

Annex 2

General Guidelines for Smallpox Vaccination Clinics

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Introduction

This document provides detailed guidelines for conducting smallpox vaccination clinics. It assumes that smallpox vaccinations will not be incorporated into immunization services in existing clinical settings, but rather that smallpox vaccinations will be administered either in the context of bioterrorism readiness or as a response to a probable or confirmed case of smallpox. Guide B in the *CDC Smallpox Response Plan* include information on vaccination strategies; indications for vaccination; reconstitution, administration, and storage of vaccine; recognition of vaccine reactions/take; recognition of adverse events; indications for Vaccinia Immune Globulin administration; recommendations for handling, cleaning, and sterilizing bifurcated needles; and contingencies for alternative diluent use. Annex 5 of this document contains information on ALL planning activities. This Annex offers general guidance to planning and conducting smallpox vaccination clinics. The following section, Annex 3, provides information for conducting large scale clinics to administer vaccinations against smallpox.

Preparing for Smallpox Clinics

1. Understand the Vaccination Strategy

In order to organize a vaccination operation to reach a target population, it is critical that the vaccination strategy be clearly understood. For example, the *immediate* response to a confirmed or probable case or cases of smallpox would be vaccination of first responders [i.e., medical personnel who will attend the infected person(s) and vaccinate contacts of the case(s)]. State and local health department smallpox preparedness plans should include locality-specific lists of all persons who must receive vaccine immediately if a case of smallpox occurs. (See Annex 5). In addition, all face-to-face contacts of the case(s) must be vaccinated. Because the rapidity with which this can be accomplished will determine the ultimate extent of the outbreak, organizing a separate vaccination operation (clinic site, staff, supplies, etc) for each group is recommended.

As soon as possible after the first case is confirmed, state and local health officials, in collaboration with CDC epidemiologists onsite, will determine the appropriate scope (who, where, and when) of the vaccination response, based on size of the initial outbreak, the amount of vaccine available, and the possibility that additional new and epidemiologically related cases will be identified in subsequent days.

Ultimately, a decision may be made to vaccinate the entire population either in response to an outbreak of smallpox or on a purely cautionary basis as part of bioterrorism readiness. However, any implementation of targeted or universal vaccination of persons at unknown risk for smallpox will require the authorization of the State Health Officer in consultation with CDC and will depend on the adequacy of vaccine supplies. In either case, the vaccination strategy may include prioritizing selected groups, such as 1) medical staff potentially involved in care of persons infected with smallpox, public health staff potentially involved with identifying, tracing

and vaccinating contacts, and security staff who would potentially accompany first responders and support quarantine efforts; 2) persons necessary to maintain essential community infrastructure, and 3) persons providing basic community services.

2. Determine Resource Needs

Based on the vaccination strategy, the number of clinics, duration of clinics, and number of staff required should be calculated. Although the precise number of personnel needed for any one clinic will vary depending on the size and layout of clinic facilities, location of clinic, geographic area being served by the clinic, and estimated number of vaccine recipients at each clinic, the over-all staffing needs should be estimated based on the model described under Clinic Operations.

3. Identify Potential Clinic Sites

As discussed in Guide B, the recommended strategy involves vaccinating primary and secondary contacts of cases identified. An essential ingredient of this approach requires the establishment of vaccination clinic sites to which contacts can be referred if necessary.* Potential clinic sites should be selected based on the estimated number of people and the size and layout of the facility. The clinic sites must be located in close geographical proximity to the outbreak, and clinic operators must be prepared to relocate the operation to another site rapidly when the outbreak focal point changes.

The size and type of the facilities needed for smallpox immunization clinics will vary depending on the number of persons to be served. Very small clinics, such as those to immunize first responders or primary contacts, can be conducted in almost any available space, most likely a local health department or similar facility. Larger clinic sites could be industrial locations, office buildings, or apartment complexes.

Schools are the preferred location for any clinic larger than can be held in the local health department. Schools have parking lots, long corridors, large classrooms, cafeterias, private offices, and other immediately available resources, such as tables and chairs, and offer an ideal physical structure that can meet most clinic needs. Elementary schools are preferable if staffing is adequate, because they are numerous and serve fairly well defined neighborhoods convenient to the public. The use of the largest number of locations that staffing permits will minimize parking and crowding problems. Use of middle or high schools may also be considered.

If smallpox cases expose many people in locations like schools and office buildings, these locations may be sites where vaccine clinics can offer vaccine quickly and efficiently to many

*If authorized by CDC and circumstances dictate, vaccine may also be administered in *field settings* in the community, while tracking case contacts, to individuals at highest risk of infection (i.e., contacts and contacts of contacts). If authorized, a secondary strategy may be to vaccinate the population on a house-to-house basis in expanding geographic rings around cases and contacts. However, to avoid wasting reconstituted vaccine, clinics should be selected and organized to administer one vaccine vial –or multiples thereof – each day. (Each vial of smallpox vaccine contains 100 (or 500 with the use of the 5:1 dilution strategy) individual doses of

vaccine.

In selecting clinic sites, consideration should be given to ensuring a smooth flow of clients, accessibility of the facility to major streets, restroom facilities, parking, refrigeration, heating/air conditioning, and protection from elements if lines will form outside. Before final selection, a visit should be made to the location to ensure that the facility meets the needs of the vaccination operation.

4. Obtain Authorization / Standing Orders

Before a clinic can be implemented, standing orders must be obtained from the public health authority, usually the state and/or local health officer to provide authorization for administration of the smallpox vaccine. Standing orders are also needed for responding to medical emergencies that occur during vaccination clinics. In addition to providing standing orders, the health officer or his/her designee must approve the content of informational materials and serve as medical consultants for nursing staff.

5. Plan Training

All public and private health care workers who may become involved in smallpox vaccination efforts should receive training in the proper administration of smallpox vaccine and screening for contraindications to smallpox vaccination. Training should also emphasize procedures for reporting suspected cases and maintaining communications with CDC. Large numbers of clinic staff can be trained through a train-the-trainer approach through CDC's satellite-based courses, Web pages, video cassettes, CD-ROM courses and written training materials. A supplemental chapter on smallpox will be included in the next edition of the "Pink Book."

Educational materials targeted to local health workers staff should be made ready for rapid distribution. These materials should provide detailed medical information about smallpox and the smallpox vaccine, and should highlight potential vaccine side effects and their clinical management.

6. Publicize the Clinic

Patient education materials should be developed in multiple languages, reproduced in appropriate quantities and readied for rapid distribution. Patient education materials should be developed in consultation and coordination with immunization partners to ensure that the information the materials provide is adequate and culturally appropriate for local audiences. Informed consent materials and including the most recent smallpox VIS (attached) must also be modified for local use, if necessary, and readied for rapid distribution.

After a smallpox vaccination clinic site and recipient populations are determined, public announcements with information about the clinic should be released as expediently as possible.

The information disseminated must clearly describe the groups for whom the clinic is intended (and not intended). Specific zip codes or alphabetic letters may be designated for a specific date and timeframe. Certain language groups may be asked to come at a specific time and date when translator resources are available. Also state the clinic location and directions, dates and times of operation, length of time the vaccination process may take, type of clothing to wear, and culturally appropriate information in as many languages as needed. It should be stated that those who do not meet the defined criteria will not be accepted for vaccination. If the vaccination clinic will be identifying and screening for possible contacts or first responders, state this clearly in the publicity information.

Using professional public relations assistance when available, announcements should be prepared and released for the television, radio, and newspaper media. If specific groups require additional information, (e.g., to counteract misconceptions about vaccination by certain groups,) clinic organizers may need to distribute flyers to targeted populations in apartment buildings, neighborhoods, workplaces, schools, and/or religious centers.

If special transportation can be provided for physically disabled or elderly persons, the telephone number for requesting special transportation should be included in all clinic publicity. To ensure accurate reporting by the media a list of subject experts and media spokespersons from state and local public health agencies, CDC and community partners should be developed and made easily accessible to the media through an approved format. If necessary, individuals who can be called upon to serve as interpreters should be identified to help inform non-English speakers. This list should note the foreign languages spoken by these individuals. To improve understanding of the subject matter, photographs and graphics should be provided in various media.

In addition to information about the specific clinic being publicized, a concerted effort should be made to provide information to the public that emphasizes:

- The rationale of the vaccination strategy.
- Disease containment measures are effective.
- All possible measures are being taken to prevent the further spread of the disease.

Clinic Operations

1. The Vaccination Clinic Process

The following paragraphs describe operation of a medium to large clinic. However, regardless of clinic size and location, the functions and routing procedures remain essentially the same. Staffing needs will vary depending on clinic size, and in a small clinic situation some roles can be consolidated or eliminated.

Step 1: Orientation and Paperwork

As vaccine recipients arrive, they are routed to the clinic entrance by security personnel who are

handling outside traffic flow and parking. Upon entering the building vaccine recipients are directed to a location where the greeter-educator briefs groups (up to 30) about what is going to take place during the clinic process, provides all required paperwork (preferably in a packet form) and instructs the vaccine recipients how to complete the necessary paperwork. Time is allowed for reading and filling in the required personal information (name, address, etc). The number of persons in the orientation briefings can vary to accommodate the rate at which people arrive. Multiple educator-greeters locations may be necessary, since people arriving after an orientation has begun will be directed to another location where another orientation will soon begin. Orientation locations can also serve as holding locations if bottlenecks occur along the clinic line. This method will insure a steady flow of vaccine recipients to the next step.

Step 2: Registration

After orientation and completion of the paperwork, the clinic flow coordinators direct vaccine recipients to registration tables where staff check each vaccine recipient's form for completeness and accuracy.

Step 3: Medical Assessment

After insuring that the paperwork is completed appropriately, vaccine recipients are directed by clinic flow controllers to the medical assessment area. Here medical screening personnel discuss with each vaccine recipient individually the medical conditions that would prevent receipt of the vaccine and determine if any such conditions are present. They will also review the common reactions to the vaccine with each vaccine recipient. Persons with suspected medical contraindications are directed to a separate station for more in-depth evaluation. Each vaccine recipient is asked to sign the consent form before proceeding further.

Step 4: Vaccination

After medical assessment, vaccine recipients with no medical contraindications are directed to the vaccination area. This area is a screened area that affords privacy to persons who find it necessary to remove clothing in order to expose to vaccination site. A vaccination assistant helps vaccine recipients expose their upper arm and cleanses the vaccination site if necessary. The vaccine recipient then proceeds to the vaccine administrator who administers the vaccine and completes the necessary documentation. Immediately thereafter, a vaccination assistant applies a bandage to the vaccination site and instructs the vaccine recipient on post-vaccination care of the vaccination site.

Step 5: Forms Collection and Exit

Before leaving the clinic, vaccine recipients are routed to a forms collector stationed near the exit. This individual collects all required paperwork, answers any remaining questions and informs vaccine recipients that they are finished with the process.

2. Staffing and Training

The official responsible for overall direction of the vaccination operation must assign a *clinic manager* who is responsible for overall clinic operation, is the primary decision maker for the site, and supervises all nonmedical personnel. All staffing assignments should be documented on a clinic assignment sheet.

Management and Coordination Functions

To assist the manager with large clinic operations, coordinators should be identified for the various clinic functions as outlined below:

Nurse Coordinator: Oversees nursing staff assigned to the clinic; assists clinic manager in making clinic assignments for nursing staff; assists on-duty nurses as needed.

Supply Officer/Vaccine Manager: Ensures that all necessary clinic supplies are on site and are available in sufficient quantities during clinic operations; maintains an inventory of supplies; oversees distribution of supplies to appropriate locations in the clinic; ensures that sufficient vaccine is available, that the cold chain is maintained through proper handling and storage; ensures that vaccine is stored in a secure manner at the clinic site and that unused vaccine is returned and accounted for; and maintains adequate vaccine and other supplies at the vaccination station.

Security Coordinator: Oversees personnel assigned to security activities at the clinic site; assists the clinic manager in making duty assignments of security personnel; determines appropriate number of security staff necessary according to clinic size and location; maintains a list of authorized clinic staff and their phone numbers; assigns and coordinates use of cell phones and pagers; establishes staff check-in and check-out procedures; ensures that all staff wear ID badges; maintains communication with local law enforcement officials.

Volunteer Coordinator: Oversees volunteer activity at the clinic site. Assists the clinic manager in making duty assignments of volunteer staff; maintains roster of persons available for volunteer duty; and maintains a schedule of times that volunteers will be available to work.

Staff Functions

Following is a summary of suggested responsibilities of the staffing roles as outlined in the operational concept above:

Greeter-Educators: Greet and conduct initial orientation of potential vaccine recipients upon their arrival; provide basic information (verbally or with a video presentation) about the vaccine and the vaccination process; distribute informational material and clinic document; explain how to complete the documents and answers questions.

Greeter-educators must be able to explain the purpose of receiving the vaccine, outline the vaccination clinic process, and distribute and explain the clinic documents to vaccine recipients individually and in groups.

Registration Staff: Review each vaccine recipient's documents for completeness and accuracy; assist clients with completing documents.

The registration staff must be familiar with each form that is distributed. They must be able to follow instructions on how to respond to exceptional situations such as non-English speaking patients or patients who are anxious, hostile, or disoriented. If the form has not been completed correctly or completely, registration staff must be able to address and correct these problems. They should be prepared to read the forms to illiterate or semiliterate persons needing their assistance.

Medical Screeners: Assess clients for contraindications to vaccination; when necessary perform physical examination of patients who state that they have dermatological conditions that may constitute contraindications; and answer medical questions.

This role should be filled by a physician, nurse or paraprofessional who has good interviewing skills and is well-versed in the technical information regarding exposure risks, medical contraindications to vaccination, risks of vaccination, and risk-benefit analysis. Medical screeners will review the list of normal or expected reactions to the vaccine with each vaccine recipient. If necessary, medical screening personnel will contact a designated physician consultant to assist in making a final decision about whether or not to vaccinate. If the vaccine is still on Investigational New Drug status, medical screening personnel should ensure that the consent form has been read, understood and signed by each potential vaccine recipient and ask vaccine recipients to sign the consent form.

Vaccination Assistants: Assist the vaccine administrator with all aspects of pre- and post-vaccination activities; prepare vaccine with diluent, ensure that vaccination station maintains adequate supplies; instruct recipients on location of vaccination; assist vaccine recipients in preparing the vaccination site (roll up sleeve, remove arm from shirt/blouse, etc.); clean vaccination site with acetone, if necessary; apply dressing to the vaccination site; instructs clients about care and changing of the dressing.

Vaccination assistants must have a thorough understanding of the vaccination process and the necessary supplies, proper technique for reconstituting the vaccine with diluent, proper care and handling of vaccine in the clinic, how to disinfect contaminated surfaces and dispose of

soiled materials, and where to access additional. Vaccination assistants are also responsible for entering the vaccine and diluent lot numbers on the patient's consent form and clinic record and providing the vaccine recipient with vaccination card that documents when and where the vaccine was administered.

Vaccine Administrators: *Oversee the vaccination process; administer the vaccine; sign the clinic record; observe vaccine recipients for immediate reaction or complications.*

Vaccine administrators can be nurses, physicians, or designated paraprofessionals who have received technical training in administration of smallpox vaccine. Vaccinators must have the ability to quickly develop a high level of skill in vaccinating with a bifurcated needle. They must have in-depth understanding of proper vaccination techniques, methods to prevent contamination of the vaccine, exposure risks, the medical conditions that constitute contraindications for vaccinations, the risks of vaccination, preparation of the vaccination site, normal and abnormal post vaccination responses, and proper follow-up care of the vaccination site. Vaccinators must also be prepared to respond to medical emergencies that may occur within the vaccination area.

Forms Collectors: *Verify that forms are correctly completed; collect all necessary forms from recipients before departure.*

The forms collector is responsible for checking that the vaccination team has signed the clinic record and entered the lot numbers on the appropriate documents. As the last staff to have contact with vaccine recipients, the forms collector must have the ability to ensure a response by the appropriate staff to any remaining concerns that clients may have.

Clinic Flow Controllers: *Direct vaccine recipients through the clinic process and monitor clinic flow.*

Clinic flow coordinators are responsible for continuously monitoring and directing client activity throughout the facility. They must be able to calmly manage and assist people who may be anxious and unable to follow directions. When congestion (backlog) is noted, flow controllers determine if staff at other locations are less busy and request assist in the congested area. They are also responsible for feeding back information about the number and rate of "upstream" clients to the vaccination assistants to enable them to maximize use of all vaccine doses in opened vaccine vials. Flow controllers may be in a position to provide early alert of situations that that may require additional security personnel.

Security Staff: *Ensure an orderly flow of traffic and parking at the clinic site; assist in maintaining orderly movement of vaccine recipients through the clinic process; provide necessary control if persons become unruly; assist supply officer in maintaining security of vaccines and other clinic supplies.*

Security staff can be off-duty law enforcement officers, professional security personnel and/or volunteers who are experienced and trained in crowd control. Potential responsibilities of security staff are describe in detail below (under Security).

Emergency Medical Personnel: Respond to medical emergencies.

Emergency personnel must be able to respond to medical emergencies, including reactions ranging from the minor to anaphylactic shock and serious medical emergencies that are incidental and unrelated to vaccination but can be expected to occur whenever large groups of people congregate. For large operations, a physician, physician's assistant, nurse practitioner or emergency medical technician should be on-site at all times during clinic operations.

Staff Training

The staff operating a clinic site should receive a group orientation to the overall purpose, function, and flow of the vaccination clinic as well as specific verbal and written directions for their individual roles.

During the orientation a diagram with annotations should be provided to show traffic flow (see Figure 1: Clinic Layout), the functions of all clinic stations, and a list of staff assigned to each role and each station, if possible. The general responsibilities of each area of the vaccination clinic are reviewed with the entire staff. All staff need to know where they will work, where their supplies and resources are located, and who their consults are as well as how to summon them.

In small clinics there are roles within the clinic that be flexed to accommodate to the needs of the clinic and decrease congestion and waiting time (“bottlenecks” and “lags”) and to permit breaks for staff. In larger clinics, this can be accomplished by cross-training. Therefore, orienting staff in small, interchangeable teams is suggested.

For training vaccine administrators and assistants, a demonstration video is available from CDC. Ideally, vaccinators should practice on each other and other staff before administering vaccine to the public. Copies of package inserts, MMWR, VIS, and any other significant administration materials should be available during training and actual vaccine clinic.

If time permits, a mock vaccination clinic or role-playing session should be conducted to train and evaluate the potential performance of staff. Vaccinating clinic staff as well as first responders and other health care providers is suggested as a way to provide critical training and experience for all staff, especially the vaccine administrators.

Emergency personnel should also attend the group orientation and be given information about smallpox and managing potential exposure to smallpox. They should be familiar with the layout of the clinic site and know where ill patients will be maintained prior to transport.

Daily postclinic debriefings should be held to assess staff performance and ascertain if additional training or clinic reconfiguration is needed.

3. Clinic Layout and Flow

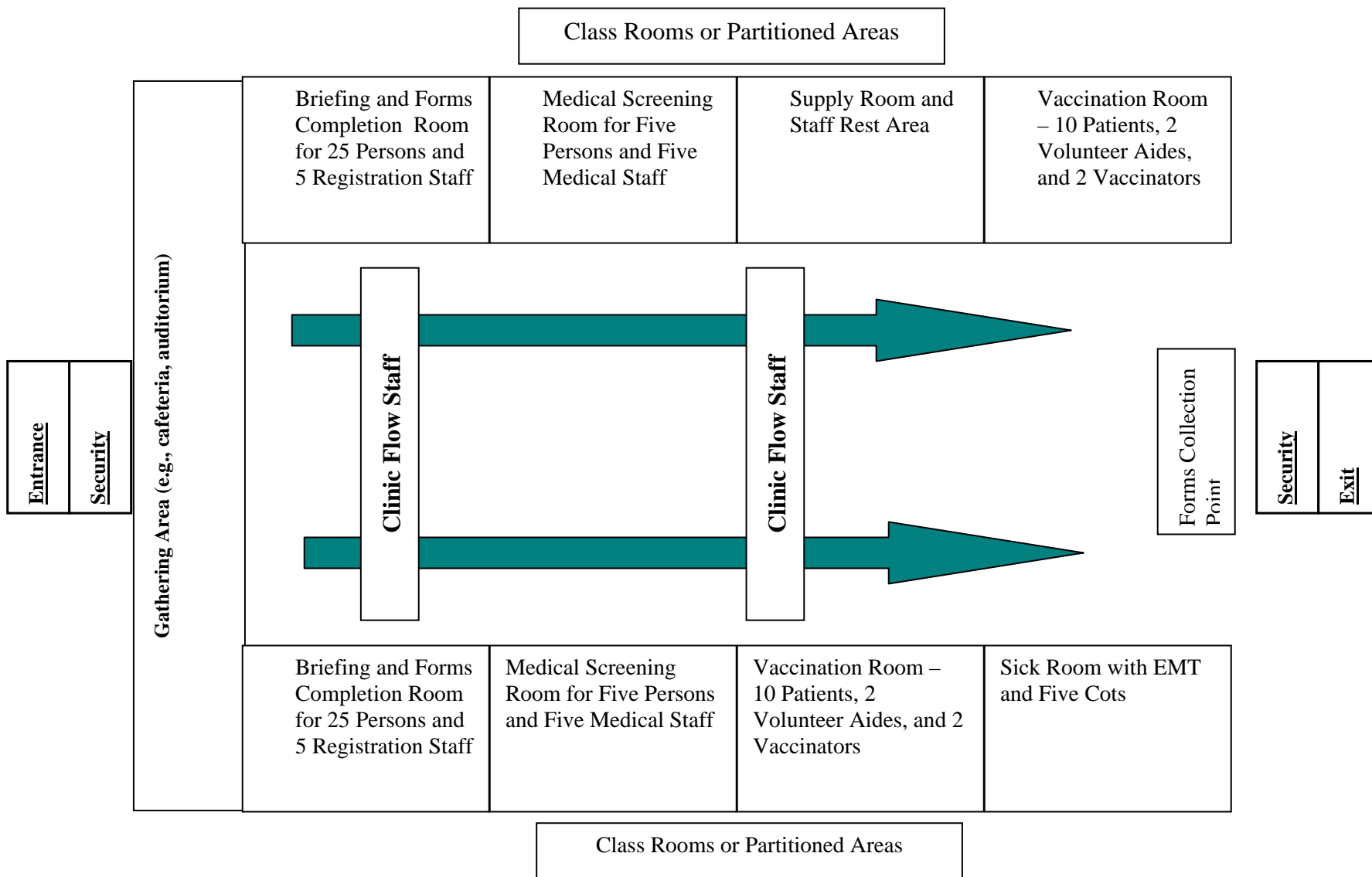
Clinics should have clearly marked entrance and exit points with adequate “waiting” space for queues of people seeking vaccination. Security staff should be posted at both locations to maintain order. The traffic flow within the clinic should be controlled and should follow a logical path from entry into the clinic to exit from the clinic. A linear path of traffic flow from entry to exit on opposite sides of the facility is optimal. If time permits, easy-to-read signage should be provided to guide people through the clinic process. See Figure 1 for a sample clinic flow diagram.

If the clinic is being held in response to a smallpox attack, some persons may arrive at the clinic with a referral form indicating that they are a contact to a diagnosed case of smallpox. These persons must be given the highest priority and be escorted directly to a registrar who will orient them and expedite the paperwork, medical assessment and vaccination process. Security personnel and greeter-educators must be alerted to this possibility.

Ideally, greeter-educators and registration staff should be located in a separate room from the vaccine administration station.

It is likely that the registration and medical screening processes will be the most time-consuming clinic activities. Sufficient staff should be assigned to move persons through these areas with some dispatch, to keep a steady flow of persons to the vaccination areas can be opened. In preclinic planning, locations should be designated for this contingency.

Figure 1 - Smallpox Clinic Setup



Traffic in the area where vaccine is being administered should be kept to minimum. Ideally, the vaccine administration tables should be set up so that staff have their backs to the wall and patients are not congregating or walking behind them. The three steps of the actual vaccination process (site preparation, vaccination, and dressing application) will all take place in a relatively small space (one or two tables) in the same area. Since some vaccine recipients may need to remove shirts or blouses to be vaccinated, a separate, screened privacy area should be available out of view of other persons lined up for vaccination.

The medical emergency area should be located as close to the vaccine administration area as possible.

4. Documentation and Paperwork

Table 1 provides a list of recipient-specific documents required in a smallpox vaccination operation and a summary of the information that must be collected. **One copy of each of the documents listed in Table X must be available (and in appropriate languages) for each vaccine recipient.** CDC will make these documents available as web-based applications as part of an electronic smallpox data management system (SDMS). If computer resources are available, data should be entered on each vaccine recipient in “real time” during registration and at appropriate points throughout the vaccination process. In the ideal scenario, all person-specific documents will be printed on-site for each vaccine recipient. However, paper copies of all documents must be available in sufficient quantities so that clinic operations can continue if the computer system fails. Whether during the clinic or later, electronic entry of critical data will be necessary.

It should be noted that each vial of vaccine will be shipped with three peel-off labels per dose contained in the vial. At standard dilution, a roll of 300 stickers will accompany each vial. One sticker will be for the patient's signed consent that becomes part of the IND documentation returned to be returned to the IND sponsor (CDC). Depending on the setting in which vaccination occurs (medical clinic, public building vaccination session, or field vaccination in patient's home, office, or elsewhere), the second and third stickers may be applied to the Clinic Vaccination Record of the patient retained by clinic and either the Vaccine Information Statement retained by the vaccine recipient or a take-home record documenting the vaccination.

Certain administrative documents and worksheets will be required to assist in clinic management and keeping track of the vaccine. These documents are summarized in *Table 2*. Additional information is provided under **Vaccine Security and Tracking**.

5. Security

In the event of a bioterrorism event involving smallpox, the level of threat perceived by the public – whether real or imagined – may be extreme. In these circumstances, state and local public health officials should be prepared for a high level of demand for vaccine by the public.

TABLE 1
VACCINATION DOCUMENTS
(Documents are under development)

Document	Information Collected	How Used
Medical/Epidemiologic Risk Screening Sheet	Medical Contraindications Epidemiological Risk Status	Used as preliminary screening tool; persons with potential risk routed for in-depth medical screening or priority vaccination
IND Informed Consent	Name, Address, Age/DOB, M/F, lot number, date, other?	Information entered; Vaccine recipient reads and signs in presence of staff
Vaccine Recipient Diary	Name, address, age/DOB, M/F, lot number, date, list of contraindications, list of symptoms	Vaccine recipients take home and check of any symptoms they may have each day for 4 weeks.
Vaccine Information Statement	Verbal Yes/No: Have you read? Do you understand?	Given to Vaccine recipients to takes home
Instructions on Care of the Vaccination Site	How to care for vaccination site; what vaccination should look like; who/where to call if reaction	Given to vaccine recipients to take home
Clinic Vaccination Record	Name, Address, Age/DOB, M/F, SS#, lot number, date, other?	Official clinic medical record
Vaccination Card	Name, Address, Age/DOB, M/F, lot number, date, signature/stamp, other?	Information entered on card; Vaccine recipient receives/keeps card to verify receipt of vaccine
Vaccination Referral	Name, physical description, M/F, signature of referring case worker, case ref #., date, risk category	Presented by persons referred for priority vaccination because of their epidemiological risk status (e.g., contact to a case of smallpox)
Expanded Vaccine Adverse Events Report	Name, Address, M/F, date, lot number,	Documentation of adverse events for IND and the Vaccine Adverse Events Reporting System (VAERS)

TABLE 2
ADMINISTRATIVE WORKSHEETS
(Documents are under development)

Document	Type of Information	How Used
Daily Vaccine Tracking Record	Beginning Inventory Doses received Doses Administered Ending Inventory Doses Wasted Disposition of Ending Inventory Signature of clinic official	Documents where, when and how vaccine was used
Staffing Assignment Sheet	Date of Clinic Clinic Roles Individuals Assigned	Records staffing assignments

With a significant level of anxiety among the public, the public health system may quickly lose the capacity to identify and limit vaccine to individuals who meet the criteria for exposure and consequent vaccination. Vaccination sites might become quickly known, and areas around these sites may experience traffic gridlock, thereby limiting egress to and exit from the clinic site by individuals in critical need of vaccine and clinic staff (including those delivering supplies and vaccine).

In the extreme case, state and local health authorities may find it necessary to call on the state and local law enforcement agencies, or even the National Guard, for traffic and crowd control near vaccination clinics, to support logistical and clinic supply needs and/or to impose geographic quarantines around outbreak areas. The ability of law enforcement and the military to supply security for a public health response may be limited by the demands of their duties as defined by individual state emergency response plans.

Management Responsibilities

The clinic manager must ensure that the following activities are handled at each site:

- Notify state/local police and EMS of the time and location of the clinic
- Assign a security coordinator
- Ensure presence of police or other security personnel
- Require that all staff wear identification cards
- Determine need for trained security guards, crowd control and traffic control personnel
- Designate entrances/exits for staff use
- Provide list of authorized staff for each clinic site
- Establish staff check-in/check out procedures
- Establish methods and locations to safeguard vaccine and other clinic supplies
- Maintain a system to vaccinate clients in their order of arrival

Staff Responsibilities

Security staff functions include: (1) maintaining orderly clinic operations; (2) protecting patients;

(3) protecting employees; (4) protecting facility property, including medical supplies and vaccine; and (5) enforcing quarantine measures (may be unrelated to clinic operations, but handled by the same personnel). To fulfill these functions, security staff must have the capacity to:

- Manage the facilities' security resources.
- Monitor the physical plant.
- Recognize potential for mob behavior.
- Control access to the facility.
- Control access to specific areas of the facility (e.g., pharmacy).
- Identify and provide a means for security/facility staff to identify authorized employees.
- Update an authorized personnel list on an ongoing basis.
- Coordinate with other security agencies.
- Enforce of mandatory isolation of contagious patients.
- Direct persons in need of care to alternative facilities.
- Remove, detain or isolate individuals who pose a risk to the facility and its operation.
- Follow the emergency response plan of the state, local and/or facility.
- Communicate with clinic staff, the command center, and external security personnel.
- Perform a secure lock down of the facility quickly.
- Demand and receive additional security resources in a predefined "emergency" situations.
- Respond with appropriate force if required.
- Provide information to persons massed outside the facility.

Security Strategy

To manage a large numbers of people arriving at clinic sites, the main strategy of security personnel should be to 1) secure a limited access perimeter at a designated distance from the physical plant; and 2) secure the clinic itself (interior perimeter; e.g., the facility's main and secondary entrances, front drive, and parking area); 3) maintain order within the facility. To carry out these strategies, security personnel must be prepared to:

- Intercept and detain individuals attempting unauthorized entry to the facility.
- Detain persons for examination and quarantine.
- Continuously provide situation information to state/local disaster command and control.
- Disseminate public information, including leaflet distribution.
- Control and disperse crowds.
- Operate available security equipment such as closed circuit television, metal detectors, security alarm systems and radio communications systems.

Emergency Protocol

In a medical or public safety emergency, security staff should immediately undertake the following activities:

- Set up an outer perimeter.
- Arrange to meet emergency vehicles at the outer perimeter and guide them to the appropriate entrance.
- Meet mass transit and supply vehicles at the outer perimeter and direct them to the appropriate entrance.
- Meet individuals coming to the facility at the outer perimeter and identify them as either

authorized staff or eligible for care.

- Deny ineligible or unauthorized persons admission using standard scripts.
- Direct authorized persons to the admission station at the interior perimeter. Offer disabled persons, the elderly, and parents with small children an escort, when appropriate.
- Monitor length of lines at the clinic entrance and relay information to the outer perimeter to limit admission, when necessary.
- Refer over-flow to other clinics, if necessary.
- Lock down the facility in the event the security objectives were compromised.

6. Clinic Supplies and Equipment

A secure area should be identified for maintaining clinic supplies. A list of clinic supplies should be kept on hand at the clinic site to be used for staff training, clinic set-up, and restocking. A check-off list of suggested supplies is provided in *Table 3*.

7. Transportation

Depending on circumstances, three types of people may require transportation assistance:

- Clinic staff,
- Persons exposed to known cases and other high-risk individuals, and
- The general public (i.e., persons with low or unknown risk of exposure).

In addition, transportation will be needed to ensure adequate amounts of vaccine, vaccine diluent and various clinic supplies. Pick-up locations for staff and supplies should be arranged and clearly communicated to drivers and staff.

Although transportation of clinic staff can be handled with agency motor pool or rented vans, special security arrangements may be required. Until vaccine supplies are no longer critical, vaccine should be transported in law enforcement or similar secure vehicles. If transportation of large numbers of vaccinees is required, public and/or private buses may need to be pressed into service. In these cases, a hot line or other mechanism must be established to enable individuals to obtain information about bus departure locations and schedules. Special consideration should be given if transportation of special populations becomes necessary [e.g., children, the elderly, homeless persons, remote populations, and disabled (including homebound) persons]. The ability to communicate with drivers via radio or cell phones is critical.

8. Vaccine Storage and Handling

Guidelines for handling and storage of smallpox vaccine are appended. The package insert should be consulted for optimal cold storage criteria. Although smallpox vaccine has proven to be hardy at ambient temperatures for extended periods of time in emergency situations, the cold storage recommendations for smallpox vaccine are similar to that of DTaP (2 to 8 °C). Styrofoam containers and cool packs are adequate for local transport and day use. If the clinic lasts for more than one day, arrangements must be made to store the smallpox vaccine in a secure location. Vaccine usage should be monitored closely, and arrangements should be made to

obtain additional vaccine, if needed. Arrangements should also be made for returning unused vaccine. Recommendations for Handling and Storage of Smallpox Vaccine are appended.

**TABLE 3
SMALLPOX CLINIC SUPPLIES AND EQUIPMENT**

General Supplies and Equipment	Vaccine Administration Supplies	Emergency Supplies
----- Tables Chairs Water and cups Paper Pens, pencils Envelopes Rubber bands Tape Stapler/staples Scissors Post-it Notes Clipboards File boxes Telephone Paper towel Kleenex tissue Table pads and clean paper to cover table for work site Garbage containers and trash bags ID badges for staff List of emergency phone numbers	----- Smallpox vaccine cooler/refrigerator for vaccine Vaccine diluent Sterilized bifurcated needles "Sharps" containers Latex gloves Latex-free gloves Antibacterial handwashing solutions Acetone Rectangle band-aids Gauze Adhesive tape Spray bottle of bleach solution	----- Standing orders for emergencies Ampules of epinephrine 1:1000 SQ Ampules of diphenhydramine 50mg IM 3cc syringes with 1", 25-gauge needles 1.5" needles Tuberculin syringes with 5/8" needles (for epinephrine) Alcohol wipes Tongue depressors Adult and pediatric pocket masks with one-way valve Adult and pediatric airways Tourniquet Gurney Stethoscope Flashlight Cots Blankets Pillows
	Crowd Management Supplies ----- Signs for clinic stations and between stations Queue partitions (to keep people in lines)	Computer Equipment and Supplies ----- Computers Printers Paper Internet access

9. Disposal of Needles and Medical Supplies

All vaccination operations should observe universal precautions for preventing blood exposures and bloodborne pathogen transmission (i.e., hepatitis B and C viruses [HBV, HCV], and human immunodeficiency virus [HIV]). Specific guidelines for the proper disposal of instruments and other potentially contaminated material during a smallpox response operation (see also Guide B - Vaccination Guidelines) are summarized below:

1. The following guidelines should be observed for appropriate disposal of pre-sterilized bifurcated needles after use (when reuse of the same needle is not planned):
 - Medical waste sharps containers should be available in the area where the sharp is used.
 - Bifurcated needles should be deposited into a sharps container immediately after use.
 - Arrangement should be in place for transport and destruction of filled sharps containers.

2. Because bifurcated needles may be in short supply until more are manufactured, they may need to be resterilized for reuse. For proper handling of bifurcated needles that need to be sterilized prior to use (i.e. received from the manufacturer in bulk) and/or resterilized and reused (i.e., when supplies are limited), specific guidelines have been provided in Section H - CDC Recommendations for Handling, Cleaning and Sterilizing Bifurcated Immunization Needles in healthcare Settings - of Guide B - Vaccination Guidelines. Some of the key points to remember include:
 - Bifurcated needles can be resterilized and reused up to 50 times.
 - Needles received in bulk from the manufacturer are assumed to be clean and ready for packaging and sterilization. If there is any concern regarding the cleanliness of these items, they should be cleaned before sterilization.
 - Used needles must be cleaned prior to sterilization. The needles may be cleaned by placing them in a soaking solution after use and then cleaning with an ultrasonic cleaning device (preferable) or commercial dish/glassware washer.
 - Bifurcated needles that are cleaned and dried, are ready to be packaged and sterilized. Preferred methods of sterilizing are either autoclaving or by dry-heat sterilization. However, if an autoclave or a forced dry heat is not available, acceptable alternate methods, as described in Section H of the Vaccination Guideline, may be used.

3. Medical waste, including gauze or cotton used during administration of vaccine, other potentially contaminated material, and empty vaccine vials should be bagged in appropriately marked biohazard bags and incinerated or autoclaved on-site if possible. Specific guidelines for proper handling of contaminated material have been provided in Guide F - Decontamination Guidelines.

10. Vaccine Security and Tracking

Since the supply of smallpox vaccine is limited and the demand for vaccine may be extremely high, care must be taken to protect the vaccine supply from theft and fraud. In addition, because each vaccine vial contains 100 to 500 doses, great care and preplanning must occur to minimize vaccine wastage that may result from discarding partially used vials. Because of these factors, each and every dose and vial must be accounted for before and after each clinic session.

If CDC's electronic smallpox information system is used and data is entered online in "real time" as vaccine recipients are being processed, the number of doses administered will automatically be counted and recorded as doses administered on the *Daily Smallpox Vaccine Tracking Report*. If CDC smallpox data management system (SDMS) is used or not operational, the number of doses administered must manually tallied from the paper copies of the *Clinic Vaccination Records* of persons receiving vaccine that day. If SDMS is not used or is not operational,

vaccine doses must be manually tallied at the end of each day in each clinic location and entered on the *Daily Vaccine Tracking Record*.

The *Daily Smallpox Tracking Record* also requires entry of the following additional information:

- Beginning inventory balance, i.e., the number of vials and doses from the previous day
- Vials/Doses received (i.e., the number of new vials and doses received during the day of the clinic)
- Total doses administered by age and lot number (brought forward electronically or manually from the Smallpox Vaccine Administration Forms)
- Ending Inventory (i.e., vials and doses at the end of the day)

The number of doses wasted will be determined automatically by SDMS (*Beginning Inventory* plus *Doses received* minus *Ending Inventory*). If paper forms are used, the number of doses wasted must be calculated and entered manually.

11. Communication Systems

Each clinic must have a working phone, preferably with internet connectivity so that forms can be accessed and data entered directly into the CDC Smallpox Data Management System. If available, walkie-talkies, cell phones, pagers should be distributed to the clinic staff. Ideally, replacement batteries and/or battery chargers for each device also should be made available. A list of important phone numbers should also be distributed to all clinic staff.

12. Post Clinic Activities

Post-clinic activities are necessary to ensure that the event is documented for the public record, to determine the cost of the operation and to enhance efficiency for future efforts. In this context, evaluation of smallpox clinics should include review of expenditures and in-kind costs incurred in the operation, identification of gaps and problems, recommended changes in emergency response plans, and a description of implications for the public health infrastructure.

RECOMMENDATIONS FOR HANDLING AND STORAGE OF SMALLPOX VACCINE

VACCINE

Vaccinia virus vaccine (Dryvax) is a live-virus vaccine that must be reconstituted with diluent. It is prepared from calf lymph. Manufacturer is Wyeth..

DILUENT

Prefilled syringes with transfer needle. Manufactured by Baxter.

CONDITION ON ARRIVAL

Vaccine should be between 2 to 8 °C (35 to 46 °F). Refrigerate upon arrival.

Diluent should be between 2 to 8 °C (35 to 46 °F). Refrigerate upon arrival.

STORAGE REQUIREMENTS FOR UNRECONSTITUTED VACCINE AND DILUENT

Vaccine:

Long-term storage - vaccine can be preserved indefinitely at –20 °C.

Short-term storage - store in the refrigerator between 2 to 8 °C (35 to 46 °F).

Local Transportation and Day Use - Styrofoam containers and cool packs are adequate.

Diluent: Store in refrigerator between 2 to 8 °C (35 to 46 °F).

DIRECTIONS FOR RECONSTITUTION

Reconstitution of Vaccine with Commercially Packaged Diluent

Diluent is required for the reconstitution of the smallpox vaccine prior to administration.

The previously licensed diluent for use with smallpox vaccine contained 50% glycerin, 0.25% phenol in Sterile Water for Injection USP, and 0.005% brilliant green.

Reconstitution of a single vial of smallpox vaccine with 0.25 mL of diluent would yield approximately 100 doses. However, this pre-packaged diluent is no longer available.

The diluent that will be utilized in this protocol is similar in formulation to the licensed diluent except that it lacks the 0.005% brilliant green. This change in formulation does not affect **the ability of the vaccine to produce immunity to smallpox**

Directions for Reconstitution

1. Remove vaccine vial from refrigerated storage, allow vial to come to room temperature.
2. Lift up tab of aluminum seal on vaccine vial. **DO NOT BREAK OFF OR TEAR DOWN TAB.**
3. Wipe off vial stopper with an alcohol pad and allow to dry.
4. Place vaccine vial upright on a hard, flat surface.

5. Remove cap from the pre-filled syringe. Take a 1.0 cc syringe (e.g., tuberculin syringe) and withdraw 0.25 mL from the opening in the prefilled diluent syringe. Inject the 0.25 mL of the diluent in the 1.0 cc syringe into the vaccine vial to reconstitute the vaccine.
6. Withdraw needle and syringe and discard in the appropriate biohazard sharps container.
7. Allow the vaccine vial to stand undisturbed for 3 to 5 minutes. Then, if necessary, swirl vial gently to effect complete reconstitution.
8. In the space provided on the vaccine vial label, record the date and time that the diluent vial was entered for the purpose of vaccine reconstitution. The vaccine is now ready for use.

STORAGE REQUIREMENTS FOR RECONSTITUTED VACCINE

Store reconstituted Dryvax in the refrigerator between 2 and 8 °C (35 to 46 °F).

SHELF LIFE AFTER RECONSTITUTION

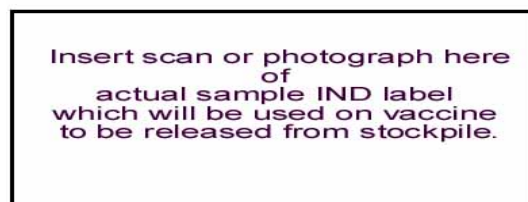
Reconstituted Dryvax may be used for 3 months if stored below 4 °C (39 °F), or preferably below 0 °C (32 °F) when not in use.

VACCINE LABELING AND PACKAGING

1. Labels

The existing inventory of smallpox vaccine was manufactured by Wyeth Laboratories, Inc. The vaccine vials on hand at CDC have commercial labels: "Smallpox Vaccine, Dried, Calf Lymph Type, DRYVAX®". However, they are considered an investigational new drug (IND) product because they are now being used with a diluent other than the one originally approved for use with them. These commercially-labeled vials have lot numbers of seven digits.

The vaccine vials to be deployed in an emergency are stockpiled outside of CDC. They have all been tested for potency, but have not gone through the battery of tests for commercial release. Thus, they will have neither a commercial label with a trade name, nor a National Drug Code (NDC) number (assigned by FDA and manufacturer to uniquely identify all pharmaceutical products and packaging). **They will be labeled before shipment with special IND labels (see figure for example).** >>>Policy Issue<<<



2. Vaccine Packaging and Doses

Although packaging may change in case of large-scale release for deployment, the vaccine

currently is contained as a freeze-dried pellet in a glass vial of size comparable to single-dose vaccine vials in current use, approximately 3.5 cm in height and 1.1 cm in diameter.

The vaccine must be reconstituted before use. The diluent used for reconstitution contains 50% glycerin and 0.25% phenol in Sterile Water for Injection, USP, for a final volume of 0.25 mL. It is packaged in prefilled 0.25-mL syringes.

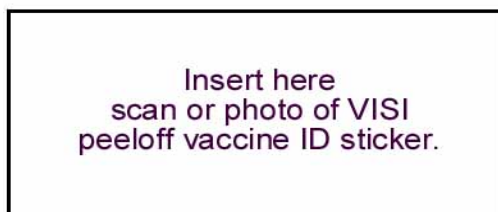
Fifty vials of vaccine are packaged in each carton (secondary packaging). Up to 12 cartons will fill special "VaxiCool" insulated shipping containers (about the size of a large Coleman®-style beer cooler) without further tertiary packaging or overwrap. Diluent need not be refrigerated and may be shipped outside of the VaxiCool containers.

Using current practice for standard reconstitution with 0.25 mL of diluent per vial, it is calculated that vaccination with bifurcated needle will allow approximately 100 vaccinations to be made from each vial, which converts to 5000 vaccinations from each 50-vial carton of vaccine, and up to 60,000 doses capable of being carried in one VaxiCool container.

If clinical studies underway confirm the immunogenicity and safety of further diluting each vaccine pellet to a total liquid volume of 1.25 mL (1:5), then each vial of vaccine could theoretically be used to vaccinate approximately 500 persons, each carton 25,000 persons, and each VaxiCool 300,000.

Identification of Vaccine Lot Received

The identify of the vaccine and its lot number received by the vaccine recipient must be transferred accurately and conveniently onto the IND consent form, the clinic vaccination record and the take-home proof-of-vaccination card. In conformance with the guidelines of the Vaccine Identification Standards Initiative (VISI, www.cdc.gov/nip/visi), CDC plans to supply with the vaccine peel-off stickers, approximately 2-inches wide by 1-inch tall, on rolls or sheets. **The following image illustrates such a sticker:**



Information on the peel-off stickers includes:

- a. The full, official, generic name of the vaccine
- b. The boldfaced standardized abbreviation for the vaccine type: **SMA_{vac}**
- c. The full name of the manufacturer and/or distributor (e.g., Wyeth Laboratories, Inc.), and/or its VISI-conformant abbreviation (WAL).
- d. Other required text per the investigational nature of the product
- e. The lot number of the vaccine (and, possibly, the lot number of the diluent on either the same or a separate sticker)
- f. The expiration date printed on the vaccine vial, identified by the prefix "Exp."

- g. A full-size UCC-EAN-128 one-dimensional barcode, or a Reduced Space Symbology™ (RSS) two dimensional barcode, containing:
- 1) An identifying number for the vaccine (in lieu of a National Drug Code)
 - 2) The expiration date
 - 3) The lot number of the vaccine
 - 4) Check digits and article identifiers for the above
 - 5) An official “Proof of Vaccination” card or badge, documenting vaccination for purposes of restricting entry into any *cordon sanitaire* that may be established around known cases in isolation or under quarantine

Technical Specifications for Sticker Production

1. 40-pound liner “flexo” stock
2. permanent adhesive
3. water-resistant ink, label, and adhesive
4. 2" X 1" die cut label, with 1/8" gap, wrapped around cardboard rolls
5. 300 labels per roll
6. Barcoding with X-dimension of minimum 8 mills