



CDC Guidance for Post-Event Smallpox Planning October 29, 2002

CONTEXT

Described below are the likely stages of a smallpox outbreak and the critical responses required by state and local public health agencies. This information is intended as a context to aid state and local planners in developing a post-event smallpox plan. The activities listed may occur in the context of with many other activities in collaboration with a wide range of federal, state, and local agencies, organizations, elected officials. In some circumstances smallpox outbreak response activities may be placed under decision making structures outside of normal public health authorities, including the lines of command and control specified by the Federal Response Plan, if it is activated. Planners should review the of the Federal Response Plan, Emergency Support Function 8 (ESF-8) and its state and local equivalents to understand how responsibilities will be divided between public health and emergency management agencies if a significant public health threat occurs.

1. **Isolation, and treatment of cases** – Suspected and confirmed cases will need to be quickly moved to facilities that provide appropriate health care and isolation to prevent additional spread of smallpox.
2. **Diagnosis** – Rapid preliminary diagnosis can be based on clinical characteristics of the illness with sequential laboratory confirmation at regional (Laboratory Response Network (LRN)) laboratories and confirmation of the diagnosis at CDC.
3. **Vaccination of public health and healthcare response personnel and first responders in affected communities** – A large number of public health personnel, e.g., public health and law enforcement personnel and first responders, will be needed to control the outbreak, and healthcare workers will be needed to diagnose, manage, and treat cases are likely to be exposed to smallpox cases as part of their work responsibilities. These individuals must be vaccinated as soon as possible after the first case is confirmed. For additional information on prioritization of health care workers for vaccination, see ACIP Smallpox Vaccination Recommendations, October 21, 2002. (www.bt.cdc.gov/agent/smallpox/vaccination/acip-recs-oct2002.asp)
4. **Surveillance for new cases** – It will be important to quickly and efficiently diagnose new cases to ensure that the ring vaccination program (below) will quickly control the outbreak.
5. **Containment Activities** that would include:
 - a. Contact and contact of contact tracing - Identification of contacts of smallpox cases (contact with cases beginning with the initial symptoms (fever)) and household contacts of these contacts will need to be identified, vaccinated and isolated if they develop illness. Contacts of cases should be vaccinated as soon as possible to maximize the effectiveness of post exposure vaccination and minimize the number of new cases. (With a highly

suspicious clinical case of smallpox this can be done while diagnostic confirmation is being done). It will also be important to track patient movement (where they have been) after onset of symptoms and identify all possible contacts of the case.

- b. Vaccination and monitoring of contacts – Post exposure vaccination may prevent or ameliorate disease and vaccination may protect from additional exposures from other contacts that develop smallpox. Contacts are monitored for illness to ensure that they can be isolated to prevent transmission to others and given appropriate medical care, if they develop smallpox.
 - c. Community vaccination – It may be necessary to vaccinate all persons in exposed communities in addition to contacts and household contacts of contacts.
6. **Epidemiologic investigation** - Any potential linkages between the patients (review travel history for 2-3 weeks prior to symptom onset) must be identified to determine if there is a common source for exposure and to determine if any additional persons may have been exposed to initial source (so they can be traced and evaluated for illness or watched for illness onset – if ill, isolate and vaccinate their contacts (identify contacts similar to above), if not already ill, and to ensure that all who need to be included in the ring vaccination program are included.
 7. **Large Scale vaccination** – A decision may be made by public health officials and/or political leaders to offer vaccine to all persons within the city, county or state. Although smallpox vaccine is not currently licensed, plans should be developed with the assumption that the vaccine will have been licensed by the time a smallpox event occurs or that emergency provisions will be enacted so that smallpox vaccine can be administered without adherence to an investigational new drug protocol.
 8. **Information Management** - Detailed information will be needed on an ongoing, real-time basis to inform policy makers, health officials, clinic managers, and the public about the status of smallpox response activities. Data must be analyzed and shared continuously to enable managers at all levels to identify and resolve problems, evaluate progress toward program objectives and redirect the activities, as necessary.
 9. **Communications** - To address public questions, minimize false rumors and misinformation, and reassure the public that the public health system is responding effectively, it is imperative that public health officials acknowledge the seriousness of a smallpox outbreak and provide accurate, timely information to the public through the media.

Although smallpox vaccine is not currently licensed by the Food and Drug Administration, given the short time frame post-event smallpox preparedness plans should be developed with the over-all assumption that the vaccine will have been licensed at the time a smallpox event occurs or that emergency provisions will be enacted so that smallpox vaccine can be widely administered. However, plans should also acknowledge the possibility that vaccinations may be given under an IND protocol and, therefore should also briefly address an approach for rapid consenting procedures (in groups, if necessary) and monitoring of vaccinee take rates and adverse events. Planners should also assume that vaccine will be delivered only by specialized vaccination clinics (as opposed to by individual private providers) and that liability concerns related to administration of smallpox vaccine will be addressed on a national basis. Additional

information, on vaccination operations under an IND are provided in Annex 3 of the *CDC Smallpox Response Plan and Guidelines* (SRPG) which can be accessed at www.bt.cdc.gov/agent/smallpox/response-plan/index.asp.

PREPAREDNESS CAPACITIES

Described below are some basic concepts related to the critical preparedness capacities required to control a smallpox event. Also listed are examples of plan elements that can be used as a basis for developing your draft plan. Additional information about important preparedness activities are described in *Annex 5* of the SRPG

Organization and Management

Planning and implementing a post-event smallpox vaccination response will require state and local public health agencies to establish an organizational structure for command, control and decision making. Plans should provide a description how this structure will function within your agency. Examples include:

- an organizational chart showing the structure and location of a smallpox response coordinating unit within your agency;
- an emergency response management decision model;
- a list of the positions/individuals assigned responsibility for managing the key operational functions; and
- a list of key contacts within state, local and federal agencies that will be involved in smallpox response efforts;
- a process by which your agency will work with hospitals and hospital organizations to develop a plan for treatment of smallpox cases

Assignment of Staff Roles and Responsibilities

Each grantee should have at least one public health smallpox response team. Case investigation teams should include a medical expert as team leader, medical epidemiologists, disease investigators, diagnostic laboratory scientists, nurses, vaccinators, and other necessary personnel as determined by state and local officials. All members of the response team(s) must be vaccinated before they begin control activities. Projects should be prepared for the possibility that hundreds of public health and public safety workers could potentially be required to control a smallpox outbreak. In addition to case investigation teams, each project should identify individuals who will operate vaccination clinics if a large scale vaccination program becomes necessary. For additional information about clinic staffing requirements, see *Annex 3* of the SRPG.

Plans should cover the following critical staffing issues:

- the number of response teams, their composition by position title and agency affiliation;
- a strategy for completing vaccination of all workers involved in control activities within 1-3 days of the confirmation of the first smallpox case;
- a strategy for ensuring a *rapid* response throughout the state;
- plans to ensure adequate staffing to receive, provide security for and distribute vaccine and other National Pharmaceutical Stockpile items;
- plans to add or reassign staff to handle potential influx of specimens submitted for testing to the state laboratory;

- a description of the sources for clinic personnel (e.g., local health departments, community health centers, Visiting Nurses Association, community volunteers); and
- a generic staffing plan for each clinic, including a listing of individual staff responsibilities.

Enhanced Surveillance, Epidemiology, and Laboratory Testing

Surveillance preparedness will require close collaboration with medical and hospital organizations and individual hospitals to ensure the rapid reporting of additional suspected cases of smallpox. *Guide A* of the SRPG provides detailed information about surveillance for smallpox. Enhanced surveillance plans should include:

- plans to enhance surveillance systems after an initial case is confirmed (within jurisdiction or elsewhere) to ensure rapid identification and reporting of additional cases; and
- plans to conduct epidemiological analysis to estimate the population at risk, identify unexpected epidemiological features of the outbreak, and evaluate the characteristics and extent of the outbreak to develop the most effective containment and communications strategies.
- plans to enhance laboratory testing capabilities to respond to the need to quickly diagnose cases of smallpox and differentiate from other illnesses and adverse reactions to the vaccine.

Identification of Clinic Sites

Each grantee will be responsible for identifying sites for specialized vaccination clinics to prepare for the possibility that a large number of vaccinations may need to be administered in a short period of time (e.g., within 5-10 days). Although vaccination of contacts of cases may be handled in the field by case investigation teams, large numbers of contacts and/or potential contacts may need to be referred to fixed clinic sites or vaccinated on an ad hoc basis at other convenient locations. Plans should be scalable to accommodate vaccination of a population ranging from a few hundred persons to the entire population, depending on the nature, location and size of the outbreak. *Annex 2* and *Annex 3* of the SRPG provide additional information concerning selection of clinic sites. State and local agencies should coordinate this process carefully to ensure appropriate clinic coverage throughout your jurisdiction and where jurisdictions meet and/or overlap. Plans should include:

- the criteria used for selecting fixed clinic sites
- a list of potential and confirmed clinic sites; and
- a description of arrangements with neighboring jurisdictions to vaccinate and follow-up persons who would not have reasonable access to a clinic within jurisdiction.

Training and Education

Many state and local health departments, hospitals, health care professional organizations, communication professionals, public safety workers and others will require general education and training on smallpox and smallpox vaccine issues. Specific personnel such as clinic screeners, vaccinators, adverse event responders, communications staff, hotline staff, laboratory workers, data enterers, and vaccine take readers will need highly detailed information. While many materials and some

centralized training will be provided by CDC on a preparedness basis, state and local health department personnel will need to distribute informational and educational materials and undertake the actual education and training efforts. To this end CDC's training efforts focus on training-the-trainer. CDC will continue to develop satellite courses, audio conferences, CD-ROMs, slide sets, vaccination training materials, handouts, etc. You should consider including a plan for conducting critical training functions over the next 12 months. Examples of elements in a training plan include:

- selection and designation of a core of capable public health personnel who will be trained by CDC to train others;
- curriculum and timeline for training sessions on specific parts of the implementation plan, venues for training, and specific personnel to be trained;
- procedures for quickly reproducing and distributing CDC materials;
- the names and positions of the key training and communications partners (infectious disease or training specialist) who are designated to receive educational materials and coordinate training activities about disease, vaccine, adverse events, contraindications, screening process, vaccination and post vaccination take reading; and
- a plan for providing clinic personnel with national and state-specific educational materials and training on adverse events and procedures for responding when patients present with potential adverse events;

Data Management

Consistent data derived from health departments and clinics must be analyzed continuously to enable managers at all levels to identify and resolve problems, evaluate progress toward program objectives and redirect the activities, as necessary. Shortly, CDC will provide grantees with specifications for smallpox systems and data exchange. This information will include the functional needs for operating information systems at the grantee level, specific data formats and terms that need to be exchanged in real-time with CDC, and process rules for the management of data on vaccination events, adverse event tracking, cases and case contacts, laboratory results and the necessary data exchanges for successful system integration. Since the complexity of the functional information technology needs in these areas is significant, CDC is developing software to provide to grantees who do not have the capabilities to address all of these functional needs. To meet immediate planning needs, grantee plans should cover the following details:

- the name and position of the individual designated to oversee, coordinate and collaborate with state, local, and CDC data management and information experts to facilitate full knowledge, understanding, acceptance and support of the system, its implementation and maintenance, and its evaluation;
- a description of how patient information will be entered into CDC's record keeping and data system;
- plans for ensuring adequate electronic connectivity at each clinic site and other data access areas;
- a description of technical assistance potentially needed from CDC to support the information technology needs of State and clinic sites; and
- plans to acquire computers, printers and other related supplies for all vaccination clinic sites and other access points;

- plans for compliance with the Information Technology Functions and Specifications of the Public Health Information Network (www.cdc.gov/cic/functions-specs)

RESPONSE CAPACITIES

Described below are some basic concepts related to the critical response capacities required to control a smallpox event. Also listed are examples of plan elements that may be and, as indicated in some cases, must be addressed in your plan. Planners should refer to *Guides A-F* in the SRPG for detailed information about the roles of CDC and state and local agencies in responding to a smallpox outbreak.

Case Investigations

Since smallpox is a contagious disease, the highest priorities for public health officials are to reduce risk of transmission by immediately identifying and vaccinating close contacts of cases and isolating the cases. One confirmed case of smallpox requires urgent detailed case investigation. Additional information about case investigations is provided in *Guide A* of the SRPG. Please include in your plan the following critical plan elements for identifying clinic sites:

- a smallpox diagnosis classification and case definition;
- procedures for identifying tracing, vaccinating and monitoring contacts;
- plans to impose isolation of confirmed, probable and suspected cases;
- plans to monitor the outcome of confirmed cases; and
- a strategy for maintaining case investigations and vaccination/monitoring of contacts at all costs despite demands for large scale vaccination efforts or other urgencies.

Vaccination Strategy

Plans should reflect the vaccination strategy described in *Guide A* and *Guide B* of the SRPG and the process that will be followed to expand vaccination of contacts to expanding rings involving the community, urban areas and ultimately wide area (“mass”) vaccination, if necessary. Please include the following elements in your plan:

- a strategy for vaccinating health care providers and public safety workers who may be required to play a role in response efforts and who have not yet been vaccinated;
- the process and procedures for vaccinating and monitoring contacts and potential contacts;
- a strategy for isolating contacts who refuse vaccination;
- plans for implementing quarantine requirements, if necessary;
- documentation of state legal authority for invoking quarantine; and
- a description of the decision and approval process in concert with CDC and DHHS for expanding the scope of the vaccination program from surveillance and containment (ring strategy) to wide area vaccination.

Vaccine Logistics and Security

Each grantee needs to designate a person with overall responsibility and a clinic based person to be responsible for ensuring the safety of vaccine and its appropriate handling upon receipt from CDC, transporting to and from vaccination sites, ensuring appropriate

handling and storage of vaccine at the clinics, and implementing vaccine accountability and usage reporting in accordance with CDC's specifications for smallpox information systems and data exchange (to follow under separate cover). Additional information about vaccine logistics and security is provided in Annex 2 and Annex 3 of the SRPG. All plans should include the following:

- the name and position of an individual who will be responsible for collaborating with the CDC National Pharmaceutical Stockpile and clinics concerning receipt, distribution, security, refrigeration, transport, accountability of the combined vaccine, diluent and bifurcated needle 'kits', and the disposal of waste materials;
- plans for documenting and reporting vaccine usage in accordance with CDC specifications for smallpox information systems and data exchange;
- plans to ensure security of the vaccine during transport and clinic operations;
- a description of the facilities and refrigeration equipment to store and continuously monitor the temperature of vaccine;
- a description of how and where vaccine will be held between vaccination sessions;
- a detailed description of how accountability for vaccine will be accomplished daily at state and clinic levels; and
- a strategy for minimizing wastage of vaccine by maximizing the number of doses administered per 100-dose vial.

Clinic Operations and Management

Project planners should establish an integrated clinic strategy and flow to maximize the efficiency of the clinic. Annex 2 of the SRPG provides general guidelines for smallpox clinic operations, and Annex 3 provides detailed information about clinic operations for large-scale clinics.) Clinic staff will be responsible for participating in scheduling of patients, establishing patient flow, record keeping, educating and screening potential vaccinees, ensuring adequate educational materials, forms, and other supplies, stocking of medical supplies, worker safety, obtaining informed consent, vaccine handling, vaccination, acute medical reaction management, collection/entry of data about vaccination events into an information system compliant with CDC's specifications for smallpox information systems and data exchange (to follow under separate cover), post vaccination wound management, waste disposal, advice on adverse events and reporting, completing the vaccinee's vaccination card, and evaluating for vaccine take. Plans should provide a description how smallpox clinics will be managed and operated.

Examples include:

- brief job description for each clinic function, including supervisors;
- a clinic flow/operations schematic;
- a strategy for maintaining medical and vaccination supplies and other equipment, educational and screening materials, forms, and cold storage;
- a plan for providing and maintaining adequate phone lines, telephones, computers, furnishings (tables, chairs, etc), waste disposal, medical related supplies, forms and informational materials at each clinic site; and
- a plan for providing adequate crowd control measures and security for staff and vaccine at each clinic site.

Vaccine Safety Monitoring, Reporting, and Patient Referral

Up to an estimated 30% of vaccinees will feel uncomfortable enough following vaccination to curtail their normal activities and seek additional information about their reaction to the vaccination; between 14 and 52 per million vaccinees may have life threatening side effects; and an estimated 1 to 2 per million vaccinees will die from vaccine-associated side-effects. Some vaccinees with life threatening side-effects may need short term hospitalization with a very small proportion needing to receive VIG or perhaps Cidofovir (both IND drugs). Protocols for use of VIG and Cidofovir and for evaluation and treatment of neurologic and dermatologic adverse events are under development by CDC and will be made available when complete. Grantees should integrate plans for participating in a national and/or hotline(s), educating providers in clinically diagnosing and treating reactions, identifying subspecialists in dermatology, neurology, allergy/immunology, infectious diseases, and ophthalmology to act as referral physicians for severe adverse event evaluations, hospitalizations, treatment and longer term follow-up, and collecting, receiving and analyzing state specific data on adverse events.

Planners should carefully review *Annex 4* of the SRPG for detailed information about vaccine safety monitoring activities during a smallpox outbreak. CDC's specifications for smallpox information systems and data exchange (to follow under separate cover) will provide additional guidance. Based on these guidelines, plans should describe how adverse event reports will be managed. The following are critical plan elements for ensuring vaccine safety monitoring and reporting and patient referral:

- the name and position of the individual designated to oversee and coordinate Vaccine Safety monitoring, data collection, data analysis and appropriate distribution;
- development of a jurisdiction-wide hotline staffed with qualified medical personnel to medical questions from the public if this service is not provided at the national level;
- arrangements are made for hotline coverage on a 24/7 basis;
- a process for referring eligible potential vaccinees to medical providers for additional consultation and laboratory testing, if needed;
- a plan to alert providers about smallpox vaccination, vaccine takes and adverse event following vaccination, hotline number, referral physicians and the Vaccine Adverse Event Reporting System;
- a list of the potential subspecialists that will be available to evaluate, treat and consult on smallpox vaccine adverse events;
- a training plan to ensure that all staff involved in vaccine safety monitoring are fully aware of their responsibilities and how the other participants fit into the strategy; and
- a timeline for completing follow-up of persons with adverse events that is consistent with the CDC's IND protocol, if applicable.

Communications

In the event of a smallpox outbreak, the public must be assured that federal, state, and local health officials are effectively responding to the smallpox emergency. Programs should have plans in place to inform the public, health professionals, policy makers, partner organizations and the media about smallpox disease, the status of the outbreak,

who should receive vaccine, where to go for vaccinations, risks of vaccination, and control strategies. *Guide E* of the SRPG provides information about CDC's communication plans and activities.

Many resources are available to assist grantees in developing smallpox communication plans. For communication professionals, the following materials are available from CDC:

- Emergency Risk Communication CDCynergy (cd-rom with risk communication templates, tools and planning guides.) (Available as cd-rom in January. Currently usable at www.orau.gov/cdcynergy/erc)
- Smallpox "Key Facts" Fact Sheet (to be used to support message development) (Will be provided through NPHIC, ASTHO, NACCHO and other direct networks.)
- Media resources, telebriefing transcripts at www.cdc.gov/communication

For the public, the CDC Public Response Hotline (888-246-2675 (English), 888-246-2857 (Español), or 866-874-2646 TTY)) is available. States may contact the CDC hotline and request state response assistance from the Project Officer (Judy Gantt) at 404-639-0831, or 404-639-7290. A wide variety of downloadable and printable documents and images are available to the public at www.cdc.gov/smallpox.

The following documents and images are available for health care professionals at www.cdc.gov/smallpox:

- Smallpox Response Plan & Guidelines
- Vaccination Clinic Guide
- Chart: Smallpox Vaccine Adverse Event Rates (from 1968 national and 10 state surveys)
- Adverse Reactions Fact Sheet
- Medical Management Fact Sheet (key facts about the two medications that may help persons who have certain adverse events: VIG and cidofovir).
- Contraindications Fact Sheet (Overview of conditions that put persons at higher risk of experiencing adverse reactions)
- Smallpox Vaccination and Adverse Events Training Module
- Smallpox: What Every Clinician Should Know Online Training
- Summary of October 2002 ACIP Smallpox Vaccination Recommendations
- Draft Supplemental Recommendations of the ACIP on the Use of Smallpox (Vaccinia) Vaccine (June 20, 2002)
- Telebriefing transcript: Public Health Recommendations for Smallpox Vaccine Use (June 20, 2002)
- Developing New Smallpox Vaccines (Emerging Infectious Diseases 2001 Nov-Dec)
- Vaccinia (Smallpox) Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)
- MMWR Recommendations and Reports (2001 Jun)
- Bioterrorism Readiness Plan: A Template for Healthcare Facilities
- Consensus Statement: Smallpox as a Biological Weapon: Medical and Public Health Management

- Smallpox: Clinical and Epidemiologic Features (Emerging Infectious Diseases 1999 Jul- Aug)
- Current Status of Smallpox Vaccine (Emerging Infectious Diseases 1999 Jul- Aug)
- Vaccine Administration and Complications (JAMA 1999)
- Reactions to smallpox vaccinations
- Vaccine and Adverse Events Training Module
- Video “Smallpox: What Every Clinician Should Know” (December, 2001)
- Video Webcast “Smallpox Vaccine and Vaccination Strategies” (March 25, 2002)
- Smallpox and Vaccinia (Vaccines. 3rd ed. W.B. Saunders Company. 1999)

In the event of a smallpox event, individual states would use systems developed under Focus Area F of state terrorism preparedness grants to communicate with the public through the media and community-based outlets. Therefore, smallpox preparedness plans should include:

- designation of staff so serve as spokespersons, conduct notifications, coordinate communication across state and local agencies and all hospitals and other partner groups participating in the state’s smallpox response plan.
- a pool of clinically trained personnel that will be dedicated to responding to a large volumes of calls from state and local health care professionals involved in the response; (as indicated above, public calls may be directed to the CDC Public Response Hotline.)
- arrangements for translation/interpretation services for special populations requiring information in languages other than English.