

Guide B

Vaccination Guidelines for State and Local Health Agencies

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The state epidemiologist, health officer, or other authorized health or state official should assign a person or persons to assume organizational responsibilities for state and local resources for vaccine administration during a smallpox outbreak (defined as a single laboratory confirmed case). This person(s) should work with federal and other state emergency management authorities to implement the following vaccine administration strategies.

I. Overview of a Response to an Outbreak of Smallpox

The public health response to an outbreak of smallpox is a multi-faceted event, evolving over an extended period of time. The smallpox vaccination response strategy is one of many concurrent public health activities that will be employed to stop an outbreak of smallpox. This interim response plan is organized according to the key activities of such a response: epidemiology and surveillance, vaccination strategies, isolation and quarantine, diagnosis and treatment of patients, decontamination, and communications. For logistical purposes, response activities can be sub-divided by time and location into:

- those that need to be initiated early (first 12-24 hours of the response) or later and
- those that would be initiated nationally and or in communities (either affected or unaffected communities).

Activities can also be subdivided by those responsible for the activity (i.e., the different federal, state, and local agencies).

Below is an outline of the initial response activities to a suspected smallpox outbreak. While vaccination activities are integral to the overall plan, they must flow within the schema below. It should be recognized that a smallpox outbreak response would require ongoing and continuous modifications based on the information about a release, the course of the outbreak, public response, etc. This overall outline can be used as a guide for developing state and local public health response plans, including logistics of outbreak response activities, personnel, and other resources that will be needed to conduct an effective outbreak response.

FIRST 12-24 HOURS: Clinical and epidemiologic diagnosis of a rash illness with high risk of smallpox (based on [Evaluating Patients for Smallpox: Acute, Generalized Vesicular or Pustular Rash Illness Protocol, Guide A, Appendix 1](#)) and/or a laboratory confirmed case of smallpox.

1. National
 - a. Collect and transport clinical specimens for confirmation of diagnosis.

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- b. Deploy state and CDC smallpox response teams. Some vaccine will be carried by the CDC response team and some can be shipped simultaneously (e.g., 150,000 doses, with additional supplies shipped as needed).
 - c. CDC/HHS notifies state and local health officials of probable smallpox cases, who will initiate enhanced smallpox surveillance and activate smallpox response plans.
 - d. Mobilize CDC Emergency Communication Network (ECN) teams to ensure real-time up-to-date information exchange with federal, state, and local public health response and communication teams.
 - e. Alert healthcare providers, hospitals, etc., (through state health departments and other avenues such as Prepare Health Alert Messages and Epi X alerts) of suspect case and advise them of the need to look for new cases and to activate healthcare response team plan.
 - f. Activate all CDC response teams.
2. Affected communities
 - a. Activate enhanced case finding/surveillance (see [Guide A](#)).
 - b. Activate enhanced laboratory diagnostic system/protocols (see [Guide D](#)).
 - c. Identify contacts of cases and vaccinate contacts of confirmed or highly probably case(s) (see [Guide A](#)).
 - d. Activate public health and healthcare response teams to assist in outbreak investigation and control procedures and diagnosis, management, and treatment of suspect and diagnosed cases of smallpox (see [Guides A](#), [Guide C part 1](#) and [part 2](#), and Annex 1 [part 1](#), [part 2](#), and [part 3](#)).
 - e. Initiate program to vaccinate healthcare workers, first responders, law enforcement staff, etc. (to expand response capability).
 - f. Activate large scale vaccination plans (initiate vaccination as indicated) (see Annex 3).
 - g. Initiate outbreak communication plan (see [Guide E](#)).
 - h. Establish command center to coordinate roles and activities of various outbreak response teams.
 3. Unaffected communities
 - a. Activate enhanced case finding/surveillance (see [Guide A](#)).
 - b. Activate enhanced laboratory diagnostic system/protocols (see [Guide D](#)).
 - c. Activate public health and healthcare response teams to assist in outbreak investigation and control procedures and diagnosis, management, and treatment of suspect and diagnosed cases of smallpox (see [Guides A](#), [Guide C part 1](#) and [part 2](#), and Annex 1 [part 1](#), [part 2](#), and [part 3](#)).
 - d. Initiate program to vaccinate healthcare workers, first responders, law enforcement staff, etc. (to expand response capability).
 - e. Initiate outbreak communication plan (see [Guide E](#)).

AFTER 12-24 HOURS: (Confirmed case of smallpox)

1. National
 - a. Characterize outbreak virus.
 - Genetic studies
 - Clinical and epidemiologic features of the outbreak

- b. Establish continuous evaluation of clinical and epidemiologic features of the outbreak and status of outbreak control.
 - c. Distribute additional vaccine to meet needs of affected communities and vaccine to vaccinate healthcare workers, first responders, etc. to unaffected communities throughout the nation.
 - d. Distribute vaccine to vaccinate entire population as indicated.
 - e. Evaluate local response capabilities, deploy additional response teams, and identify additional resources as needed.
 - f. Establish continuous evaluation of vaccination and control programs.
 - g. Initiate vaccination of health care workers, first responders, law enforcement staff, etc. throughout the nation.
 - h. Initiate large scale vaccination throughout the nation as indicated (see [Annex 3](#)).
 - i. Maintain/enhance ongoing communication activities.
 - j. Enhance vaccination adverse event support, treatment, and surveillance capabilities (monitor status of VIG supplies).
 - k. Monitor status of laboratory diagnostic capabilities and enhance these capabilities as needed.
2. Affected communities
- a. Complete vaccination of healthcare workers, first responders, law enforcement staff, etc., to expand response capabilities, (for unexposed, only vaccinate those without risk factors for adverse events), and vaccinate others critical to maintain essential services.
 - b. Maintain enhanced case finding/surveillance and evaluation of findings.
 - c. Continue to identify contacts of cases and vaccinate contacts of confirmed or highly probable cases and household contacts of smallpox contacts.
 - d. Evaluate and maintain enhanced laboratory diagnostic system/protocols.
 - e. Begin large scale vaccination as indicated (for unexposed, only vaccinate those without risk factors for adverse events) (see [Annex 3](#)).
 - f. Maintain outbreak communication plan.
 - g. Maintain command center to coordinate roles and activities of various outbreak response teams.
 - h. Monitor response capacity, status of control efforts, and status of community support services.
 - i. Establish vaccine adverse events support, treatment, and monitoring system.
3. Unaffected communities
- a. Continue enhanced case finding/surveillance.
 - b. Evaluate and maintain enhanced laboratory diagnostic system/protocols.
 - c. Complete vaccination of healthcare workers, first responders, law enforcement staff, etc., to expand response capabilities (for unexposed, only vaccinate those without risk factors for adverse events). Expand vaccination program to others to maintain essential community services as indicated
 - d. Activate large-scale vaccination plan (initiate vaccination as indicated).
 - e. Initiate outbreak communication plan.
 - f. Monitor status of essential community services and support structure.

II. Overall Vaccination Strategy

Background

Throughout the smallpox eradication program, vaccination of close contacts to smallpox cases played the most important role in stopping transmission of disease. Public health authorities may supplement this strategy with broader vaccination campaigns to increase the level of community immunity to smallpox. However, targeted vaccination of close contacts is the mainstay of smallpox outbreak control as it assures the administration of vaccine to those with the greatest risk of developing and transmitting smallpox and thus the greatest need for vaccination. Although smallpox vaccine is safe and effective, vaccine adverse events can occur and prioritizing vaccination based on risk of exposure can help minimize vaccination of those at risk for serious adverse events.

The following activities must take place to support vaccination administration in a smallpox emergency:

1. Establish controlled, non-hospital vaccination sites for contacts in case large-scale vaccination or other broader public vaccination campaigns must be implemented. See [Annex 2: General Guidelines for Smallpox Vaccination Clinics](#) and [Annex 3: Guidelines for Large Scale Smallpox Vaccination Clinics](#)
2. Establish a system for vaccine adverse events tracking, reporting, and treatment.

Primary Strategy: Surveillance and Containment

Surveillance and containment is based on:

1. identifying cases of smallpox,
2. isolating the case-patients, and
3. vaccinating persons who have already or are most likely to come into contact with the smallpox case-patients, as these are the people that have the greatest chance of developing the disease.

This strategy sometimes has been referred to as “Contact Identification” or “Ring Vaccination.” Vaccination within 3 days of exposure will prevent or significantly lessen the severity of smallpox symptoms in the vast majority of people. Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of disease. Since smallpox is usually transmitted by close contact except under special circumstances (to be discussed later in this section), people with face-to-face or household contact with a smallpox case are the ones at greatest risk for developing the disease and should be prioritized for vaccination.

Individuals most likely to come into contact with an asymptomatic (not exhibiting signs or symptoms of smallpox) contact to a smallpox case (e.g., household members of a contact) should also be vaccinated to prevent infection of those individuals, should the initial smallpox contact later develop the disease. In addition, contagious individuals (those with clinical smallpox) must be isolated to prevent contact with nonvaccinated or susceptible individuals during their period of infectiousness, further limiting the opportunity for disease transmission. Intensive surveillance for cases and their contacts will help to quickly identify other persons for isolation, treatment, and priority vaccination.

Primary smallpox vaccination strategies in an outbreak should be based on:

1. Quickly identifying and isolating smallpox cases.
2. Identifying and vaccinating their primary/secondary contacts.
3. Monitoring the vaccinated contact and isolating the contact if fever develops.
4. Vaccinating household members of contacts without contraindications to protect them if the contact develops smallpox. If a household member cannot be vaccinated because of contraindications, the household member should be instructed to avoid physical contact with the primary contact until the incubation period of the disease has passed (18 days) or all vaccinated persons in the household are noninfectious for vaccinia virus (after the scab at the vaccine site has separated, 14 to 21 days after vaccination).
5. Vaccinating healthcare and public health workers (physicians, nurses, EMTs, etc.) who will be directly involved in evaluating, treating, transporting, or interviewing potential smallpox cases or administering smallpox vaccine.
6. Vaccinating other response personnel who have a reasonable probability of contact with smallpox patients or infectious materials (e.g., law enforcement, emergency response, or military personnel).

Supplemental Strategy

Instances where federal and state health authorities may initiate a broader vaccination campaign to enhance outbreak control while continuing contact tracing and vaccination activities include:

1. The initial number of smallpox cases or identified locations of smallpox outbreaks is considered too large to allow contact tracing with vaccination to be effective as the **only** vaccination strategy for outbreak containment.
2. The risk of further smallpox releases is considered to be high.

Interpretation of Vaccination Results – Procedures for vaccination follow-up to confirm vaccine take will utilize a vaccine site reaction recognition card given to vaccine recipients at the time of vaccination. If personnel resources permit, vaccine takes should be confirmed and recorded by health personnel 6-8 days following vaccination. If personnel resources do not permit direct followup for vaccine take confirmation, recipients should be given instructions to call for evaluation if the vaccine site does not look similar to that depicted on the card at day 7.

Use of Diluted Vaccine

Because of the supplies of smallpox vaccine are currently limited, it may be necessary to utilize diluted preparations of the vaccine to support broader vaccination campaigns that may be instituted as a supplemental strategy for outbreak control. Although studies have indicated that diluted preparations of the current smallpox vaccines have take rates and reaction profiles similar to undiluted vaccine, diluted vaccines have not been licensed and must be administered under an Investigational New Drug (IND) protocol. Once the decision to utilize diluted vaccine has been made by federal authorities, protocols for preparing and initiating vaccination with diluted vaccine will be distributed to state and local public health authorities.

(Document continues in Guide B – Part 2 of 3)