

Smallpox Vaccine Clinic Operations and Management

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In this segment, I will cover a variety of issues related to organizing and implementing vaccination clinic operations. My comments are primarily intended for public health staff who will be responsible for setting up and operating the clinics. I will also address issues concerning individuals who potentially will receive smallpox vaccine in the clinics. These individuals will comprise the public health response teams responsible for investigating smallpox cases and conducting broader vaccination operations. They will also include the hospital-based healthcare response teams that will be responsible for treating and caring for people infected with smallpox in the event that such a terrible event would occur in our country.

Smallpox Vaccine Clinic Operations and Management

- **Learning Objectives**
 - Describe the overall process/logistics for smallpox preparedness vaccination clinics
 - Use the CDC recommendations to equip and organize clinic operations so that vaccination proceeds safely and effectively
 - Establish workstations and job functions within the clinic for medical screening, vaccination, vaccinee education, and emergency response to adverse reaction



Program Issues: General Concepts

- **Vaccination limited to Public Health Smallpox Response Teams and hospital-based Healthcare Smallpox Response Teams**
- **Sites established considering population density, hospital clusters, judicious use of vaccine, vaccine security, and accessibility**



Before discussing the operational issues related to clinic operations, I would like to go over several concepts that are basic to the vaccination program we are preparing for. First, vaccination will be limited to individuals who volunteer for public health smallpox response teams and hospital-based healthcare smallpox response teams. Next, the location and number of clinic sites will depend on several factors, such as population density, hospital location and clustering, judicious use of the vaccine and the availability of suitable clinic facilities. States and in some case, local health departments have the responsibility for coordinating this vaccination program. These agencies will determine the number and location of vaccination clinics based on the factors given above, but in general, clinic operations should be as centralized as possible to maximize the efficiency that comes with higher volume operations. A major issue related to selection of clinic sites is the fact that the vaccine is packaged in 100-dose vials, which have a limited shelf life once the vial has been open and reconstituted with diluent.

Program Issues: General Concepts

- **Vaccinators should be vaccinated before or at the time clinic begins**
- **Emphasis will be on safe, efficient vaccination of personnel on Public Health or Healthcare Response Teams**
- **Control and security of clinic process will be essential**



Vaccinators should be vaccinated before clinic operations begin. CDC will work with the coordinating state and local health departments to develop a system to vaccinate the vaccinators. There will be significant emphasis on safety. Careful medical screening must be done to prevent adverse events caused by the vaccine. Last, we must provide good management of clinic operations to ensure control of the interrelated processes of planning, clinic operations, records management, and communications involving multiple agencies, health care organizations and clients. These processes require a substantial level of planning and management and are far too complex to figure it out as you go along.

Pre-Clinic Issues: Facility and Team Identification

- **States to poll hospitals for willingness to see and treat smallpox cases**
- **Hospitals to self-identify as treatment centers**
- **Identified hospitals to seek volunteers for Healthcare Response Teams**



Another important preclinic consideration is the selection of the hospitals that will participate and the identification of the individual health care workers within those hospitals. The public health departments responsible for coordinating the vaccination program will initiate this process by contacting hospitals to determine their interest and willingness to provide care for smallpox cases should they occur. Hospitals will be given the opportunity to self-identify as treatment centers and offer vaccine to appropriate staff. The types of staff who may be considered for vaccination are described in another section of this broadcast by Dr. Jane Siegel. Participating hospitals will then give staff an opportunity to volunteer to be vaccinated as part of a smallpox response team.

Pre-Clinic Issues: Facility and Team Identification

- **Volunteers to be “pre-screened” with education material that describe risk factors**
- **Arrangements made for “take” evaluation**



In addition, potential volunteers will be prescreened by providing them with educational material that describes the risk factors associated with vaccine adverse events. This will permit persons with contraindications about which they have privacy concerns to withdraw if they wish. Arrangements should be made for evaluating vaccine “takes”, since potentially this can occur at the hospitals participating in the program with appropriate staff training. Alternatively, “take” evaluations can be conducted at the vaccination clinics or at other locations arranged by the coordinating state or local public health agency. In connection with this, it will be critical for arrangements to be made for transmitting the vaccine “take” information for each vaccinee to a designated point for data entry into the information management system. We'll talk more about data management systems in the next broadcast segment.

Clinic Issues: Clinic Characteristics

- **Large, open, well lighted and well ventilated space**
- **At least 2 large doors for access and egress**
- **Easy public access**



Moving on to issues more directly related to the vaccination clinics, in many, if not most cases, local health departments or other existing clinical facilities will probably be used. If existing suitable clinic space is not available in an area where a smallpox vaccination clinic is needed, arrangements must be made to find alternative venues that are suitable. In any case, the clinics should be, first of all, large enough to handle the staff and the expected client volume, with all of the obvious amenities such as restrooms, waiting areas and so on. The space should be well lighted and ventilated. In addition, a separate room or screened area should be available for persons that have become sick while in the clinic either as a result of the vaccination or for unrelated incidental reasons. The facility should have separate doors for entry and exit to maximize a smooth flow of people through the clinic process. The clinic should have good access to transportation and parking.

Clinic Issues: Clinic Characteristics

- **Easy receipt of supplies (including vaccine) without disruption of clinic flow**
- **Geographically central with good regional access**
- **Appropriate MOU/MOA for facility use signed (if necessary)**



Other important characteristics of the ideal clinic include a layout that facilitates delivery and receipt of clinic supplies and vaccine, and does so without disrupting the clinic. A central geographic location that is convenient to potential vaccinees. However, given the constraints related to the site selection factors mentioned earlier, it may not be possible for all vaccinees to have a clinic as close as they would like. Lastly, it may be necessary to establish formal arrangements for using clinic space through signed memoranda of understanding or agreements MOUs or MOAs, or through contracts.

Clinic Issues: Vaccination Scheduling

- **Hospitals submit list of Healthcare Response Team volunteers names to state**
- **Schedule identified response team volunteers for vaccination**
- **Persons not on list will not be vaccinated unless authorization is given by the hospital response team liaison**



Before and during clinic operations, it will be necessary to create a schedule for vaccinees to come in for vaccination. To make this possible, participating hospitals will need to submit a list of all response team volunteers to the state or local health department that will in turn provide these lists to specific vaccination clinics. The response team volunteers will be scheduled for vaccination individually or in small groups. In most cases, scheduling vaccination appointments for all volunteers, both public health and hospital workers, will probably be and should be handled at the clinic level. However, during this process, clinic schedulers should work closely with the hospitals to make sure that the hospitals do not have requirements related to staggering their workers' vaccinations at different times. Persons not on the list submitted by the hospitals should not be vaccinated without special authorization by the designated hospital liaison.

Clinic Issues: Security and Entry

- **Allows for orderly entry to clinic**
- **Allows responses to more general questions about access, hours of operation, parking, etc.**
- **Ensures clinic packet distribution**



At this time, I'd like to explain the clinic process that must be in place before vaccinations can occur. Upon entry to the clinic, appropriate security staff should be present to limit entry to staff and clients. The clinic entrance should have appropriate signs so that clients know they are at the right place. A staff member should be assigned as a greeter to direct clients to the clinic area, if necessary. And answer general questions about things like clinic hours and parking. This is also the best time to distribute a pack of information and documents to each client. This packet will have, at minimum the following contents -- a patient history form with a check-off list of potential contraindications. This form also includes a consent line for the clients' signature and it will become part of the medical record. Next, a Vaccine Information Statement that provides information about the risks and benefits of the vaccine and a vaccination card for the client to take home. Also, an informational sheet about the contraindications and potential adverse events associated with the vaccine. And lastly, instructions on care of the vaccine site, what a normal and abnormal site looks like and who to call if they have questions or concerns. CDC is in the process of finalizing these documents, which will be provided electronically to the coordinating public health agencies as soon as possible.

Clinic Issues: Clinic Briefing

- **General process overview**
- **Appointments verified**
- **Packet information read**
- **Packet forms completed and consent signed**
- **Questions answered**



The next step in the process is the client briefing. This can be conducted with clients individually or in groups. The briefing should include, first, a general overview of the process, a verification of each client's appointment, time for clients to read the information in the packet, completion of the documents by the clients, including signing of the consent form and an opportunity for clients to ask questions and have those questions answered.

Clinic Issues: Medical Screening

- **Vaccination packet materials reviewed**
- **Eligibility determined/verified**
- **All who are determined to be eligible and who consent are referred for vaccination**



The next step in the clinic process is medical screening. Each client's medical history must be reviewed by a medical professional who has been trained on the specific contraindications related to smallpox vaccine. The medical screeners will determine or verify medical eligibility of each client. Persons who are determined to be eligible and who have consented can proceed to the vaccination station.

Clinic Issues: Medical Screening

- **Designated Response Team volunteers may be ineligible due to:**
 - **Immunosuppression or household contact**
 - **Pregnancy or household contact**
 - **Eczema/atopic dermatitis or household contact**
- **If further evaluation needed, Healthcare Response Team member is referred to the screening team manager (an MD) for final decision**



Speaker should say to review contraindications and screening guidance more fully. Very briefly, let's review the contraindications that would make a person ineligible for smallpox vaccination. First, immunosuppression of any kind or having household contact with immunosuppression. Next, pregnancy or having a pregnant household contact; a history of eczema or atopic dermatitis or having household contact with these conditions. If the medical screener is uncertain about the medical eligibility of any client, the client should be reserved to the physician who serves as the screening team manager for that person to make a final decision.

Clinic Issues: Medical Screening

- **For those who are medically ineligible OR who “opt out” at this point – terminate the process**



Persons who are determined to be medically ineligible or who opt out for any reason terminate the clinic process at this time. The topic of medical screening will be covered in a different segment of this broadcast by Dr. Bill Atkinson.

Clinic Issues: Vaccination

- **If Response Team volunteer accepts:**
 - **Administer vaccination**
 - **Observe standard (bloodborne pathogen) precautions**
 - **Clean arm only if excessive contaminants on skin**
 - **Use bifurcated needle to administer the vaccine; discard needle**
 - **Dress site**
 - **Give site care/reaction information**
 - **Schedule “take” evaluation**



Having gone through the briefing process, completion of forms, and medical screening, the response team volunteer, our client, finally arrives at the vaccination station to accept vaccination. What are the issues to be concerned with at this time? First, vaccinators should observe all of the standard precautions to prevent transmission of bloodborne pathogens. Arms do not need to be cleaned before they're vaccinated unless there are excessive contaminants on the skin at the vaccination site. Use a bifurcated needle to administer the vaccine, then discard the needle. Place a dressing on the vaccination site. Briefly give the client site care and basic information about potential reactions. Give a preliminary message about the need to schedule a “take” evaluation.

Clinic Issues: Data Collection

- **Review clinic forms for completeness**
- **Authenticate vaccination card**
- **Review site care/reaction information**
- **Verify Response Team volunteer has vaccination card, medical history form, important telephone numbers, signed consent forms**



After each client is vaccinated, clinic staff will again need to deal with issues related to forms and data collection. Staff should be assigned to review all forms for completeness. The peel-off sticker that come with the vaccine should be placed on the patient's medical record and any other documents that require information about the vaccine, such as the vaccine manufacturer and the lot number. Ensure that the date of vaccination and other critical information is on the client's vaccination card to authenticate it. Again, review site care and reaction information sheet with the client. And verify that the client has his or her vaccination card, vaccine information sheet, other fact sheets and the site care instruction sheet with the important phone numbers. Make sure that the signed consent form, however, is retained at the clinic.

Clinic Issues: Data Collection

- **Appointment for “take” evaluation**
- **Enter clinic data into CDC data system or equivalent**



Two final post-vaccination items. Each client must be given clear instructions as to when and where they should report to have their vaccine “take” evaluated. And second, information from the clinic forms must be entered into CDC data system or an equivalent system established by the state or local health department. Additional information about the CDC data system will be provided in the next presentation by Vicki Kipreos.

Clinic Issues: Exit

- **Ensure steady egress from the clinic**



The response team volunteer has completed the vaccination process and is ready to leave the clinic. Clinic staff should be assigned to a station near the exit to ensure that all is well with each client and to monitor the flow of clients as they leave. If the flow of clients is noticeably uneven, this should be brought to the attention of the clinic manager so that staffing at the various stations can be adjusted appropriately.

Vaccination Issues: “Take” Evaluation

- **If “take” successful:**
 - Update vaccination card
 - Review site care and adverse reactions information with vaccinee
- **If “take” is not successful, vaccinee will be referred for re-vaccination**
- **If second vaccination unsuccessful, medical referral will be necessary**



During another segment of the broadcast, Dr. Joanne Cono will discuss evaluating vaccine “takes” in some detail. However, I would like briefly go over some vaccination “take” issues as they relate to clinic operations. First, if the “take” is successful, this should be noted on the patient's vaccination card. Therefore, clients should be reminded to bring their vaccination card with them when they have their vaccination “take” evaluated. This may or may not occur at the clinic, depending on the system arranged by the state or local health department. As I mentioned earlier, if some or all of the vaccine “takes” will be evaluated at locations other than the clinic where the client is vaccinated, it is important that arrangements be made for transmitting the vaccine “take” information to a designated point for entry into the information system. When the client comes in for “take” evaluation, this is a good time to review site care and adverse reaction information with him or her. If the take is determined to be not successful, the client should be referred for revaccination. And lastly, if a second vaccination is unsuccessful, medical referral will be necessary before another vaccination is attempted.

Vaccination Issues: Adverse Reactions

- **Significant adverse reaction rates per 1,000,000 for smallpox vaccine (unimmunized population)**
 - **Inadvertent inoculation** 25 - 529
 - **Eczema vaccinatum** 10 - 39
 - **Progressive vaccinia** 1 - 2
 - **Post-vaccinial encephalitis** 3 - 12
 - **Death** 1 - 2



Before we go on to discuss additional issues directly related to clinics, I would like to take a few moments to give a little background information about why we are so focused on vaccine safety and medical screening of our patients.

Here are some data about adverse events related to smallpox vaccinations. In unimmunized populations, inadvertent inoculation will occur in 25 to 529 persons per million. Between 10 and 39 persons per million will have eczema vaccinatum. 1 or 2 persons per million will suffer progressive vaccinia. 3 to 12 persons per million will suffer post-vaccinial encephalitis and 1 or 2 people per million will die as a result of complications from the vaccine. This will be covered in detail by Dr. Gina Mootrey in another one of our segments.

Clinic Issues: Clinic Staffing

- Suggested Clinic staffing pattern

<u>Position</u>	<u>Number</u>
—Clinic manager	1
—Appointment scheduler	1
—Clinic briefing staff	1
—Medical screeners	5 - 6
—Supervisory screener (MD)	1
—Vaccinators	2



Getting back to operational issues, implementing the smallpox vaccination program will require substantial commitments in terms of personnel resources. This slide provides some estimates of the number of staff that will be required to staff a vaccination clinic capable of vaccinating approximately 150 persons per day. Bear in mind these staffing patterns are designed for the current circumstances where we are conducting vaccinations in the absence of smallpox disease and are, therefore, taking extra care to prevent vaccine adverse events. In a large-scale mass scale vaccination effort where smallpox has occurred, the per day ratio of staff to vaccinees would increase dramatically. The estimates for clinic staffing are as follows: you will need one clinic manager, one appointment scheduler, one health care educator to brief clients, five or six medical screeners and one supervisory screener. This is the most time-consuming part of the process. You will need two vaccinators.

Clinic Issues: Clinic Staffing

- Suggested Clinic staffing pattern

<u>Position</u>	<u>Number</u>
• Vaccinator assistants	2
• Clinic supplies specialist	1
• Traffic controllers	2
• Data entry personnel	2
• Entry/exit monitors	2
• Security personnel	2



In addition, you will need two vaccinator assistants. One supply specialist will be needed to monitor supply inventories and to order more when necessary. Two roamers to monitor and assist with clinic traffic flow and to do other duties as assigned. Two data entry personnel, two monitors, one at the clinic entrance and another at the exit. And finally, two security personnel, perhaps one outside the clinic and one inside. The total number of staff required for this configuration is 22 or 23 FTEs (full time equivalents). It is possible that this level of staffing could be reduced after the clinic has been operating for several days, but for planning purposes, care should be taken to avoid underbudgeting in this critical area. It should also be pointed out this level of staffing can and should be adjusted to reflect the actual client flow scheduled for each clinic.

Clinic Issues: Security

- **Clinic parking: adequate, close, protected**
- **Well marked clinic entrance(s)**
- **Clinic traffic monitors**
- **Provide telephone numbers for police, fire, utilities, facility owner/manager to security personnel**



Because this is an initiative that has drawn a lot of national and international attention in the context of the war on terrorism, the vaccination clinics may draw more people than we would like. And not all of them may there be for helpful reasons, therefore, a few comments and reminders about security issues may be in order. Clinic parking should be adequate, close and protected. The clinic entrance should be well marked. It is advisable that one of the security staff be stationed outside the front entrance. Internal traffic monitors should be alert for disruptions. And finally, make sure the security staff have the telephone numbers for fire, police, utility companies and the owner or manager of the facility.

Clinic Issues: Worker Safety

- **Security on duty when staff arrive and easily accessible and responsive to clinic staff**
- **Clinic facility secure, well lighted, and functional**



Worker safety is another significant consideration. Security staff should be on duty when the staff arrive and easily accessible and responsive to the staff. Again, clinic facilities should be secure, well lighted and functional.

One special concern relates to handling the vaccine, which contains live virus. Great care must be taken to prevent needle sticks with the bifurcated needles. In this connection, vaccinators should not hold the vaccine vial in their hand while inserting the bifurcated needle into the vial. This probably should also be avoided because this practice will cause the vaccine to become warm. Care should also be taken that the vaccine is not spilled. Because of this concern, along with the vaccine, CDC will include special holders to prevent the vaccine vials from being tipped over accidentally. These holders will also insulate the vaccine to help keep it cool while it is being used.

Clinic Issues: Worker Safety

- **Workers should:**
 - **Receive adequate initial job training**
 - **Be given occasional work breaks to maintain attention to detail**
 - **Be cross-trained to relieve stress of repetitive motion or lack thereof**
 - **Have back-up personnel available in case of absence**



To assure worker safety, workers should be given adequate initial job training. They should be given occasional work breaks so they can maintain attention to detail. They should be cross-trained to relieve the stress of repetitive motion. And backup personnel should always be available.

Clinic Issues: Clinic Supplies

- **Have a 2-day supply of clinic supplies on hand to initiate operations**
- **Keep supplies in a secure place separated from clinic traffic flow**
- **Inventory and track supplies for use and re-supply**
- **Dispose wasted supplies in accordance with regulations**



On November 22, 2002, CDC distributed a supplemental guidance document to all recipients of federal funding through the bioterrorism cooperative agreement. Annex three of this guidance document includes a list of suggested supplies for use in a smallpox vaccination clinic. This slide provides additional suggestions about clinic supplies. First, start with a minimum two day supply of clinic supplies as you begin your operations. Keep the supplies in a secure place, separated from the clinic traffic flow. Conduct a daily, more frequently if necessary, inventory and track supplies for use and resupply and finally, dispose of wasted supplies in accordance with pertinent regulations and accepted policies and procedures.

Clinic Issues: Vaccine Handling

- **Inspect, log in and refrigerate vaccine immediately upon receipt**
- **Keep at 35 - 46° F until ready for use**
- **Storing in coolers with “cold packs” is acceptable**



Earlier Dr. Sue Gorman discussed the logistical considerations related to receiving and storing vaccine. To reiterate some of this information briefly: when the vaccine arrives, it should be inspected, logged in and refrigerated immediately. Vaccine should be stored at 35 to 46 degrees Fahrenheit or 2 to 8 degree Centigrade until it is needed in the clinic. Temporarily storing the vaccine in coolers with ice or cold packs is acceptable, but you should avoid placing the vaccine directly on ice. Put a sheet of plastic or cardboard between the vaccine and the ice.

Clinic Issues: Vaccine Handling

- **Reconstitute vaccine just before use; do not reconstitute more than needed**
- **Receiving/inventorying vaccine done by Clinic Supplies Manager**
- **Reconstitution and delivery to vaccination station done by Assistant Vaccinator**



In addition, you should reconstitute vaccine just before use. Do not reconstitute more vaccine than is needed. Remember that when reconstituted, each vial contains 100 doses. One person - probably the supplies manager - should be designated to receive and do a daily vaccine inventory and ensure the security of the vaccine. The responsibility for reconstituting the vaccine and bringing it to the vaccination station should also be specialized. Probably this would be an appropriate role for one of the assistant vaccinators.

Clinic Issues: Vaccine Handling

- Use standard precautions, which include bloodborne pathogen precautions
- Clean vaccine spills with a tuberculocidal agent
- Dispose of materials used to clean a vaccine spill as medical waste
- Discard used bifurcated needles in a sharps container



In handling the smallpox vaccine use standard precautions, including bloodborne pathogen precautions. Clean all vaccine spills with a tuberculocidal agent. Materials contaminated with smallpox vaccine, for example as the result of a spill, should be considered and disposed of as medical waste. Bifurcated needle should be discarded in a sharps container

Clinic Issues: Vaccine Handling

- **Keep unused, reconstituted vaccine up to 30 days at 35 - 46° F**
- **Make sure vial is dated**
- **Do not use inappropriately stored vaccine; dispose as waste**
- **Ensure security of vaccine**



Some final notes on vaccine handling. If stored appropriately at 35 to 46 degrees Fahrenheit or 2 to 8 degrees Centigrade, vials of reconstituted vaccine can be kept for up to 30 days. This includes vials that have been partially used. Be sure to note the date on each vial when it is opened and reconstituted. Do not use inappropriately stored vaccine – dispose of it as medical waste and document the estimated number of doses that are being discarded. Finally, ensure security of vaccine. This means that the refrigerator must have a lock on it.

In conclusion, I would like to emphasize a few last points. We are preparing to implement the first large scale smallpox vaccination program in the United States since routine smallpox vaccination was discontinued in the 1970s. This program will require substantial commitment in terms of management and personnel resources. It is critical that clinic operations be implemented efficiently so that we can succeed in offering vaccine to all those who are potential response team members. And effectively so we can expeditiously vaccinate all of the volunteers who are eligible, most importantly, safely to keep to an absolute minimum the adverse events that can result from the vaccine. Since this vaccination program could prove to be the beginning of a much wider, possibly ongoing vaccination program, it is important that we develop an operational infrastructure that can be built upon and expanded as necessary. Thank you for your hard work and commitment in preparing for this smallpox vaccination program and thank you for your attention this afternoon.

For More Information

- **CDC Smallpox website**
www.cdc.gov/smallpox
- **National Immunization Program website**
www.cdc.gov/nip

