passaic, and Morris Counties)

St. Joseph's Hospital
703 Main St.
Paterson, NJ 07503

Central West Region (Serving Hunterdon, Somerset, and Mercer Counties)

Hunterdon Health Care System
2100 Wescott Drive
Flemington, NJ 08822

Central East Region (Serving Union, Middlesex, Monmouth, and Ocean Counties)

Raritan Bay Medical Center – Perth Amboy
530 New Brunswick Avenue
Perth Amboy, NJ 08861

South Region (Serving Burlington, Camden, Gloucester, Salem, Cumberland, Atlantic, and Cape May Counties)

Lourdes Medical Center of Burlington County
218 Sunset Road
Willingboro, NJ 08046

Virtua Memorial Hospital Burlington County
175 Madison Avenue
Mt. Holly, NJ 08060

Shore Memorial Hospital
1 East New York Avenue
Somers Point, NJ 08244

Smallpox Vaccination Aftercare Instructions

There are four important things for you to keep in mind following today's clinic:

- What to do and where to go if you should have an adverse reaction from today's vaccination.
- How to care for your vaccination site
- Why and where to have your "take" read.
- How to use your diary and what to do with it when it is completed.

Adverse Reactions:

- Refer to Supplement A in your packet to become familiar with normal and adverse vaccine reactions.
- If you experience a life threatening reaction, call 911.
- If you experience possible vaccine related adverse reactions, go to the hospital designated for your region. (See attached list)
- If a close physical contact experiences any adverse reactions (as outlined in your packet materials) call his or her primary care physician. Also report the adverse reaction to the NJ Dept. of Health and Senior Services during regular business hours at 609-588-7500.

Care of Vaccination Site:

- Refer to the color brochure and Supplement B in your packet to become familiar with vaccination site appearance and care.
- Keep the site dry and covered with gauze in order to prevent inadvertent spread of the vaccinia virus to other parts of your body or to your contacts. Cover it with plastic wrap or a waterproof dressing when showering.
- Check the outside of your dressing DAILY for evidence of leaking or stains.
- Change your dressing as needed (minimum of every third day). Be sure to allow for air circulation when applying the tape.
- Keeping the site dry and allowing air circulation will help speed healing.

Take Reading:

- You must have your vaccination site examined in 6-8 days in order to determine if your vaccination was successful. This is called a take reading.
- It is very important to have a take reading since you cannot be considered vaccinated without having this done.
- Your take reading is scheduled for (*date*) at (*location.*)
- Bring your green vaccination card and diary to the "take" visit. Your card will be completed and returned to you, and your diary will be reviewed.

Use and Submission of Diary:

- Record any and all symptoms you are experiencing (normal, variant and adverse) on the Smallpox Vaccination Diary in your packet.
- Your diary is considered complete at the time a "no take" is determined **or** when the scab falls off after a successful vaccination.
- Submit your diary to (*address*) when it is complete.

For questions regarding the vaccine or vaccine reactions that are not answered in the educational materials provided, you may contact the following:

NJ Dept. of Health and Senior Services
General information on smallpox vaccine and adverse events
Mon-Fri, during business hours (609) 588-7500

CDC Public Response Service
General information on smallpox vaccine and adverse events
Mon – Fri, 8am – 11pm; Sat-Sun, 10am – 8pm
English: (888) 246-2675
Spanish: (888) 246-2857
TTY: (886) 874-2646

8. Workstations

The vaccinee goes through a fixed sequence of activities before and after being vaccinated. These steps involve education, screening, informed consent, and after care. While it is possible for one person to take each vaccinee through the entire process, greater efficiency can be achieved by locating individual functions at workstations. Each participant will then pass through the series of workstations in order to receive complete care. Monitors are positioned between workstations to guide participants through the path and assist workers as needed.

This chapter outlines the activities/actions that occur at each station. Workstations are listed in the order through which the participant would pass during the vaccination event. Depending on the size of the clinic to be implemented, some stations may be combined, as the clinic planners deem appropriate. For instance, a small clinic operation may combine mental health/crisis counseling with medical consultation, using the same staff member for both functions.

The medical consultation and mental health/crisis counseling stations are resources to be used by staff and participants as needed. All other stations/functions are mandatory. In order to follow CDC guidelines, it is imperative that the participants not be permitted to skip any mandatory stations.

The smallpox vaccination clinic stations are as follows: Check-in, Registration, Education, Medical Screenings, Medical Consultation, Vaccination, After Care/Observation, Mental Health/Crisis Counseling, and Check-out. Job descriptions for staff at each of the stations are included in the following chapter. It is important to note that only clinical health professionals can staff those workstations marked with a star (★).

Smallpox Vaccination Clinic Workstations

- Check-in
- Registration
- Education
- Medical Screening ★
- Medical Consult (if needed) ★
- Mental Health/Crisis Counseling (if needed) ★
- Vaccination ★
- After Care/Observation ★
- Check-out

Check-in

All potential vaccinees and staff working at the vaccination event must check-in before entering the clinic site. This is to prevent unauthorized persons from gaining entry to areas where vaccine is stored and clinical services are to be provided. Workers at check-in must have sign-in sheets of expected workers and participants. Persons not on the list must be cleared by the clinic planner before being allowed access to the clinic site. Participants must show employee identification from their referring organization. Nurses and physicians who are working in a clinical capacity must show proof of current New Jersey licensure. Any vaccinees who are not employed by a health department or hospital must sign the OEM Log to ensure compensation coverage for Adverse Events. Security may be needed at the check-in station to assist with crowd control. Mental Health Counselors may also be used to monitor crowd control, as well as to identify and refer anxious and overly worried individuals to the Mental Health/Crisis Counseling station.

Registration

Registration is the second station for prospective vaccinees. At this station, they receive the participant packet and are logged into the PVS computer system. Registrars will take the participants' demographic information and ask about their vaccination history. Participants should be instructed to fill out sections A-D of the 5-page *Medical History & Consent Form* as they wait for the education video.

Education

At this station vaccinees watch the patient advice video, *"Smallpox Vaccine, Decision Point for the Smallpox Vaccine Candidate"*, from the CDC. This station allows participants a final opportunity to hear vaccine information and decide about being vaccinated. The video is approximately 13 minutes long. A transcript may be found on the CDC website. The video is best viewed in small groups so that vaccinees will feel more comfortable interacting with education staff. Personnel at this station may be clinical health professionals and/or health educators, but at least one clinical person must be available to address clinical questions from participants. Education station staff will answer vaccination questions and/or refer participants to Medical Consultation. If the participant has no questions, he or she will move on to medical screening.

Medical Screening

By the time the participants arrive at this station, they will have attended education sessions, read vaccine materials and seen an advice video. They should have self-screened and deferred, or declined vaccination as appropriate. The purpose of the medical screening workstation is to confirm and document the participant's eligibility for vaccination. Only registered nurses or physicians can staff this station. The medical screener will assess the health status of the vaccinee and his/her contacts, and clear/defer for vaccination. Should there be any eligibility concerns, the participant is referred to medical consult as appropriate. The staff from the medical screening station may also wish to refer anxious or overly worried individuals to the mental health/crisis counseling station.

Medical Consultation

Potential vaccinees will be referred to medical consultation when they have questions after seeing the advice video, or when the medical screener or vaccinator has concerns about the participant's eligibility for vaccination. Only physicians may staff this station. The medical consultant will assess the situation, and clear or defer the participant. The medical screener may also refer the client to mental health/crisis

counseling station when appropriate. In some smaller clinic settings, the medical consultant may provide mental health counseling as well.

Vaccination

Two people, one to administer vaccine and one to record in the PVS, should staff each vaccination workstation. The vaccinators should follow CDC recommendations on alleviating repetitive motion stress and fatigue by switching tasks regularly. Participants will arrive at this station having been educated about vaccination and screened for contraindications. Vaccinators will confirm that the participant desires vaccination, check information in the PVS, obtain informed consent signatures on the "*Medical History & Consent Form,"* administer vaccine, dress the site and complete the green "proof of vaccination" card. **Only registered nurses or physicians licensed in New Jersey, who have been vaccinated and trained in vaccine administration can staff this station.**

After Care/Observation

Vaccinees remain at this workstation for at least 20 minutes to be observed for untoward reactions, and to learn about vaccination site care. Nurses and emergency medical personnel staff this station. Emergency medical personnel can provide first aid and assistance with observation. Nurses meet with vaccinees individually discuss vaccination site care, handling of possible Adverse Events, and the importance of getting their "take" read. During this time, they distribute the After Care packet (see Chapter 7), and make an appointment for "take" reading. After meeting with the nurse to discuss various After Care issues, vaccinees should complete the *Smallpox Vaccine Clinic Participant Evaluation*.

Mental Health/Crisis Counseling Station

This station may exist in conjunction with After Care/Observation or be a free-standing station. The mental health/crisis counseling station is where anxious or overly worried individuals may discuss their feelings with a mental health professional(s).

Individuals who are referred to this station may or may not receive the vaccine and may be escorted from the clinic based on recommendations from the counselor.

Check-Out

The Check-Out station is the last station of the clinic. Staff at this station collect the completed *Medical History and Consent Form* and verify that all information in the PVS is correct. In addition, they confirm that an appointment has been made for a "take " reading, and collect evaluation forms from participants and staff.

9. Job Responsibilities

The clinic planner is responsible for recruiting and assigning staff for all aspects of the clinic. This includes physical set-up, work at the various stations, take-down/clean-up, and provision of the 7/21/28 day follow-up. Adequate staffing at the vaccination clinic is important since understaffed areas create delays in patient flow. Overstaffing, however, can also be a problem. It is not only wasteful of resources, but also can lead to loss of worker effectiveness due to boredom or inattention. Adequate staff coverage must be available to allow for orientation and training before the clinic opens, and for meal/rest breaks during the actual event.

Chapter 10 of this manual contains information about the amount of time vaccinees spend at each of the clinic's various workstations. The clinic planner can use this information as a guide when allocating personnel, floor space and other resources for the clinic event. This chapter is devoted to the actual tasks that various workers will perform in order to get the participants vaccinated. It is meant to help the clinic planner and clinical manager understand the types of workers needed for the many jobs of the clinic. Job Action Sheets, which list detailed duties for staff at each station, are included. These itemized sheets may be tailored to fit the needs of your clinic or used "As Is".

Clinic Planner

The Clinic Planner is responsible for administrative oversight of the entire vaccination event. S/he should have had experience in organizing health-related group activities, and in personnel management. Specific tasks of the Clinic Planner are listed below.

- Choose a date for the clinic
- Secure a site to accommodate the vaccination clinic
- Coordinate with the NJDHSS concerning feasibility of the clinic date, access to PVS, and other technical support issues
- Obtain supplies and equipment

- Identify a clinical manager
- Recruit and assign non-clinical staff
- Orient and supervise non-clinical staff
- Ensure security of site and vaccine
- Oversee clinic setup, operation and take down
- Serve as trouble-shooter and resource person during clinic operation

Clinical Manager

The Clinical Manager is responsible for all clinical aspects of the vaccination event and follow-up of Adverse Events. CDC approved materials about Adverse Events are included at the end of this chapter. A comprehensive set of materials regarding Adverse Events may be found on the CDC website: http://www.bt.cdc.gov/agent/smallpox/vaccination/clinicians.asp#ae.

The clinical manager should be a nurse or physician with experience in immunization, general clinic operations, and clinical supervision. Specific tasks of the Clinical Manager are listed below.

- Participate in site selection, focusing on clinical needs
- Coordinate with the NJDHSS concerning acquisition of vaccine and other clinical issues
- Obtain clinical supplies and equipment
- Recruit and assign clinical staff
- Check proof of current license for nurses and physicians, as needed
- Orient and supervise clinical staff
- Oversee vaccine reception, reconstitution, storage and use
- Oversee clinic setup, operation and take down, focusing on clinical issues
- Serve as trouble-shooter and resource person for clinical operations
- Provide Adverse Events follow-up

Check-in Station Clerk

The Check-in Station Clerk is the gatekeeper who prevents unauthorized persons from gaining entry to areas where vaccine is stored and clinical services are to be provided. The person(s) at this station should have experience working with the public in a receptionist-type role. Specific tasks of the Check-in Station Clerk are listed below.

- Use official lists to check-in **everyone** (volunteers, workers, vaccinees, county officials, press, etc.) before allowing entrance to the clinic
- Verify photo ID of workers and vaccinees
- Obtain signatures on the sign-in sheet
- Notify the clinic planner of individual(s) not on the list; deny access until cleared
- Refer vaccinees who are not employed by a hospital or health department to sign the Office of Emergency Management (OEM) logbook
- Contact scheduled vaccinees who are over one hour late to determine if they will attend

Monitor

The Monitors are responsible for smooth flow of traffic between workstations, and can assist with courier and communication support. In addition, they can assist the Clinic Planner and Clinical Manager as trouble spotters. Monitors may also act as observers to ensure that individuals who appear anxious are referred to the mental health/crisis counseling station. Staff working in this position should be experienced in dealing with the public and have good organizational skills. Specific tasks of the Monitor are listed below.

- Ensure smooth flow of traffic between workstations
- Answer questions about clinic, as needed
- Give directions, as needed (restrooms, break rooms, public telephones)
- Monitor workers and vaccinees for signs of fatigue or stress. Notify Clinic Planner or Clinical Manager as needed
- Direct vaccinees to next station

Registrar

Registrars take participants' demographic information, ask about their vaccination history, and log the information into the PVS. They should be experienced in working with the public, and have good computer skills. Specific tasks of the Registrar are listed below.

- Enter vaccinee information into the PVS
- Supply each vaccinee with a *Participant Packet* and five-page *Medical History and Consent Form* with PVN numbers attached
- Instruct vaccinee to complete "Section A" of the *Medical History and Consent Form*
- Direct vaccinee to the education waiting area

Educator

Educators screen the pre-vaccination education video and are available to answer any questions vaccinees may have. Educators may be clinical health professionals and/or health educators, but at least one person must be available to address clinical questions from participants. Specific tasks of the educator are listed below.

- Show the education video approximately once every 15 minutes
- Answer vaccinee questions and/or refer to Medical/ Mental Health Consult as needed
- Direct vaccinees to the appropriate waiting area

Medical Screener

The Medical Screener assesses the health status of the potential vaccinee and his/her contacts, then clears or defers for vaccination. If the screener judges that there are eligibility concerns, the participant may be referred to medical consultation or mental health/crisis counseling as appropriate. Only registered nurses or physicians licensed in New Jersey can staff this position. Specific tasks of the Medical Screener are listed below.

- Locate vaccinee's record in the PVS
- Using the questions contained in PVS, obtain vaccinee's medical history and perform medical screening
- Following clinic protocols, clear/defer participant for vaccination, or refer to medical or mental health/crisis consultation as needed

- If the vaccinee has a potentially contraindicating condition and has not discussed the question of vaccination with their primary provider, then DEFER from vaccination

- If the vaccinee has a potentially contraindicating condition, but has a letter from his/her primary physician stating the client is eligible for vaccine, then CLEAR for vaccination. Attach the letter to the paper medical history form. Document on the paper form (page 2) in the comments section and in the PVS
- Enter participant disposition in PVS
- Direct participant to the appropriate waiting area

Mental Health/Crisis Counselor

Mental Health/Crisis Counselors are responsible for assisting individuals who are unable to cope with stress or anxiety during the vaccination clinic. Nurses, physicians, mental health counselors, psychologists or other health professionals with mental health training should staff this position. Specific tasks of the Mental Health/Crisis Counselor are listed below.

- Monitor vaccinee/staff for signs of fatigue or stress. Notify Clinic Planner or Clinical Manager as needed
- Provide mental health/crisis counseling, as needed
- Provide mental health resources, as needed

Medical Consultant

During the clinic, the Medical Consultant makes a final determination of the participant's eligibility for vaccination after reviewing the medical history, potential contraindications, or other concerns. Prior to the clinic opening, the Medical Consultant will sign the standing orders to vaccinate. Additionally, depending on the size and scope of the clinic, the Medical Consultant may provide mental health assessment/referral. Only physicians licensed in New Jersey may staff this position. Specific tasks of the Medical Consultant are listed below.

- Sign standing orders to vaccinate
- Locate vaccinee's record in the PVN

- Review medical history, contraindications and other concerns
- Provide mental health assessment/referral/services as needed
- Make appropriate recommendation: to vaccinate or to defer
- Enter participant disposition in PVS
- Direct participant to the appropriate waiting area or care station

Vaccinator

The Vaccinators confirm the participant's desire for vaccination, administer vaccine, dress the site, and record the vaccination. Two people should staff each vaccination workstation, one to administer vaccine and one to record in the PVS. Vaccinators should follow CDC recommendations on alleviating repetitive motion stress and fatigue by switch tasks regularly. Only registered nurses or physicians licensed in New Jersey who have been vaccinated and trained in vaccine administration can staff this station. Specific tasks of the Vaccinator are listed below.

- Set up and maintain vaccination station
- Ensure proper reconstitution and storage of vaccine
- Confirm participant's desire and medical eligibility for vaccination
- If eligibility concerns arise, call monitor to escort vaccinee back to Medical Consultation
- When ready to vaccinate, sign the paper consent form and obtain vaccinee's signature
- Vaccinate participant and dress vaccination site
- Record vaccination in the PVS
- Complete the green "Proof of Vaccination" card (including PVN #)
- Direct participant to the After Care area

Post Vaccination Observer

The Post Vaccination Observers monitor participants for untoward reactions for at least 20 minutes following vaccination. They should be capable of providing first aid measures, and recognizing the need for medical care. Emergency medical technicians, paramedics, or nurses can staff this station. Specific tasks of the Post Vaccination Observer are listed below.

- Provide for timing of twenty-minute observation period
- Offer first aid or secure medical care as needed

After Care Counselor

The After Care Counselor meets with vaccinees individually to discuss vaccination site care, handling of possible Adverse Events, and the importance of getting the "take" read. Additionally, s/he distributes the after care packet, and makes an appointment for "take" reading. S/he also ensures that participants complete an evaluation of their clinic experience. Registered nurses or physicians licensed in New Jersey staff this position. Specific tasks of the After Care Counselor are listed below.

- Distribute packet of After Care information and review its contents with the vaccinee
- Educate and counsel the vaccinee about proper vaccination site care
- Explain use and disposition of the diary
- Instruct on the requirement for "take" reading, and make appointment for location and time of reading. Remind vaccinee to bring diary and the green "Proof of Vaccination" card to the 7-day follow-up visit
- Instruct vaccinees to make alternate arrangements if, for any reason, they cannot keep the follow-up visit. Give directions to and contact information for "take" reading site
- Educate and counsel the vaccinee about self-identification of Adverse Events. Distribute list of hospitals designated to treat Adverse Events
- Ensure that vaccinee is observed for twenty minutes following vaccination
- Ask vaccinee to complete the *Participant Evaluation Form* and release him/her to the checkout station if there were no untoward reactions

Check-Out Station Clerk

The Check-Out Station Clerk is the last person that the vaccinee sees at the clinic. Staff at this station collect the completed *Medical History and Consent Form*, and verify that all information in the PVS is correct. In addition, they confirm that an appointment has been made for take reading, and collect evaluation forms from participants and staff. Staff working at this position should have experience in dealing with the public

and good organizational skills. Specific tasks of the Check Out Station Clerk are listed below.

- Collect *Medical History and Consent Form* (five page document). Ensure that Section A, is completed and legible, and that the Consent Section is signed
- Confirm appointment for “take” reading
- Collect completed evaluations (vaccinee and staff)
- Locate vaccinee’s record in the PVS. Verify spelling of name and completeness and accuracy of all information
- Thank the vaccinee for their participation and direct to the exit

Job Action Sheet:

Check-In Clerk

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic "walk through" with other clinic workers
4.	Greet vaccinees and staff
5.	Obtain official lists and check-in everyone (vaccinees, staff, volunteers, officials, press, etc.) • Obtain signatures on the sign-in sheet • Individuals who arrive at clinic and are not on the list may not be admitted until they are cleared by Clinic Planner/Clinic Manager
6.	Verify worker credentials (RN, MD, RPh, EMT) • Licenses required • Photo identification required
7.	Verify vaccinees referring organization • Photo identification required
8.	Vaccinees not employed by a health department/hospital must sign the Office of Emergency Management log book
9.	Contact scheduled vaccinees who are one hour late for appointment to determine if will attend clinic
10.	Direct vaccinees to registration
11.	Give directions, as needed (restrooms, break rooms, public telephones)
12.	Answer questions about clinic, as needed
13.	Complete evaluation at the conclusion of the clinic
14.	Other duties as assigned

Job Action Sheet:

Registrar

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic “walk through” with other clinic workers
4.	Enter vaccinee demographic information and vaccination history into PVS
5.	Distribute **Participant Packet** and **Medical History & Consent Form** to each vaccinee
6.	Have vaccinee complete Section A of **Medical History & Consent Form**
7.	Attach PVN numbers to each **Participant Packet** (set of 6)
8.	Direct vaccinee to next station
9.	Give directions, as needed (restrooms, break rooms, public telephones)
10.	Answer questions about clinic, as needed
11.	Complete evaluation at the conclusion of the clinic
12.	Other duties as assigned

Job Action Sheet:

Monitor

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Receive and put on "monitor vest"
3.	Attend briefing with Clinic Planner/Clinic Manager
4.	Attend clinic "walk through" with other clinic workers
5.	Answer questions about clinic, as needed
6.	Give directions, as needed (restrooms, break rooms, public telephones)
7.	Monitor colleagues for signs of fatigue or stress. Notify Clinic Planner or Clinical Manager as needed.
8.	Monitor vaccinees for signs of fatigue or stress. Notify Clinic Planner or Clinical Manager as needed.
9.	Direct vaccinees to next station
10.	Complete evaluation at the conclusion of the clinic
11.	Other duties as assigned

Job Action Sheet:

Educator

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic “walk through” with other clinic workers
4.	Operate patient education video (every 15 minutes)
5.	Answer questions regarding video • If cannot answer questions, refer to medical screening
6.	Refer to Mental Health/Crisis Counselor, as needed
7.	Give directions, as needed (restrooms, break rooms, public telephones)
8.	Answer questions about clinic, as needed
9.	Direct vaccinee to next station
10.	Complete evaluation at the conclusion of the clinic
11.	Other duties as assigned

Job Action Sheet:

Medical Screener

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic “walk through” with other clinic workers
4.	Locate vaccinee’s record in the PVS
5.	Using the questions contained in PVS, obtain vaccinee’s medical history and perform medical screening
6.	Following clinic protocols, clear/defer participant for vaccination, or refer to medical or mental health/crisis consultation as needed
7.	Enter participant disposition in PVS
8.	Direct participant to the appropriate waiting area
9.	Complete evaluation at the conclusion of the clinic
10.	Other duties as assigned

Job Action Sheet:

Medical Consultant

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic “walk through” with other clinic workers
4.	Answer questions about video, as needed
5.	Locate vaccinee’s record in the PVN
6.	Review medical history, contraindications and/or other concerns
7.	Provide mental health assessment/referral/services as needed
8.	Make appropriate recommendation: to vaccinate or to defer
9.	Enter participant disposition in PVS
10.	Direct participant to the appropriate waiting area or care station
11.	Complete evaluation at the conclusion of the clinic
12.	Other duties as assigned

Job Action Sheet:

Vaccinator

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES

Only registered nurses or physicians who have been vaccinated and trained in vaccination technique may staff this station*

1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic "walk through" with other clinic workers
4.	Set up vaccination station
5.	Reconstitute vaccine
6.	Confirm **Medical History & Consent Form** is complete
7.	Verify patient is requesting vaccination
	Sign paper **Medical History & Consent Form**
	Obtain vaccinee's signature on consent
8.	Administer vaccine
9.	Dress vaccination site
10.	Complete **Proof of Vaccination** card • Include PVN #
11.	Switch positions with Vaccination Recorder, as needed
12.	Give directions, as needed (restrooms, break rooms, public telephones)
13.	Answer questions about clinic, as needed
14.	Direct vaccinee to After Care
15.	Complete evaluation at the conclusion of the clinic
16.	Other duties as assigned

Job Action Sheet:

Vaccination Recorder

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES

Only registered nurses or physicians who have been vaccinatedand trained in vaccination technique may staff this station*

1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic “walk through” with other clinic workers
4.	Set up and maintain vaccination station
5.	Reconstitute vaccine
6.	Access and verify vaccinee information in PVS
7.	Enter vaccination information into PVS
8.	Switch positions with Vaccinator, as needed
9.	Give directions, as needed (restrooms, break rooms, public telephones)
10.	Answer questions about clinic, as needed
11.	Direct vaccinees to After Care
12.	Complete evaluation at the conclusion of the clinic
13.	Other duties as assigned

Job Action Sheet:

After Care Counselor

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic "walk through" with other clinic workers
4.	Meet with vaccinee post-vaccination
5.	Assist vaccinee in completion of **Participant Evaluation Form**
6.	Distribute packets of After Care information to vaccinee
7.	Review entire aftercare packet with vaccine
8.	Explain post-vaccination follow-up procedure to determine "take" • 7/21/28 day site checks • Inform vaccinee of "take" locations
	Record vaccinee's choice of location to get "take" read on **Take Location Form**
9.	Affix remaining PVN # to vaccine diary card
10.	Explain diary card to vaccine and its usage • Remind to bring card to 7 day follow-up visit
11.	Identify Adverse Events hospital(s) in vaccinee region • Explain Adverse Events • Give directions to hospital(s)
12.	Provide additional packet of dressing materials to vaccinee
11.	Refer to Mental Health/Crisis Counselor, as needed
12.	Give directions, as needed (restrooms, break rooms, public telephones)
13.	Answer questions about clinic, as needed
14.	Direct vaccinee to next station
15.	Complete evaluation at the conclusion of the clinic
16.	Other duties as assigned

Job Action Sheet:

Post-Vaccination Observer

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic “walk through” with other clinic workers
4.	Inform vaccinee of activities at After Care station
5.	Observe vaccinee post-vaccination for a minimum of 20 minutes, looking for signs of illness or stress
6.	Time vaccinee arrival and departure at the After Care station to verify 20 minute minimum observation
7.	Refer to Mental Health/Crisis Counselor, as needed
8.	Give directions, as needed (restrooms, break rooms, public telephones)
9.	Answer questions about clinic, as needed
10.	Direct vaccinee to next station
11.	Complete evaluation at the conclusion of the clinic
12.	Other duties as assigned

Job Action Sheet:

Mental Health/Crisis Counselor

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic “walk through” with other clinic workers
4.	Monitor vaccinee/staff for signs of fatigue or stress. Notify Clinic Planner or Clinical Manager as needed.
5.	Provide mental health/crisis counseling, as needed
6.	Provide mental health resources, as needed
7.	Answer questions about clinic, as needed
8.	Give directions, as needed (restrooms, break rooms, public telephones)
9.	Direct vaccinee to next station or to clinic exit
10.	Complete evaluation at the conclusion of the clinic
11.	Other duties as assigned

Job Action Sheet:

Check-Out Clerk

Position assigned to: _____

Clinic area assigned to: _____

You report to: _____

DUTIES	
1.	Register yourself at check-in
2.	Attend briefing with Clinic Planner/Clinic Manager
3.	Attend clinic “walk through” with other clinic workers
4.	Verify vaccine information in PVS
5.	Refer to Mental Health/Crisis Counselor, as needed
6.	Confirm appointment for take reading
7.	Ensure **Medical History & Consent Form Section A is completed,** and **Consent** has been signed
8.	Collect **Medical History & Consent Form**
9.	Collect **Participant & Staff Evaluation Forms**
10.	Direct vaccinee to clinic exit & thank for participation
11.	Answer questions about clinic, as needed
12.	Give directions, as needed (restrooms, break rooms, public telephones)
13.	Complete evaluation at the conclusion of the clinic
14.	Other duties as assigned

10. Patient Flow and Site Layout

The physical layout of the vaccination clinic should provide for efficient traffic flow for vaccinees and ease of effort for workers. If at all possible, the workstations should be arranged so that vaccinees move from station to station in one direction only. Issues of privacy and confidentiality are important and must be taken into consideration when setting up the various clinic stations. Separating the workstations with floor space and physical barriers such as screens will improve the comfort level of both participants and workers.

All stations must be well lighted and identified with easy-to-see signage. Signage should be posted at or above eye-level to direct individuals from station to station. The size of signs and the letters on them is also an important consideration, as individuals should be able to read the signs from a distance; the CDC recommends “Arial” font.

Adequate numbers of monitors should be available between stations to guide participants to their next position, or provide assistance to staff. It is helpful to give vaccinees a written floor plan. This will not only help them get from station to station, but will also help them to see where they are in the vaccination process. A sample floor plan map is included.

The clinic planner and clinical manager will need to work together in deciding the site layout so that all logistic and clinic considerations may be addressed. Avoiding bottlenecks for vaccinees and/or periods of inactivity for staff is difficult, but not impossible. If at all feasible, layout should remain somewhat flexible. The ability to add or delete specific workstations during the actual clinic event would be ideal.

The number of each type of station required will depend on the number of participants to be vaccinated. Additionally, the amount of time the participant typically spends at each station should be factored in. For instance, medical screening often takes longer than actual vaccination. Therefore, more screening stations than

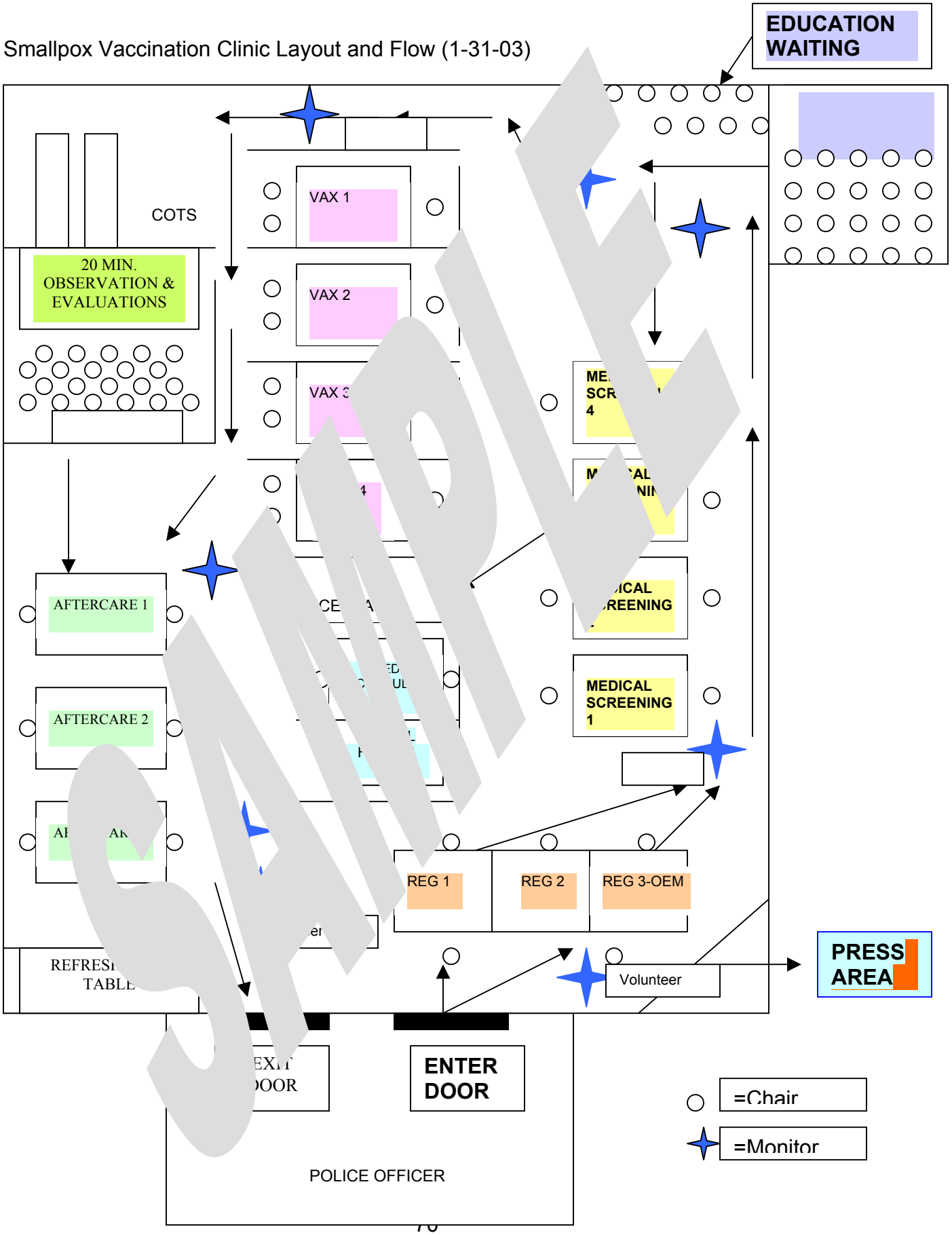
vaccination stations should be available. The following information is offered as a guide in figuring the number of stations to be set up.

One last item to consider when planning the clinic layout is the location and availability of refreshments. Inexpensive food items such as bagels/muffins, juice and coffee are minor details in the clinic experience but provide a positive lasting effect among participants and staff. Planners might consider placing refreshments that are accessible to all in an area with the longest wait time.

The chart below provides clinic planners with an approximation of time spent by participants at each clinic station. This chart does not include time spent waiting between stations, or restroom/refreshment breaks.

Approximation of Time Spent Per Participant at Each Clinic Station	
Clinic Station	**Time**
Check-in	2 minutes
Registration	5 minutes
Education	15 minutes
Medical Screening	15 minutes
Medical Consult and Mental Health/Crisis Counseling	Varies; most participants skip these stations
Vaccination	10 minutes
After Care	20 minutes
Check Out	5 minutes

Smallpox Vaccination Clinic Layout and Flow (1-31-03)



11. Evaluation

Evaluation and feedback are important aspects of the overall clinic planning process. Evaluation allows clinic planners to assess the clinic's strengths and/or weaknesses and offers insight for improvement in future clinics. All persons participating in any capacity (staff, volunteers and participants) of the clinic should be urged to give their critique of the clinic experience.

Assessments of the clinic experience range from formal paper and pencil surveys to informal briefings during and/or immediately following a clinic. Clinic planners should determine what type of evaluation they wish to use while planning the clinic, not merely as an afterthought. Lessons learned from evaluations are helpful in future clinic planning and implementation.

If clinic planners choose to make use of paper surveys, they should note that separate evaluations should be used for participants and staff so that all viewpoints may be considered. Paper surveys are a preferred evaluation method, as they allow individuals to provide constructive criticism surrounding their clinic experience. Surveys should not contain personal identification information (name, address, etc.), to allow for honest feedback without fear of retaliation. Samples of New Jersey's smallpox clinic evaluations, for both participants/vaccinees and staff, are included.

Holding a debriefing session or a "hotwash", immediately after the clinic, is another evaluation method. At a "hotwash", all staff and volunteers report their observations of clinic events. This technique yields information about what was observed by the staff during the clinic. It should be noted that not all staff may wish to report negative aspects of the clinic or inadequacies of fellow clinic staff or volunteers. That being said, this method is not as effective in obtaining complete feedback.

Another type of immediate feedback mechanism might occur during the clinic. This involves monitors and other clinic staff asking clinic participants questions about

waiting time and other logistical questions. Staff might ask participants how long they waited in line, participant's experience with making a clinic appointment, whether participants had difficulty locating the clinic site, etc. This information should be reported by staff during the "hotwash" but may also be reported directly to the clinic planner.

In closing, evaluation is an important component of clinic planning. Every clinic is unique with its own set of issues that might have been overlooked or unaccounted for by planners. Lessons learned during the clinic and are important and should be shared with others. Information exchange is an integral aspect of evaluation; individuals should feel able to express their opinions about their role during the clinic and their observations. To maximize the feedback obtained at a clinic, the clinic planner may wish to use a variety of evaluation techniques.

Smallpox Vaccination Clinic Participant Evaluation and Feedback Form

Thank you for participating in the today's smallpox vaccination clinic. We would like to ask you some questions about your experience at the clinic so that we can make improvements for future smallpox vaccination clinics. Please take a few moments to answer the following questions. **Note that the first 14 questions refer to activities <u>before</u> today's clinic.**

Clinic Location: _____ Clinic Date: _____

Name of your organization/agency: _____

Pre-Clinic Activities (before today)

1. Prior to this clinic did you attend an education/information session about smallpox vaccination?

- ❑ Yes - If Yes, specify where it was: _____
- ❑ No - If No, provide reason:
  - ❑ Education/information session was not offered
  - ❑ Unable to attend session that was offered
  - ❑ Felt that written materials were sufficient

2. Which of the following educational activities were provided by your organization in order to help you make a decision whether or not to be vaccinated against smallpox? (Check all that apply)

Written educational materials	❑ Yes	❑ No
Video tape	❑ Yes	❑ No
Slide presentation	❑ Yes	❑ No
Discussion session with hospital smallpox coordinators	❑ Yes	❑ No
Satellite or web-based broadcasts	❑ Yes	❑ No
CD Rom training	❑ Yes	❑ No
Web-based training program	❑ Yes	❑ No
Audio-conference	❑ Yes	❑ No

3. What issues were covered by these educational efforts: (Check all that apply)

Purpose of the national smallpox vaccination program	❑ Yes	❑ No
Roles and responsibilities of smallpox response team volunteers	❑ Yes	❑ No
Smallpox disease (symptoms, seriousness, etc)	❑ Yes	❑ No
Smallpox vaccine	❑ Yes	❑ No
Common/normal reactions to the smallpox vaccine	❑ Yes	❑ No
Serious reactions to the smallpox vaccine	❑ Yes	❑ No
What to do if you think you are having a serious reaction	❑ Yes	❑ No
Reasons why a person would not be allowed to receive the smallpox vaccine (contraindications)	❑ Yes	❑ No
How to prevent the vaccine virus from spreading to other body parts or other people	❑ Yes	❑ No
How to properly care for your vaccination site	❑ Yes	❑ No
How to properly dispose of soiled bandages	❑ Yes	❑ No

4. Did you read the educational materials that were provided to you?

❑ Yes
❑ No

If No, why not? _____

If Yes, please answer the following questions about the written educational materials you received:

Easy to understand	❑ Yes	❑ No
Easy to read	❑ Yes	❑ No
High quality	❑ Yes	❑ No
Provided adequate information about smallpox vaccination	❑ Yes	❑ No

5. Do you feel that the information that you received prior to the clinic was adequate for making the decision to be vaccinated against smallpox?

❑ Yes
❑ No

6. Do you feel that issues regarding disability issues were addressed appropriately?

❑ Yes
❑ No

If no, what else could have been provided? _____
_____

7. Do you feel that issues regarding workers' comp issues were addressed appropriately?

❑ Yes
❑ No

If no, what else could have been provided? _____
_____

8. Do you feel that issues regarding liability issues were addressed appropriately?

- ❑ Yes
- ❑ No

If no, what else could have been provided? _____
_____

9. If you become ill as a result of the smallpox vaccination and need to take time off from work, were you told to use:

- ❑ Sick time
- ❑ Administrative time
- ❑ Do not know

10. Do you know where to get more information about smallpox or the smallpox vaccine?

- ❑ Yes
- ❑ No

11. Did the person providing the education fully answer audience questions about smallpox and the vaccine?

- ❑ Yes
- ❑ No

12. What more could have been done to educate you about smallpox and the smallpox vaccination program?

_____
_____

13. Prior to this clinic were you screened for medical problems (contraindications) that may prevent you from volunteering for the smallpox vaccine?

- ❑ Yes
- ❑ No

14. Was the registration/scheduling process convenient?

- ❑ Yes
- ❑ No

Clinic Activities Today

15. Please tell us about your experience at the vaccination clinic.

Was the clinic conducted at a convenient location?	❑ Yes	❑ No
Were the clinic times convenient to your schedule?	❑ Yes	❑ No
Was the clinic conducted in an efficient manner?	❑ Yes	❑ No
Was the clinic staff friendly and courteous?	❑ Yes	❑ No
Was the consent form easy to understand?	❑ Yes	❑ No
Was the amount of waiting time you spent at the clinic reasonable?	❑ Yes	❑ No
Was the clinic layout easy to follow?	❑ Yes	❑ No
Upon your arrival, did you have a clear idea of what would happen at the clinic?	❑ Yes	❑ No
Were all of your questions adequately answered at the vaccination clinic?	❑ Yes	❑ No
Upon leaving the clinic, did you understand how to take care of your vaccination site?	❑ Yes	❑ No

16. Do you know where to get more information about any adverse reactions you may experience in the days following the vaccination?

- ❑ Yes
- ❑ No

17. Did you have any special needs during the vaccination clinic that were not met?

- ❑ Yes (If yes, please specify: _____)
- ❑ No

18. Do you have any suggestions on how the smallpox vaccination clinic can be improved?

19. Which of the following best describes you?

- ❑ Hospital employee
  - ❑ Hospital Nurse
  - ❑ Hospital Physician
  - ❑ Respiratory Therapist
  - ❑ Laboratory worker
  - ❑ Housekeeping/Laundry worker
  - ❑ Administrative
  - ❑ Non-clinical management
  - ❑ Food and nutrition services worker
  - ❑ Other: _____
- ❑ Public health nurse
- ❑ Public health physician
- ❑ Other public health worker
  - Please specify: _____
- ❑ Emergency responder – medical
- ❑ Law enforcement
- ❑ Other emergency responder (ie; firefighter, HazMat)
- ❑ Other: _____

Smallpox Vaccination Clinic
Staff Evaluation and Feedback Form

Thank you for participating in today's smallpox vaccination clinic. We would like to ask you some questions about your experience and observations of today's vaccination clinic so that we may make improvements for future smallpox vaccination clinics. Please take a few moments to answer the following questions. When you have completed the survey, please place it in the basket located at the Check-out station.

1. What was your role in today's smallpox vaccination clinic?
   - ❑ Check-in station
   - ❑ Registration station
   - ❑ Education/Video station
   - ❑ Medical Triage station
   - ❑ Medical Consultation station
   - ❑ Vaccination station
   - ❑ After Care/Observation station
   - ❑ Check-out station
   - ❑ Monitor

2. What type of vaccination clinic training did you participate in prior to the clinic? **(Check all that apply)**
   - ❑ CDC satellite broadcast
   - ❑ In-house training at my agency
   - ❑ Training at the clinic site
   - ❑ Self-study written packets
   - ❑ Web-based training
   - ❑ Other:
     (Please specify)

     _____

3. Do you believe that the training you received was sufficient for you to function in the role at the clinic?
   - ❑ Yes
   - ❑ No

     If No, how could training be improved in the future?

     _____

     _____

4. Was there sufficient staff available to direct the flow of traffic through the clinic?
   - ❑ Yes
   - ❑ No

5. Was there sufficient staff available to register vaccinees?

- ❑ Yes
- ❑ No

6. Was there sufficient staff available to vaccinate vaccinees?
   - ❑ Yes
   - ❑ No

7. Was there sufficient staff available to triage/screen patients?
   - ❑ Yes
   - ❑ No

8. Was there sufficient staff available to consult with vaccinees with contraindications?
   - ❑ Yes
   - ❑ No

9. Were you able to identify any traffic flow problems during the vaccination clinic?
   - ❑ No
   - ❑ Yes

   If Yes, what area(s) were particularly problematic? Please specify

   _____
   _____

10. Did you have adequate resources/supplies at your station to meet vaccinee's needs?
    - ❑ Yes
    - ❑ No

11. What was/were the most frequently asked question(s) by vaccinees at your station?

    _____
    _____

12. Were you able to answer these questions easily or direct vaccinees to a resource that could answer their question?
    - ❑ Yes
    - ❑ No

13. What overall rating would you give to the clinic in terms of its efficiency and organization?
    - ❑ Excellent
    - ❑ Very good
    - ❑ Good
    - ❑ Fair
    - ❑ Poor

14. What do you feel could have been done differently to improve the smallpox vaccination clinic?

_____

_____

Thank you!

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