Annex 5

Suggested Pre-Event Planning Activities for State and Local Public Health Authorities

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Development of state and local smallpox bioterrorism preparedness plans

This annex describes specific recommended pre-event (pre-outbreak) activities for state and local health authorities. Although essential public health activities are outlined in the *CDC Smallpox Response Plan and Guidelines* (CDC Response Plan), state and local health authorities need to develop their own strategies and outbreak control plans, and the planning and many key activities need to begin immediately. Although CDC will advise and assist state and local health departments in the event of a smallpox outbreak, state and local health departments will have primary responsibility for outbreak control.

The state or local pre-event plan should describe the necessary activities and resources for an effective response by local health staff as well as ensure effective immediate on site coordination with federal (CDC) roles as outlined in the CDC Response Plan. Ideally, the state or local plan should be part of, or reference, the state or local jurisdiction's all-hazard Emergency Operations Plan.

These plans should address:

1. Establishment of an Executive Planning Committee, including identification and involvement of key partners, stakeholders, and local elected officials,
2. Command, control, and management procedures,
3. Mobilization of necessary staff, resources, and their availability,
4. Surveillance and epidemiologic investigation procedures, including contact identification and tracing, vaccination of contacts, mobilizing laboratory resources, and alerting and training of health care providers about the identification and reporting of suspected cases of smallpox,
5. Vaccine management, including storage, distribution, protection procedures, and vaccination of essential personnel,
6. Adverse events monitoring,
7. Legal powers for quarantine and selection of isolation sites and plans for how they will be used,
8. Decontamination of smallpox-contaminated equipment, waste, rooms, and vehicles,
9. Plans for communications with health care providers, the public and the media,
10. Training identified health care staff and other first responders (e.g., police and firemen) for outbreak control, and
11. Establishment of security procedures in conjunction with local police and other law enforcement agencies, including operational procedures for essential functions including the maintenance of essential systems such as water, electricity, and waste disposal.

These activities are described briefly later in this document. More detailed descriptions of many of these activities are included in the guides and annexes of the *CDC Smallpox Response Plan and Guidelines*.

Federal Role
State and local plans must be compatible with the federal plan, so that if an outbreak occurs, there can be immediate, on site coordination between CDC and the state and local health department. Some of the federal roles at present include:

1. Delivery or standby readiness for delivery of smallpox vaccine and vaccination components to designated areas,
2. Laboratory or confirmation of smallpox infection,
3. Immediate mobilization and deployment of CDC personnel to assist local or state public health officials with epidemiological investigations, surveillance, contact identification, vaccination, record keeping for vaccine administration and adverse events, and monitoring vaccine inventory,
4. Development of vaccination strategies,
5. Distribution of guidelines and forms for surveillance, contact identification and tracing, vaccination, isolation strategies, specimen collection and transport, public/media communications, and decontamination,
6. Development and distribution of training and educational materials for the public and health care providers, and
7. Provision of technical assistance to the national authority responsible for coordinating the overall efforts for managing the event.

In addition, other federal roles may be added, such as

$ Vaccine research and development,
$ Coordinating national and international surveillance,
$ Assessing the need for and scope of a suitable liability program for vaccine manufacturers and persons administering the vaccine,
$ Managing an adverse events surveillance system at the national level,
$ Developing a central (national) secure information database/exchange/clearinghouse, and
$ Guidelines for distribution and use of antiviral agents.

Funding resources for state and local plan development.
At the present time, limited resources are available for state and local plan development and additional resources are expected from the national level for plan implementation. Possible funding mechanisms include:

$ Federal contracts and/or grants for the purchase of vaccine,
$ Federal grants and/or reimbursement for vaccine distribution and administration,
$ Federal purchase of antiviral agents, if deemed useful,
$ Federal grants for enhanced surveillance,
$ The authority for the release of federal funds would come under the auspicies of the Federal Response Plan (Stafford Act; Public Law 93-288, as amended), as is done for other natural disasters. (NOTE: Criteria to be used for the release of funds have not yet been determined.), and

$ Regardless of the options chosen, State and local jurisdictions should, for planning purposes, expect to provide supplementary resources at the time of a smallpox outbreak, including temporary redirection and training of personnel and financial resources from other programs.

Post-Event Response Plan Content

The format for the post-event response plan should follow that outlined in the document *CDC Guidance for Post-Event Smallpox Planning*).

Additional ideas for response activities can be found in *The Public Health Response to Biological and Chemical Terrorism Guide for State Public Health Officials* and *Pandemic Influenza: A Planning Guide for State and Local Officials*

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 overall 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.

The following areas should be given immediate consideration in state and local smallpox preparedness plans:

1. Isolation and treatment of cases

LEGAL AUTHORITIES

Determine if sufficient local and/or state public health legal authority exists for mandating isolation/quarantine. Legal authorities should include:

Collection of records and data, including
- Reporting of diseases, unusual clusters, and suspicious events
- Access to hospital and provider records
- Data sharing with law enforcement agencies
- Veterinary reporting
- Reporting of workplace absenteeism
- Reporting from pharmacies

Control of Property
- Right of access to suspicious premises
- Emergency closure of facilities
- Temporary use of hospitals and ability to transfer patients
- Temporary use of hotel rooms and drive-through facilities
- Procurement or confiscation of medicines and vaccines
- Seizure of cell phones and other “walkie-talkie” type equipment
- Decontamination of buildings
- Seizure and destruction of contaminated articles

Management of Persons
- Identification of exposed persons
- Mandatory medical examinations
- Mandatory vaccination of high-risk contacts
- Collect lab specimens and perform tests
- Rationing of medicines
- Tracking and follow-up of persons
- Isolation and quarantine
- Logistical authority for patient management
- Enforcement authority through police or National Guard
- Suspension of licensing authority for medical personnel from outside jurisdictions
- Authorization of other doctors to perform functions of medical examiner

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. Limiting spread of smallpox virus from patients to others is a critical part of the control strategy. Local or state legal statutes regarding public health authority to isolate or quarantine infectious or potentially infectious and incubating persons need to be reviewed and plans for coordinating with federal authorities should be made. In addition to isolation and quarantine plans, other transmission control strategies plans should be developed, such as for suspension of large public gatherings or closing of facilities. Isolation and Quarantine Guidelines are presented in *Guide C*.

Suggested pre-event activities for state and local health departments are as follows:

- Identify persons or organizations empowered to invoke and enforce isolation and quarantine authorities,
- Develop plans for emergent vaccination of personnel needed to implement and enforce quarantine measures during a bioterrorism event (e.g., first responders, health care workers, law enforcement personnel, and essential service providers),
- Identify appropriate facilities for isolation as described in *Guide C* and establish procedures for activating them,
- Establish procedures for monitoring access to facilities,
- Establish laundry service arrangements (onsite, if possible) and appropriate disposal of medical waste (see *Guide F*),
- Arrange for food service support for facility occupants,
- Establish procedures for monitoring health status of facility staff, and
- Develop campaigns which focus on educating the public and health care providers about smallpox and the potential need for using population-quarantine measures as a means to interrupt disease transmission.

2. Diagnosis

Laboratory confirmation is important for a first case in a geographic area. Laboratory diagnostic testing for Variola virus is conducted in Level C or D laboratories only. Level D laboratories include the CDC and USAMRIID. Initial confirmation of a smallpox outbreak requires testing in a Level D laboratory. Level C laboratories will assist with testing of clinical specimens following initial confirmation of an outbreak by CDC.

Suggested pre-event activities for state and local health departments are as follows:

- Train and maintain staff to assist in the initial evaluation of suspected smallpox patients,
- Establish procedures for packaging and shipping specimens to the Level D laboratory,
- Establish procedures for packaging and shipping specimens to the nearest Level C laboratory after the initial case has been confirmed in a geographic region, and
- Establish policy outlining the priority for laboratory testing, should the number of cases overwhelm laboratory testing capacity.

More information on diagnosis and laboratory testing can be found in *Guide A*, *Guide D*, and *Annex 1*.

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. Healthcare workers that will be needed to diagnose, manage, and treat cases are likely to be exposed to smallpox 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.

Guidelines for conducting smallpox vaccination operations are in Guide B, Annex 2 and Annex 3. To prepare for the possibility of rapid vaccination if a smallpox outbreak occurs, a number of pre-event activities should be started at the state and local levels.

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. Pre-event planning should include the development of enhanced surveillance and epidemiologic protocols to respond to a smallpox emergency. These protocols should include the following:

- A listing of surveillance partners (hospitals, clinics, private practices, medical examiners, laboratories, county/local health departments, and pharmacists),
- Alerting and training health care providers about the identification and reporting of suspected cases of smallpox
  - Establishing multiple (redundant) mechanisms for reporting confirmed, probable, and suspected cases to public health surveillance personnel (potential redundant mechanisms include: secured fax, secured Web-based reporting, telephone reporting, and e-mail).
  - Establishing a centralized place for initial reporting and informing potential reporting sources of the location and methods of reporting,
- Establishing points of contact with potential reporting sources and redundant means for communicating information back to these sources in an emergency,
- Reviewing and preparing for the use of the CDC surveillance report forms in a smallpox emergency,
- Developing and establishing the laboratory capability for handling specimens, for confirmation of cases, and for secure shipment of specimens to CDC,
- Establishing methods for retrieving laboratory diagnosis for probable and suspected cases, and
- Establishing sentinel surveillance in health care settings; this will involve coordination with infection control professionals from the Association of Professionals in Infection Control (APIC), infectious disease epidemiologists and clinicians, emergency department physicians, National Nosocomial Infections Surveillance (NNIS) and National Surveillance System for Healthcare Workers (NASH) hospitals

5. Containment Activities

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.

Vaccination and Monitoring of Contacts – Post exposure vaccination may prevent or ameliorate disease. 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.

Community Vaccination – It may be necessary to vaccinate all persons in exposed communities in addition to contacts and household contacts of contacts.

- Algorithms for investigation procedures (including methods and data sources for rapid case ascertainment under emergency conditions),
- Review CDC procedures and forms for case investigation, and conduct practice sessions of various smallpox exposure scenarios (see Training),
- Review CDC forms for collection of travel and contact information from confirmed, probable, and suspected cases,
- Review CDC procedures for collection of specimens from suspected smallpox patients (Guide D),
- Develop procedures to maintain surveillance of potentially exposed persons, and
- Identify and establish mechanisms to generate electronic maps for all reported cases to show patient addresses, the geographic presentation of outbreaks and/or patients, and the types of properties surrounding the reported cases that might affect outbreak containment procedures.

6. Epidemiologic investigation

Rapid and thorough epidemiologic investigation will be vital to the description and control of the outbreak. All patients must be investigated for linkages that might indicate a common exposure. This information will also be important for determining if there are others who may have been exposed. A two to three week travel history prior to symptom onset can help to pinpoint these issues. Also, additional contacts can be discovered so that they can be vaccinated, monitored and isolated, as necessary.

To assist in these efforts, legal authorities should exist to ensure include the collection of records and data, including:

- Reporting of diseases, unusual clusters, and suspicious events
- Access to hospital and provider records
- Data sharing with law enforcement agencies
- Veterinary reporting
- Reporting of workplace absenteeism
- Reporting from pharmacies

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.

- Guidelines for conducting smallpox vaccination operations are in Guide B, Annex 2, and Annex 3. To prepare for the possibility of rapid vaccination if a smallpox outbreak occurs, a number of pre-event activities should be started at the state and local levels,
- Review scenarios 1 to 6 in the Training section and plan appropriate local responses. The vaccination response will be based on:
  - Size of the initial outbreak,
  - Amount of vaccine available,
  - Probability that new cases will be identified in subsequent days,
  - Size and distribution of the population to be vaccinated,
  - Amount of time available to prevent infection after exposure,
  - Number of clinic sites,
  - Number of vaccine administrators available,
  - Average capacity of each vaccine administrator in doses per hour,
  - Number of sessions per site, and
  - Number of hours of each clinic session,
- Identify sites for vaccination clinics for case contacts and large numbers of the public,
- Identify separate nonhospital sites to vaccinate response teams, all health care workers, and other essential community workers (See Annex 2 for a suggested list),
- Identify potential central, regional and local vaccine storage facilities, and necessary security,
- Establish or update vaccine management, storage, handling, and secure distribution procedures to include smallpox vaccine (See Guide B and Annex 2),
- Identify supplies and equipment that would be needed for conducting smallpox vaccination clinics (including supplies for patient registration and education, vaccine administration, and response to adverse events),
- Develop an outline of the organizational structure, clinic position responsibilities, operational flow and set-up diagram for large clinics (See Guide B and Annex 2). This outline should also address security maintenance, parking and traffic control, communications, and client comfort,
- Review CDC recommended smallpox vaccination procedures and train immunization personnel with smallpox vaccination techniques,
- Develop a description of the precautionary measures and guidelines staff must observe when conducting smallpox vaccination clinics, including vaccine handling, prevention of exposure to blood-borne pathogens, use of protective barriers (gloves and masks), use of sharps containers, and possible resterilization of bifurcated needles,
- Review CDC-suggested sample documents and develop or obtain all documents and forms that will be used in large clinics, including medical standing orders, Vaccine Information Statement (with informed consent if needed because of state regulation or law, or because of Investigational New Drug [IND] regulations), fact sheets, immunization records, adverse reactions, and vaccination follow-up,
- Become familiar with the protocols for receiving vaccine from the Strategic National Stockpile,

- Review state laws and regulations regarding the qualifications and licensing requirements for personnel to administer smallpox vaccine if unclear, obtain a legal opinion,
- Determine if sufficient local and state public health legal authority exists for mandating smallpox vaccination,
- Establish medical screening procedures for receipt of smallpox vaccine; develop a smallpox vaccination screening tool to detect persons with contraindications to vaccination (see Guide B),
- Review guidelines for exposed persons who refuse vaccine,
- Once CDC has issued guidelines for pre-event vaccination, vaccinate appropriate personnel, and
- Develop methods to document vaccination and vaccine take; create a database or modify an existing immunization registry for this purpose

The overall risk of serious complications following vaccination with vaccinia vaccine is low. Complications occur more frequently in persons receiving their first dose and among young children (≤5 years of age). Details on complications and treatment of complications due to vaccinia vaccine are given in Guide B and Annex1.

- Review suggested procedures for reporting and follow-up of adverse events following vaccination and plan for possible implementation (see Annex 4),
- State and local health departments should prepare an inventory of the documents and forms that will be required to recognize, treat, and report adverse events.
- Documents that each vaccine provider will need include:
    - Vaccine Adverse Events Reporting System (VAERS) report form, instructions on how to access the form electronically, and instructions on submitting it at www.vaers.org,
    - Vaccine Information Statements (VIS),
    - Clinical descriptions of known vaccinia vaccine complications, and
    - Vaccinia immune globulin (VIG) information,
- Each state health department should have in place:
    - A designated state health contact (SHC) trained and available for overseeing vaccine safety activities. The SHC will be responsible for the review of reports for completeness and if not complete, obtaining necessary critical information and ensuring the reporting of adverse event cases to VAERS,
    - Designated staff trained and available for active surveillance tracking, follow up of serious reports submitted to VAERS and for providing assistance in completing VAERS forms, and
    - Outline procedures so that at the time of vaccination, vaccine recipients or their parent/guardians will be give a VIS with instructions on how to contact VAERS and the respective State Health Department and a vaccine adverse events diary card and instructions,
- Develop plans for treating and managing patients with severe adverse events, including use of vaccinia immune globulin (VIG), and possibly antiviral agents (e.g., Cidofovir), and
- Outline procedures for managing persons with severe adverse events.

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. Options to explore include data systems distributed by CDC, or other in-house systems. All systems should comply with PHIN guidelines to facilitate the secure sharing of data across jurisdictions, as appropriate.

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.

A smallpox outbreak is a communication crisis, as well as a public health crisis. How communication is handled can affect the response from the media, the response from the public, and the public's confidence in the government. It will also influence the way the public health system handles the crisis.

Full details of communication plans and activities are given in Guide E. However, some activities should take place:

- Identification of public health officers,
- Dissemination of accurate information, rumor control, 1-800 number,
- Establishment of a command center,
- Access to elected officials,
- Access to experts in human relations and post-traumatic stress syndrome, and
- Diversity in training, cultural differences, and dissemination of information in multiple languages.

State and local health departments should:

- Become sufficiently informed about smallpox to be able to answer questions from media and the public, including general information on smallpox infection, how smallpox is spread, the incidence of smallpox, and recommendations for vaccination,
- Develop and produce or obtain informational material such as:
  - Fact sheets,
  - Frequently asked questions (FAQs) and Question and Answers (Q&A) sheets for the public and media, and
  - Technical bulletins for health care providers,
- Make arrangements to be able to establish a special around the clock hotline on short notice,
- Develop an outline of how and through what media the public will be provided information about the availability of smallpox vaccine, clinic locations, and who should be vaccinated,
- Review and, if needed, upgrade rapid-alert communication systems to ensure rapid communication capability between local and state public health and medical communities,
- Delineate the relative roles of state and local public relations offices,

- Prepare sample alert messages for key public health partners. Consider multiple mechanisms for communicating these messages to partners. Offer regular teleconferences to partner organizations,
- Prepare sample community alert messages. Format these messages for broadcast and print media; develop plans for conducting regular press conferences, and
- Assure that spokespersons are technically knowledgeable and trained for media communications.

Other Considerations

1. The establishment of an Executive Coordinating Committee

An Executive Coordinating Committee, with a named leader, should be established that is responsible for the overall planning and implementation of pre-event activities; this committee would:

$ Select lead persons that will develop each individual plan component and be responsible for overseeing implementation of pre-event activities and coordination with CDC,
$ Be responsible for ensuring the completion of the pre-event plan and sharing the plan with key partners and stakeholders, other states, and the CDC,
$ Pilot the pre-event plan using table top exercises and adapt and revise the plan as appropriate,
$ Review quarantine laws and authorities, and
$ Designate personnel that will participate in a proposed CDC train-the-trainer course.

2. Command control and management procedures

Pre-event planning should include establishing roles and responsibilities for managing an emergency situation. Suggested activities to include in command control and management plans follow.

- The state health officer should designate a person to be in charge of developing and implementing smallpox control efforts,
- Individuals should be identified and made responsible for all of the activities listed in the plan,
- An outline should be written that describes all necessary administrative tasks needed in response to an occurrence of a smallpox case. This outline should address:
    - The line of command,
    - The person(s) that would make decisions on scope of the response,
    - The personnel that would comprise an initial response team,
    - Plans for communicating with health care providers, the public, and media, and
    - Coordination with law enforcement agencies, state emergency management, hazard, and response authorities,
- A primary public health authority contact should be named in each local public health and state health department, with at least one backup contact,
- Primary contacts should be named and communication procedures established for:
    - Law enforcement agencies (e.g., local police and FBI),
    - Medical facilities (hospitals, clinics, private physician offices, and laboratories),
    - Local emergency response coordinators (including city and county offices),
    - Local media, and

- The CDC.

3. Emergency Personnel and Resource Mobilization and Needs

In order to ensure a rapid response to a smallpox emergency, certain pre-event activities need to be started now. These activities include the following:

- Identify state and local leads for coordinating surveillance and epidemiologic investigation activities in a smallpox emergency,
- Identify state and local personnel that will conduct smallpox surveillance and manage relevant databases,
- Identify state and local personnel responsible for conducting the initial epidemiologic investigation that will determine the initial source of outbreak, population at risk, and epidemiological features of outbreak,
- Determine other non health department personnel that will be involved in the initial epidemiologic investigation,
- Identify state and local leads to oversee interviews of confirmed, probable, and suspected cases to determine travel history and contact lists,
- Identify state and local personnel that will conduct the interviews of confirmed, probable, and suspected cases,
- Identify personnel for contact tracing during a smallpox emergency:
  At least 30 people, divided into 2 person teams should be designated, with contingencies for additional people. Potential local and state resources for such personnel include STD/HIV/TB public health staff and community medical training resources such as nursing or medical schools,
- Identify state and local resources for daily telephone monitoring of identified contacts,
- Identify personnel responsible for coordinating the staffing and maintenance of quarantine and isolation activities,
- Arrange public notification procedures and establish the specific roles of state and local public relations offices, and
- Identify reliable smallpox subject matter experts from local and state communities, and establish procedures to direct media inquiries to these experts for reliable disease information. (Check with CDC for any such experts already in place, such as from the Infectious Diseases Society of America.)

4. Decontamination

State and local health authorities should review the CDC Guideline for Decontamination (Guide F) and make plans for resources and personnel to handle decontamination of smallpox-contaminated medical equipment, medical waste, clothing, surfaces, bedding, rooms, and vehicles.

5. Training

An effective response requires that those overseeing operations as well as those in the field know what is in the response plan and know how to act accordingly. State and local health departments' pre-event training activities should focus on training the Case Investigation and Contact-Tracing personnel on the disease and its management.

Investigational personnel should be able to:

- Recognize the symptoms and clinical signs of smallpox,
- Identify cases and suspect cases,
- Understand reporting procedures,
- Know which forms are required, and
- Know how to arrange for isolation,

The personnel interviewing and counseling skills should include:

- Interviewing case/suspect cases on:
  - Recent (prior 3 weeks) travel, activities and possible sources of exposure,
  - Day-by-day close contacts and contact sites since onset of fever or rash,
- Tracing close contacts in order to arrange for their vaccination, and conduct surveillance of contacts for fever or rash,
- Counseling contacts, household members regarding:
  - Smallpox symptoms,
  - Fever surveillance guidelines,
  - Restrictions, and
  - What to do and who to contact if a fever or other symptoms (rash) occur,
- Screening for contraindications to smallpox vaccination,
- Counseling household members with contraindications to vaccination to avoid contact with contacts to smallpox cases, and other vaccinated household members.
- Administering vaccine to contacts and household members, and
- Assessing a smallpox vaccination take,
- Counseling vaccinees regarding:
  - Care of the vaccine site,
  - Expected vaccine reactions, and
  - Adverse events.

Case Investigators and Contact-Tracing personnel should engage in training exercises based on CDC-suggested smallpox exposure scenarios. The exercises to be conducted should be included as part of the response plan.

Scenario 1 - Exposure to substance claimed or suspected to be smallpox.

Scenario 2 - A single case of clinically compatible illness presents to hospital; local surveillance detects no other cases.

Scenario 3 - Several clinically compatible cases are identified at a hospital; local surveillance identifies other clinical cases; case investigation may or may not indicate a common exposure of up to a few hundred persons; over the next 2 days a total of 5 to 10 cases are identified.

Scenario 4 - Several clinically compatible cases are identified at a hospital; local surveillance identifies other clinical cases; case investigation indicates a common exposure at an event/site where up to a few hundred persons may have been exposed; over the next 2 days a total of 50 to 100 cases are identified.

Scenario 5 - Several clinically compatible cases are identified at a hospital; local surveillance identifies other clinical cases; case investigation indicates a common exposure at an event/site where thousands of persons would have been exposed simultaneously; over the next few days, hundreds of potential cases present for evaluation.

Scenario 6 - Several clinically compatible cases are identified at a hospital; over the next 2 days additional cases are identified locally and at hospitals in several other major urban areas; no common exposure is identified leading to a conclusion of multiple exposures.

6. Security

Law enforcement personnel may need to guard vaccine storage facilities, guard vaccine as it is transported, provide a secure environment at clinic sites, and accompany public health field workers that make home visits to provide vaccine. In addition to securing vaccine supplies, extra security measures will be needed for smallpox patients in isolation at hospitals and in quarantine facilities and may be needed for suspect cases and contacts. Health authorities should coordinate their plans and have contact lists for local police or other law enforcement agencies.

In addition, state and local health authorities need to be familiar with emergency procedures for maintaining essential systems such as water, electricity, and waste disposal at vaccine, isolation, quarantine, and other sites.

Response Plan Review Checklist

Organization and Management

O&M 1	Is there a smallpox response organizational description?	- Smallpox coordinating unit/lead - Smallpox coordination response units (public health & hospital) -Org chart & listing with integration within framework
O&M 2	Is there a smallpox emergency response management decision model?	Decision model needed for - Contact vaccination - Mass vaccination
O&M 3	Are there defined roles & responsibilities for key operational functions?	- Roles & responsibilities chart or list describing positions - Coordination units - Structure
O&M 4a	Is there a list of key state contacts that will be involved in smallpox response efforts?	- Collaborative partners - state/local health department - public safety - Integrated response - emergency management - hospitals & hospital organizations
O&M 4b	Is there a list of key local contacts that will be involved in smallpox response efforts?	- Collaborative partners - state/local health department - public safety - Integrated response - emergency management - hospitals & hospital organizations
O&M 4c	Is there a list of key federal contacts that will be involved in smallpox response efforts?	- Collaborative partners - state/local health department - public safety - Integrated response - emergency management - hospitals & hospital organizations

O&M 5	Is there documentation of integrated relationships with hospitals and hospital organizations to develop a treatment plan for smallpox cases?	- integrated relationships with hospitals & hospital organizations - contacts within hospitals - description of working relationship (e.g. MOU, working group)

Response Teams

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Roles 1	The number of response teams, their composition by position title and agency affiliation	Description of repsonse team; Estimation of # of clinics/teams needed; NPS mentioned; Sources for teams; Multiples agencies; Geographic locations; Titles of those filling functions; NPS identified as part of plan; Clinics IDed; Roles Described; People vaccinated
Roles 2	Plans to ensure adequate staffing to receive, provide security for and distribute vaccine and other National Pharmaceutical Stockpile items	
Roles 3	A description of the sources for clinic personnel (e.g., local health departments, community health centers, Visiting Nurses Association, community volunteers)	
Roles 4	A generic staffing plan for each clinic, including a listing of individual staff responsibilities	
Roles 5	Plans to add or reassign staff to handle potential influx of specimens submitted for testing to the state laboratory	Surge capacity (adding more people). Describes who is needed where. Shows if personnel are vaccinated? Agreements in place; Integrated with other agencies; Multiagency; Trained; Practices.
Roles 6	A strategy for ensuring a *rapid* response throughout the state	
Roles 7	A strategy for completing vaccination of all workers involved in control activities within 1-3 days of the confirmation of the first smallpox case	Estimates of those who need vaccination; Locations of workers; Dates of clinics/vaccination; Staff adequate for outbreak control; Staff adequate for mass immunization

Enhanced Surveillance

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Surv 1	Plans to enhance surveillance systems after an initial case is confirmed (within jurisdiction or elsewhere) to ensure rapid identification and reporting of additional cases	Define/discuss components of enhanced surveillance (e.g., personnel, roles, reporting mechanism)
Surv 2	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	
Surv 3	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	Plan for specimen handling, shipping and receiving, and reporting out from LRN lab. Surge capacity: personnel, reagents. Are there comments about specimen packaging, testing, training, certification, qualification mechanism (do they describe package)

Clinic Sites

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Sites 1	Plan includes site selection rationale/criteria	
Sites 2	Plan includes list of clinic sites	Maturity Scale: Criteria selection stated but nothing more Potential sites are listed Actual sites are listed Mock clinic held in one of the planned sites
Sites 3	Clinic Plan is scalable for volume/time	Maturity Scale: Plan to use a modeling method A modeling method is described Modeling tool selected or under development Modeling tool tested
Sites 4	Arrangements are in place for use of clinic sites	Maturity Scale: No action taken, but have plans to do so Discussions are underway MOA (or) MOU contract (or) in place Mock clinic conducted in actual clinic site Interjurisdictional

Training and Education

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Train 1	Are there core smallpox public health staff identifed who will be trained by CDC (trainers who will train others)?	- Core public health personnel named - Education training team - BT coordinator
Train 2	Is there a detailed plan for training Case Investigators and Contact-Tracing personnel?	- lists of comprehensive audiences - calendars - dates - venues for training (location and modality)
Train 3	Are there procedures for quickly reproducing and distributing CDC materials?	- CD-ROMS, e-mail, list serves, web sites - organizational structure - MOUs or contracts - Process
Train 4	Are key training and communications partners identifed by names and positions (e.g. infectious disease or training specialists who are designated to receive educational materials and coordinate training activites about disease, vaccine, adverse events, contraindications, screening process, vaccinations, and post vaccination take reading)?	- Professional organization - Medical and non-Medical organization - Names and positions and topics

Train 5	Is there 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 potential adverse events?	Adverse events. 1. Strategy- including SME and other resources 2. Logistical discussion 3. Health care professional access to training on adverse events. Means of reporting the adverse event.

Data Management

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Data 1	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;	Dedicated smallpox data management professional
Data 2	A description of how patient information will be entered into CDC's record keeping and data system;	If applicable they may have ther own.
Data 3	Plans for ensuring adequate electronic connectivity at each clinic site and other data access areas;	HAN, HL7 Exchange
Data 4	A description of technical assistance potentially needed from CDC to support the information technology needs of State and clinic sites; and	NEDDS System electronic disease reporting

Data 5	Plans to acquire computers, printers and other related supplies for all vaccination clinic sites and other access points;	
Data 6	Plans for compliance with the Information Technology Functions and Specifications of the Public Health Information Network (www.cdc.gov/cic/functions-specs)	Address sub-elements of PHIN (approximately 8) (Assess and Plan for compliance with PHIN standards)

Case Investigation

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Case 1	A smallpox diagnosis classification and case definition	Refers to *Guide A* of SPRG
Case 2	Procedures for identifying tracing, vaccinating and monitoring contacts	
Case 3	Plans to impose isolation of confirmed, probable, and suspected cases	
Case 4	Plans to monitor the outcome of confirmed cases	
Case 5	A strategy for maintaining case investigations and vaccination/monitoring of contacts at all costs despite demands for large scale vaccination efforts or other urgencies	Surge capacity

Vaccination Strategy

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Strat 1	Outbreak Control: The process and procedures for vaccinating and monitoring contacts and potential contacts;	A plan to identify contacts, vaccinate contacts; a plan to isolate exposed; legal documentation
Strat 2	Outbreak Control: A strategy for isolating contacts who refuse vaccination;	A plan to identify contacts, vaccinate contacts; a plan to isolate exposed; legal documentation
Strat 3	Outbreak Control: Plans for implementing quarantine requirements, if necessary;	A plan to identify contacts, vaccinate contacts; a plan to isolate exposed; legal documentation
Strat 4	Outbreak Control: Documentation of state legal authority for invoking quarantine; and	A plan to identify contacts, vaccinate contacts; a plan to isolate exposed; legal documentation
Strat 5	Mass Immunization: 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;	A plan to activate staff roles and responsibilities

Strat 6	Mass Immunization: A description of the decision and approval process in concert with CDC and PHS for expanding the scope of the vaccination program from surveillance and containment (ring strategy) to wide area vaccination	A plan to activate staff roles and responsibilities

Vaccine Logistics and Security

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Logis 1a	Is there a named primary contact who will be responsible for collaborating with CDC NPS with complete contact information (street address, phone, cell, email, fax)?	P.O.C. for SNS collaboration and receipt (Street Address [NO P.O. Box], redundant contact numbers & e-mail, plan for redistribution)
Logis 1b	Is there a named alternate who will be responsible for collaborating with CDC NPS with complete contact information (street address, phone, cell, email, fax, and pager)?	P.O.C. for SNS collaboration and receipt (Street Address [NO P.O. Box], redundant contact numbers & e-mail, plan for redistribution)
Logis 2	Are there plans for documenting and reporting vaccine usage in accordance with CDC specifications?	Accountability method for documenting and tracking doses, wastage minimization plan
Logis 3a	Are there plans to ensure security of vaccine during transport?	Security plan for Transport, Storage, Clinic Operations

Logis 3b	Are there plans to ensure security of vaccine during clinic operations?	Security plan for Transport, Storage, Clinic Operations
Logis 4	Is there a description of the facilities (including refrigeration equipment to store and continuously monitor temperature of vaccine)?	Store, Maintained, Monitored, Cold Chain Management maintained throughout distribution process
Logis 5a	Is there a description of how the vaccine will be held between vaccination sessions?	Storage (cold chain management) Locked/Guarded
Logis 5b	Is there a description of where the vaccine will be held between vaccination sessions?	Storage (cold chain management)
Logis6a	Is there a detailed description of how accountability for vaccine will be accomplished daily at the state level?	#2
Logis 6b	Is there a detailed description of how accountability for vaccine will be accomplished daily at the clinic level?	#2
Logis 7	Is there a strategy for minimizing wastage of vaccine by maximizing number of doses administered per 100-dose vial?	#2

Clinic Operations Management

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Ops 1	Clinic staffing needs are addressed	Clinic model tested Maturity Scale Indicators 1 - role needs to be identified 2 - job descriptions and roles 3 - assignment of training 4 - clinic model tested
Ops 2	Clinic supply needs are addressed	forms medical supplies office supplies etc. See maturity continuum
Ops 3	Facility-related issues are addressed	phone lines computers furnishings waste disposal staff assignment sharps disposal See maturity continuum
Ops 4	Vaccine management plan is described	cold chain security accountability staff assignments See maturity continuum
Ops 5	Clinic flow functions are described	triage screening PT. Ed. consent vaccination take read See maturity continuum

Ops 6	Community linkage is described	transportation security volunteers public info. Campaigns See maturity continuum

Vaccine Adverse Events Monitoring

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Safe 1	Is there a named individual designated to oversee and coordinate vaccine safety activities?	Named individual
Safe 2	Are there plans for a jurisdiction-wide 24/7 hotline to answer questions from the public about vaccine safety?	Details of hotline (staff details, training timelines, telephone scripts, provision of numbers) 24/7 coverage, all-hour access
Safe 3	Is there a process for referring eligible potential vaccines to medical providers for additional consultation and laboratory testing?	Screening plan for contraindications, informed consent plans prior to vaccination
Safe 4	Is there a procedure to alert providers about smallpox vaccine safety issues?	Education/communications with all providers, plans, methods of communication
Safe 5	Is there a list of the potential sub specialists that will be available to evaluate, treat, and consult on smallpox vaccine adverse events?	Dermatology, neurology, allergy/immunology, ophthalmology. List: details, 24 call list, schedule
Safe 6	Is there a training plan for staff assigned to vaccine safety monitoring?	Timeline for training, materials used for training; existence of a plan, timeline, content, materials contraindicators/adverse events

Safe 7	Is there a timeline for completing follow-up of persons with adverse events that is consistent with the CDC's IND protocol?	Look for acknowledgement of IND protocol & requirements

Communications

Sub-Section	Guidance Comments	Critical Observations and Keywords or Phrases
Com 1	The plan designates staff to coordinate communications across state and local agencies and all other partner groups.	Lists of spokespersons, Ensure spokespersons are adequately trained (FBI, evidence, etc.), Media content/contact lists. Specify titles and positions. Specify procedures and systems for compliance. Designate partner groups.
Com 2	This plan designates a spokesperson to carry critical communication.	
Com 3	This plan designates medically trained personnel to respond to large volumes of calls from health care professionals.	Define pool of clinically trained personnel. State criteria for "large volume of calls."
Com 4	This plan describes arrangements for translations/interpretation services for specific population groups that do not speak english.	Detail how translation and special populations will be identified & received.