

Draft Guide A: Smallpox Surveillance and Case Reporting; Contact Identification, Tracing, Vaccination, and Surveillance; and Epidemiologic Investigation

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<http://www.bt.cdc.gov/agent/smallpox/response-plan>

Guide A summarizes pre-event surveillance activities, as well as post-event activities necessary for smallpox surveillance and case reporting; contact identification, tracing, vaccination, and surveillance; and epidemiologic investigation at the local, state, and federal levels. This Guide covers the following topics:

- I. Introduction to Smallpox Pre-Event Surveillance
- II. Introduction to Smallpox Post-Event Surveillance and Case Reporting; Contact Identification, Tracing, Vaccination, and Surveillance; and Epidemiologic Investigation
- III. Smallpox Clinical Case Definitions, Case Classifications, and Clinical Types
- IV. Evaluating the Patient with an Acute, Generalized Vesicular or Pustular Rash Illness and Determining the Risk of Smallpox
- V. Pre-Event Enhanced Surveillance Strategies
- VI. Activities to Prepare for Smallpox Post-Event Surveillance
- VII. Post-Event Smallpox Surveillance and Case Reporting; Contact Identification, Tracing, Vaccination, and Surveillance; and Epidemiologic Investigation
- VIII. Appendices

I. Introduction to Smallpox Pre-Event Surveillance

Surveillance for a disease that does not currently exist anywhere in the world presents unique challenges. If smallpox disease were to reoccur in the United States or elsewhere, the most likely possible sources of reintroduction would be:

- An unintentional infection in a laboratory (currently there are only two WHO-approved smallpox virus research and repository laboratories which include the CDC in Atlanta, Georgia and the Institute of Virus Preparations in Moscow, Russia although there is concern that stocks of smallpox virus may exist in other laboratories).
- A bioterrorist attack involving deliberate infection of a person.
- A bioterrorist attack involving intentional release of smallpox virus into the environment.

For pre-event surveillance purposes, where the likelihood of smallpox occurring is considered to be extremely low, the suggested approach to surveillance relies on a highly specific clinical case definition, which is focused on identifying a classic case (ordinary type) of smallpox. This means that the first case of smallpox is unlikely to be recognized in the first few days after rash onset when the presentation is nonspecific. In addition, atypical presentations of smallpox including hemorrhagic smallpox and flat type (velvety) smallpox are also likely to be missed. These limitations are accepted and weighed against the extremely low risk of disease and the very real risks of false-positive laboratory results.

Because the likelihood of reintroduction of smallpox is extremely low, and acknowledging that there are many other causes of vesicular and pustular rash illnesses, health care providers evaluating such cases should familiarize themselves with diseases that were confused with smallpox in the past (e.g. varicella, herpes simplex, drug reactions, erythema multiforme), as well as the clinical manifestations of smallpox disease. In this way, in the unlikely event of a smallpox case, the disease will be clearly and quickly recognized.

The goal of pre-event surveillance is to recognize the first case of smallpox, should it ever occur, without generating excessive numbers of false alarms, unnecessarily disrupting the health care and public health systems, or increasing public anxiety. In the absence of known smallpox disease, the predictive value of a positive smallpox diagnostic test is extremely low, close to zero; therefore, testing to rule out smallpox should be limited to cases that fit the clinical case definition in order to lower the risk of obtaining a false positive test result. It is neither feasible nor desirable, in the pre-event scenario, to perform laboratory testing for suspected cases that do not meet the clinical case definition.

II. Introduction to Smallpox Post-Event Surveillance and Case Reporting; Contact Identification, Tracing, Vaccination, and Surveillance; and Epidemiologic Investigation

Since smallpox no longer exists as a naturally occurring disease, an outbreak of smallpox is defined as a single laboratory confirmed case. Activities and actions described here may be altered depending upon the size and characteristics of the outbreak. In that event, information regarding the new procedures or actions will be communicated to health department personnel by the state epidemiologist, other state health office personnel, or federal health authorities.

A single, laboratory confirmed case will initiate implementation of the CDC and state smallpox response plans. Other criteria for implementation of the response plan include:

- A large outbreak of a clinically compatible illness pending etiologic confirmation;
- Reports of suspected or probable cases once an outbreak has been identified elsewhere in the country; and
- Confirmation of smallpox virus in an environmental sample, package, or device associated with human exposure.

Surveillance, outbreak investigation and control activities including contact identification, tracing, vaccination and surveillance will need to be prioritized once smallpox is confirmed in a local jurisdiction. Following the confirmation of a smallpox case, especially if it is the first case confirmed in the United States, an epidemiological investigation will need to occur in collaboration with law enforcement and state and federal authorities. If a smallpox case is confirmed anywhere in the United States or in the world, enhanced surveillance for smallpox should be initiated and decisions on vaccination will be made in collaboration with state and federal authorities.

Although the specific mechanisms and logistics may differ among jurisdictional areas, the post-event activities will include:

- Surveillance and case reporting;
- Contact identification, tracing, vaccination, and surveillance; and
- Epidemiologic investigation - investigation for source of infection (conducted for initial cases in a geographic area only).

Forms have been designed to assist with the data collection needs for each of these activities.

III. Smallpox Clinical Case Definition, Case Classifications and Clinical Types

A. Introduction

Surveillance for a disease that does not currently exist anywhere in the world presents unique challenges. The goal of pre-outbreak (pre-event) smallpox surveillance is to recognize the first case of smallpox, should it ever occur, without generating excessive numbers of false alarms, unnecessarily disrupting the health care and public health systems, or increasing public anxiety. In the absence of known smallpox disease, the predictive value of a positive smallpox

diagnostic test is extremely low; therefore, testing to rule out smallpox should be limited to cases that fit the clinical case definition in order to lower the risk of obtaining a false-positive test result. It is neither feasible nor desirable, in the prevent scenario, to perform laboratory testing for suspected cases that do not meet the clinical case definition.

Thus, in the absence of smallpox disease in the world, the suggested approach to surveillance relies on a highly specific clinical case definition, which is focused on identifying the classic case presentation (ordinary type) of smallpox. Before eradication, classic (ordinary type) smallpox generally accounted for approximately 90% of smallpox cases in previously unvaccinated individuals and 70% of cases that occurred in previously vaccinated individuals who were no longer fully protected by vaccination.

Because the likelihood of reintroduction of smallpox is extremely low, and acknowledging that there are many other causes of vesicular and pustular rash illnesses, healthcare providers evaluating such cases should also familiarize themselves with diseases that can be confused with smallpox (e.g., varicella, herpes simplex, drug reactions, erythema multiforme), as well as the clinical manifestations of smallpox disease. In this way, in the unlikely event of a smallpox case, the disease will be clearly and quickly recognized.

Several resources to assist a clinician in the evaluation of a febrile, rash-illness patient for the likelihood of smallpox can be found on the “Smallpox Diagnosis and Evaluation” page (www.bt.cdc.gov/agent/smallpox/diagnosis).

These resources include:

1. The algorithm “Evaluating Patients for Smallpox,” presented in poster format that provides a standard method for evaluating patients with acute, severe vesicular or pustular rash illness. The purpose of the protocol is to provide a systematic approach for evaluating patients with generalized rash illnesses and to direct an appropriate clinical and public health response, including diagnostic testing:
www.bt.cdc.gov/agent/smallpox/diagnosis/evalposter.asp.
2. An online interactive risk evaluation algorithm (based on the poster algorithm above) that can be filled in to quickly determine the likelihood of clinical smallpox:
www.bt.cdc.gov/agent/smallpox/diagnosis/riskalgorithm.
3. A downloadable standard worksheet that can be used to collect the clinical information to classify the risk of smallpox using the CDC criteria outlined in the poster (“Evaluating Patients for Smallpox”):
www.bt.cdc.gov/agent/smallpox/diagnosis/pdf/spox-patient-eval-wksheet.pdf.

<p>ANY SUSPECTED SMALLPOX CASE SHOULD BE IMMEDIATELY REPORTED TO LOCAL PUBLIC HEALTH OFFICIALS.</p>
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B. Case definition

1. Smallpox clinical case definition

An illness with acute onset of fever $\geq 101^{\circ}\text{F}$ (38.3°C) followed by a rash characterized by firm, deep seated vesicles or pustules in the same stage of development without other apparent cause.

2. Laboratory criteria for confirmation*

- Polymerase chain reaction (PCR) identification of variola DNA in a clinical specimen, **OR**
- Isolation of smallpox (variola) virus from a clinical specimen (WHO Smallpox Reference laboratory or laboratory with appropriate reference capabilities) **with** variola PCR confirmation.

*Laboratory diagnostic testing for variola virus should be conducted in a CDC Laboratory Response Network (LRN) laboratory utilizing LRN-approved PCR tests and protocols for variola virus. Initial confirmation of a smallpox outbreak requires additional testing at CDC.

*Note: Generic orthopox PCR and negative stain electron microscopy (EM) identification of a pox virus in a clinical specimen are suggestive of an **orthopox** virus infection but not diagnostic for smallpox.*

The importance of case confirmation using laboratory diagnostic tests differs depending on the epidemiological situation. Because of the low predictive value of a positive lab test result in the absence of a known smallpox outbreak, in the pre-outbreak (pre-event) setting, laboratory testing should be reserved for cases that meet the clinical case definition and are thus classified as being a potential high risk for smallpox according to the rash algorithm poster (www.bt.cdc.gov/agent/smallpox/diagnosis/evalposter.asp).

C. Case classification

Since smallpox no longer exists as a naturally occurring disease, a single laboratory confirmed case of smallpox would be considered an outbreak. Once an outbreak of smallpox has been confirmed, the following case classifications should be used:

Confirmed case: A case of smallpox that is laboratory confirmed, or a case that meets the clinical case definition that is epidemiologically linked to a laboratory confirmed case.

Probable case: A case that meets the clinical case definition, or a case that does not meet the clinical case definition but is clinically consistent with smallpox and has an epidemiological link to a confirmed case of smallpox. Examples of clinical presentations of smallpox that would not meet the ordinary type (pre-event) clinical case definition are: a) hemorrhagic type, b) flat type, and c) variola sine eruptione.

Suspect case: A case with a febrile rash illness with fever preceding development of rash by 1-4 days.

D. Clinical types of variola major

As described by Fenner in his classic textbook “Smallpox and its Eradication” (www.who.int/emc/diseases/smallpox/smallpoxeradication.html), it has long been recognized that several clinical types of variola major could be distinguished which differed in prognosis, differential diagnosis and transmissibility. In 1968, WHO adopted a classification of clinical types based on the type and progression of the rash. This classification was shown by Dixon (1962) and Rao (1967) to have greater prognostic value than a previous classification based on density of focal eruption. In 1972, a WHO Expert Committee reaffirmed its acceptance of this classification, used in this Guide. The relative frequency and case fatality rate of these clinical types is summarized in Table 1.

Ordinary type (classic): Raised pustular lesions; three subtypes:

Confluent—confluent rash on face and forearms

Semi-confluent—confluent rash on face, discrete elsewhere

Discrete—areas of normal skin between pustules, even on face

Modified type: Like ordinary type but less severe, with an accelerated course. (Experience from the smallpox eradication era was that the most common reason for an accelerated course in variola major was vaccination was vaccination some years earlier [Fenner].)

Variola sine eruptione: Fever w/o rash caused by variola virus; serological confirmation required. This presentation was rarely observed historically and is thought to have had limited epidemiological significance.

Flat type*: Pustules remain flat; usually confluent or semi-confluent

Hemorrhagic type*: Widespread hemorrhages in skin and mucous membranes. Two subtypes:

Early: with purpuric rash

Late: with hemorrhages into base of pustule

*Both flat type and hemorrhagic smallpox were rare and probably due to host immunity factors; transmission from such cases did not result in a similar clinical type indicating that viral virulence was an unlikely explanation. Hemorrhagic smallpox occurred more commonly among pregnant women

Table 1: Frequency and case-fatality rates of different clinical types of variola major, by vaccination status (presence of scar), hospitalized patients in Madras, India (Rao, 1972)

Clinical Type	Unvaccinated Cases (N=3544)		Vaccinated Cases (N=3398)	
	% of Total	Case-fatality rate	% of Total	Case-fatality rate
Ordinary type:	88.8	30.2	70.0	3.2
Confluent	22.8	62.0	4.6	26.3
Semi-confluent	23.9	37.0	7.0	8.4
Discrete	42.1	9.3	58.4	0.7
Modified type	2.1	0	25.3	0
Flat type	6.7	96.5	1.3	66.7
Hemorrhagic type	2.4	96.4	3.4	93.9
Early	0.7	100.0	1.4	100.0
Late	1.7	96.8	2.0	89.8
Total	-	35.5	-	6.3

IV. Evaluating the Patient with an Acute, Generalized Vesicular or Pustular Rash Illness and Determining the Risk of Smallpox

With ongoing concerns over the use of smallpox virus as a bioterrorist agent, health care providers in the United States, the majority of who have never seen a smallpox case, need to learn about smallpox disease and its clinical presentations. In order to facilitate rapid diagnosis of smallpox, should a case occur in the United States, CDC, together with a variety of partners, developed an algorithm to assist in evaluating patients with febrile vesicular or pustular rash illness. This work was a collaborative effort with the American Academy of Pediatrics, the American Academy of Dermatology, the Infectious Diseases Society of America, the Pediatric Infectious Disease Society, the Association of State and Territorial Health officers, the American College of Emergency Physicians, the Council of State and Territorial Epidemiologists, the Hospital Infection Control Practices Advisory Committee, and smallpox and infectious disease experts.

Clinicians who evaluate patients with unusual or severe presentations of vesicular or pustular rash illnesses need to be able to determine quickly if their patient may have smallpox. The main disease likely to be confused with smallpox is varicella. With implementation of the varicella vaccination program, varicella cases are estimated to have declined approximately 75% throughout the country; however, declines in disease will vary according to vaccine coverage within each state. Even with 1 million cases still occurring in 2003, if 1/1000 varicella cases are misdiagnosed or present atypically, we can expect 1,000 smallpox false alarms per year. There are millions of cases of other vesicular rash illnesses in the United States including enteroviral infections, herpes simplex infections and non-infectious conditions such as erythema multiforme and contact dermatitis (Table 1). Implementation of large scale smallpox vaccination among public health responders, health care workers, and first responders, is likely to result in increased concern about acute rashes in general, with specific concerns about rashes due to vaccinia, which historically have been confused with smallpox in some settings.

Table2: Common Conditions that might be confused with smallpox and clinical clues for differentiation

Condition	Clinical Clues
Varicella (primary infections with varicella-zoster virus)	Most common in children <10 years; children usually do not have a viral prodrome
Disseminated herpes zoster	Immunocompromised or elderly persons; rash looks like varicella, usually begins in dermatomal distribution
Impetigo (<i>Streptococcus pyogenes</i> , <i>Staphylococcus aureus</i>)	Honey-colored crusted plaques with bullae are classic but may begin as vesicles; regional not disseminated rash; patients generally not ill
Drug eruptions	Exposure to medications; rash often generalized
Contact dermatitis	Itching; contact with possible allergens; rash often localized in pattern suggesting external contact
Erythema multiforme minor	Target, “bull’s eye” or iris lesions; often follows recurrent herpes simplex virus infections; may involve hands and feet (including palms and soles)
Erythema multiforme major (Stevens-Johnson syndrome)	Major form involves mucous membranes and conjunctivae; there may be target lesions or vesicles
Enteroviruses infection esp. Hand, Foot and Mouth disease	Summer and fall; fever and mild pharyngitis 1-2 days before rash onset; lesions initially maculopapular but evolve into whitish-grey, tender, flat often oval vesicles; peripheral distribution (hands, feet, mouth or disseminated)
Disseminated herpes simplex	Lesions indistinguishable from varicella; immunocompromised host
Scabies; insect bites (incl. fleas)	Itching is a major symptom; patient is not febrile and is otherwise well
Molluscum contagiosum	May disseminate in immunosuppressed persons

A. Patient Evaluation Algorithm and Poster

The algorithm, “Evaluating Patients for Smallpox: Acute, Generalized Vesicular or Pustular Rash Illness Protocol,” is presented as a poster ([Appendix 1](#)), and provides a standard method for evaluating patients with acute, severe vesicular or pustular rash illness, giving clinical clues for differentiating smallpox from varicella and other rash illnesses likely to be confused with smallpox. This section of Guide A describes the algorithm and the related worksheet ([Appendix 3](#)). These documents are also available on the CDC website at <http://www.bt.cdc.gov/agent/smallpox/diagnosis/index.asp>

Many rash illnesses can present with vesicles and pustules. The purpose of the protocol is to provide a systematic approach for evaluating patients with generalized rash illnesses and to direct an appropriate clinical and public health response.

B. Contact and Airborne Precautions

If a patient presents to an emergency department, clinic, or doctor's office with an acute generalized vesicular or pustular rash illness, care should be taken to decrease the risk of disease transmission. Patients should not be left in common waiting areas. The patient should be assessed to determine whether there is a high, medium, or low risk of smallpox, using the algorithm and the major and minor criteria.

1. If in a doctor's office or clinic, the patient should be placed immediately in a private room with the door kept closed.
2. When admitted or while being held for observation, the facility should institute appropriate airborne and contact precautions and alert the infection control department. The patient should be placed in a private, negative airflow room (airborne infection isolation). The door should be kept closed at all times, except when staff or the patient must enter or exit.
3. Staff and visitors should wear properly fitted respirators (N95), gloves, and gowns.
4. The patient should wear a surgical mask whenever he/she must be outside of their negative pressure isolation room and must be gowned or wrapped in a sheet so that the rash is fully covered.

C. History and Physical Examination

Ask detailed questions about:

- Any symptoms preceding rash onset, including prodromal symptoms and clinical features in the 1-4 days before rash onset,
- Contact with any ill individuals (especially those with a rash illness),
- Recent travel history,
- Medical history including medications,
- History of prior varicella or herpes zoster, and
- History of varicella vaccination (vaccine available since 1995).

In adults, take a history of past (routine childhood vaccinations stopped in the United States in 1972; health care workers and travelers continued to be vaccinated until the late 1970s and military personnel were vaccinated until 1990) and recent smallpox vaccinations and look for a smallpox vaccine scar.

These questions can be found in the accompanying "Worksheet: Evaluating Patients for Smallpox." ([Appendix 3](#))

This information will be helpful in evaluating the patient, determining which illnesses are in the differential diagnosis, and finally, if smallpox is a

consideration, will be used to classify a case into low, moderate or high risk categories for smallpox.

D. Risk Categories for Evaluating Patients for Smallpox (Suspect Smallpox Cases)

- High Risk: Meets all three major smallpox criteria*
- Moderate Risk: Febrile prodrome AND 1 other major smallpox criterion
OR
Febrile prodrome AND ≥ 4 minor smallpox criteria
- Low Risk: No febrile prodrome OR febrile prodrome
AND
<4 minor smallpox criteria

* Note: meets the smallpox clinical definition and would therefore be classified as a probable smallpox case, pending laboratory test results.

E. Criteria for Determining Risk of Smallpox

Major Diagnostic Criteria for Smallpox:

1. Febrile prodrome: occurring 1-4 days before rash onset: fever $\geq 101^{\circ}\text{F}$ (38.3°C) *and* at least one of the following: prostration, headache, backache, chills, vomiting or severe abdominal pain
2. Classic smallpox lesions: deep-seated, firm/hard, round, well-circumscribed vesicles or pustules; as they evolve, lesions may become umbilicated or confluent
3. Lesions in the same stage of development: on any ONE part of the body (e.g., the face, arms) all the lesions are all in the same stage of development (i.e., all are vesicles or all are pustules)

Minor Diagnostic Criteria for Smallpox:

1. Centrifugal distribution: greatest concentration of lesions on face and distal extremities
2. First lesions on the oral mucosa/palate, face, or forearms
3. Severity: Patient appears toxic or moribund
4. Slow rash evolution: lesions evolved from macules to papules to pustules over days (each stage lasts 1-2 days)

5. Lesions on the palms and/or soles

- F. Guidance for Clinical and Public Health Management

High risk: If high risk after assessment with *Evaluating Patients for Smallpox* tool, obtain Infectious Disease and/or Dermatology consultation (these specialty medical providers are experienced in assessing rashes), and if still high risk:

1. Classify as a probable smallpox case and treat as a medical and public health emergency.
2. Report the case immediately to state/local health department.
3. State health department will evaluate the case; if state health department determines the case to be high risk for smallpox, the state will contact CDC at 770-488-7100 for assistance including specimen collection and testing.
4. Take digital photos for consultation with experts.
5. Treat patient as clinically indicated. Do not delay treatment for other likely conditions in the differential diagnosis while awaiting response team.
6. ***Do not proceed with laboratory testing for other diagnoses until smallpox has been ruled out.***

Moderate Risk: If moderate risk after assessment, obtain infectious diseases and/or dermatology consultation urgently (if available); proceed with laboratory testing for confirmation or exclusion of varicella or other diagnoses in the differential diagnosis. Initiate treatment for likely etiology as clinically indicated. Preferred tests for rapid identification of varicella-zoster virus are discussed below.

Low Risk: If low risk after assessment, test for varicella if diagnosis is uncertain and manage as clinically indicated.

- G. Laboratory and Pathology Testing of Specimens for Varicella-Zoster Virus (VZV)

It is important to collect >3 good specimens from each patient for routine and confirmatory testing. No test can distinguish between chickenpox (varicella) and disseminated shingles (disseminated herpes zoster) since the same virus causes both conditions. Herpes zoster is a reactivation of the virus that persists in a dormant state in the body from the time of initial infection with chickenpox. The two conditions are distinguished on the basis of prior evidence of immunity or previous

disease and careful history of an initial locally (dermatomal) distributed rash before dissemination.

Preferred tests for rapid diagnosis of varicella-zoster virus include:

1. Direct fluorescence antibody (DFA)—rapid method for detecting VZV directly in cells using anti-VZV antibody conjugated to fluorescein dye. This technique is very sensitive and specific, but is critically dependent on careful specimen collection. Avoid contamination of the specimen with blood, since VZV antibodies introduced from the blood can result in false negatives. Do not draw fluid from a vesicle using a syringe since cellular material is needed for testing. DFA testing is available in many private laboratories and in academic medical (tertiary care) centers.
2. Polymerase chain reaction (PCR) is one of the most sensitive and specific methods available; it requires 4-6 hours using real time PCR. PCR is not widely available, though some private laboratories and tertiary care hospitals have this capability, in addition to public health laboratories. Specimens may include skin lesions, crust, oropharyngeal secretions, blood, or CSF.
3. While not specific for VZV, the Tzanck smear is widely available, and can be performed in a hospital pathology laboratory. A positive smear confirms an alpha herpes virus infection (VZV or HSV).

Note: Training state health laboratories on rapid diagnostic VZV has been provided through the laboratory response network. By the end of 2002, all states have the capacity to perform at least one rapid diagnostic VZV laboratory test.

V. Pre-Event Enhanced Surveillance Strategies

- A. Both smallpox and varicella should be made reportable in each jurisdiction to facilitate timely and appropriate public health response to a reported case.
- B. Smallpox surveillance should be integrated with varicella surveillance. Efficiency is likely to be gained by integration with varicella surveillance programs, since varicella is the most common illness that will be confused with smallpox. Varicella deaths have been reportable since 1999. Since varicella will become a nationally notifiable disease in 2003, states and localities should be in the process of developing or enhancing disease-specific surveillance. Understanding varicella epidemiology in your state or local area and understanding how varicella disease presents, especially among adults, will be useful in responding to calls of cases of acute vesicular or pustular rash illness.

State enhancements to varicella surveillance that will assist in enhancing smallpox surveillance may include:

- Reporting all varicella hospitalizations,
 - Reporting varicella cases among adults within 12 hours of rash onset,
 - Laboratory confirmation of varicella cases resulting in hospitalization or death.
- C. State and local health departments are encouraged to undertake enhanced surveillance for febrile rash illness. Additional strategies to consider include coordination with other existing surveillance systems such as measles and rubella surveillance and/or fever-rash illness surveillance established as syndromic surveillance under the bioterrorism cooperative agreement.
- D. Establishing and/or enhancing rapid laboratory diagnostic testing for confirmation of varicella zoster virus (VZV) infections is important for evaluation of varicella cases that raise suspicion for smallpox. Additional laboratory and pathology diagnostic services (e.g., as indicated for a case evaluated as medium or low risk) may assist in diagnosis of other diseases that may be confused with smallpox.
- E. Personnel Preparedness
1. Identify clinical personnel to assist with evaluation of cases that are reported to the health department (e.g., infectious disease, dermatology).
 2. Identify state/local staff for conducting surveillance activities.
 3. Familiarize key public health and clinical personnel with the algorithm and protocol for evaluating patients with febrile vesicular-pustular rash illness.
 4. Familiarize key public health personnel with smallpox response plan and guidelines, both federal as well as any existing state/local plans.
 5. Establish liaison with state and/or local law enforcement and emergency management officials.
- F. Training and Education in High Priority Content Areas for Public Health Staff
1. Surveillance for febrile vesicular or pustular rash illness.
 2. Smallpox diagnosis and indications for laboratory testing including understanding of the predictive value of a positive test (and the widespread ramifications of a false positive test).
 3. Case investigation/interview methods and skills.
 4. Isolation and infection control guidelines.
 5. Laboratory specimen collection methods.
 6. CDC Rash Illness Evaluation module, available at <http://www.cdc.gov/nip/ed/smallpox-trg/clinician-should-know/default.htm>
- G. Training and Education in High Priority Content Areas for Health Care Providers
1. Evaluation of febrile vesicular-pustular rash illness.

2. Smallpox diagnosis and indicators for lab testing including understanding of the predictive value of a positive test (and the widespread ramifications of a false positive test).
3. Procedures for reporting suspect cases to state/local public health authorities.
4. Isolation and infection control guidelines.
5. Laboratory specimen collection methods.
6. CDC Rash Illness Evaluation module, available at (<http://www.cdc.gov/nip/ed/smallpox-trg/clinician-should-know/default.htm>)

H. Case Reporting

1. Promulgation of clinical case definitions and case classifications for smallpox and varicella, establishing capability to do rapid diagnostic tests for varicella zoster virus infections (both varicella and disseminated herpes zoster), developing information management systems to monitor calls/reports received, building capability for enhanced rash illness surveillance, and designating case reporting mechanisms.
2. Designate centralized location for reporting suspect smallpox cases with 24/7 capability.
3. Identify and test after hours/emergency notification systems; ensure that on-call staff has appropriate access to communication resources (cell phones, pagers, laptops, etc.).
4. Pre-event case investigation forms.
5. Data management procedures.

I. Enhance laboratory capacity

1. Rapid diagnostic testing for varicella include:
 - a. DFA,
 - b. PCR, and
 - c. Tzanck smear (indicates alpha herpes virus infection).
2. Laboratory capacity for obtaining specimens, handling and shipping to CDC or surge laboratory capacity.

VI. Activities to Prepare for Smallpox Post-event Surveillance

Prior to the identification of a case of smallpox:

1. The number and kinds of personnel necessary for an adequate response to confirmed smallpox case and/or an outbreak should be estimated,
2. Staff and volunteers should be trained,
3. Equipment and logistic needs estimated,
4. Facilities should be identified and equipped, and
5. Table top or simulation exercises should be performed.

Staff and volunteers should include:

1. Epidemiologists,
2. Case interviewers,
3. Contact tracers,
4. Supervisors,
5. Public health advisors,
6. IT personnel,
7. Data enterers,
8. Data analysts,
9. Administrative personnel,
10. Telephone interviewers,
11. Communications personnel,
12. Security personnel, and
13. Transport staff.

A committee or team may be formed with oversight in the areas of surveillance and epidemiology, contact related activities (identification, tracing, vaccination, and surveillance), and data management. Requirements for equipment and logistics include:

1. Adequate space,
2. Office equipment and supplies,
3. Computer support,
4. Transport, and
5. Safety.

Required communications equipment includes:

1. Telephone lines,
2. Telephone banks,
3. Cell phones,
4. Pagers,
5. Computers, and
6. Printers.

Preparatory activities for post-event surveillance include:

1. Identifying state/local personnel resources available for information management with links to laboratories and vaccination sites.
2. Identifying state/local resources (team or committee) for coordinating surveillance activities, contact tracing related activities, and epidemiological investigation in a smallpox emergency.
3. Establishing redundant mechanisms for information collection/reporting from reporting sources.
4. Establishing points of contact with potential reporting sources and redundant means for communicating information to these sources in an emergency.

5. Developing forms for smallpox surveillance, contact identification, tracing, vaccination and surveillance, and source of exposure for use in a smallpox emergency.
6. Establishing methods for reporting, retrieving laboratory results, confirming diagnoses for probable and suspected cases, and follow-up.
7. Identifying state/local lead for coordinating interviews of confirmed, probable, and suspected cases to determine travel history and contact lists.
8. Identifying local/state resources available for conducting interviews of confirmed, probable, and suspected cases.
9. Identifying local/state resources available for contact tracing.
10. Identifying local/state resources available for telephone monitoring of identified contacts.
11. Designating local/state personnel responsible for activities involving initial epidemiologic investigation, determining initial source of outbreak, identifying the population at risk, and describing the epidemiological features of the outbreak.
12. Determining other non-personnel resource needs for conducting surveillance, contact tracing, epi investigation (e.g., computers, database and analytical software, telephone/fax surge capacity, city telephone/residence listings, city maps, etc.).
13. Identifying needed vaccination resources (see Guide B—Vaccination Guidelines for State and Local Health Agencies).
14. Identifying procedures to use during a smallpox outbreak (e.g., at least daily meetings or conference calls) to ensure appropriate communication with other programs (communications, vaccination, isolation and quarantine, etc.).

VII. Post-Event Surveillance and Case Reporting; Contact Identification, Tracing, Vaccination, and Surveillance; and Epidemiologic Investigation

Although the specific mechanisms and logistics may differ among jurisdictional areas, the post-event activities will include:

- Surveillance and case reporting.
- Contact identification, tracing, vaccination, and surveillance.
- Epidemiologic investigation - investigation for source of infection (conducted for initial cases in a geographic area only).

The level of investigation and reporting of smallpox cases will depend on the extent of the outbreak and the resources available to conduct these activities. In a limited outbreak, all information on the surveillance form should be obtained, whenever possible. In a larger outbreak, the state epidemiologist may decide, based on available resources, to limit data collection to selected variables. In very large outbreaks, surveillance and case reporting may be limited to aggregate reporting of cases and deaths by age group.

Forms are available to assist in these investigations, and are summarized in [Appendix 4](#) of this Guide. The forms are grouped into three categories:

- Surveillance and case reporting (Form 1),
- Contact identification, tracing, vaccination, and surveillance (Form 2 A-F), and
- Epidemiologic investigation (Form 3 A – C).

These forms, with instructions for use and completion, are found in Appendices 4-14 for Guide A (Table 3). Interviewers must be trained to use appropriate interviewing methods and techniques; individual form completion is strongly recommended. A computer system for data entry and analysis will be available from the federal health authorities.

A. Post-Event Smallpox Surveillance Strategies

The State Health Officer should designate a single person from the state and/or local health department to help coordinate overall smallpox case surveillance and reporting activities for the state or local public health jurisdiction. This person should estimate the number and kind of personnel necessary for performing these functions and request the needed assistance from the State Health Officer, who may then request federal assistance as needed. The state or local designee for surveillance coordination should work closely with state and Federal health authorities on all aspects of smallpox surveillance and case reporting; contact identification, tracing, vaccination, and surveillance; and the epidemiologic investigation.

A written state smallpox response plan that includes a plan or guide for pre-event and post-event smallpox surveillance and response should be prepared. Once the Smallpox Response Plan has been implemented, the state, regional, and local public health authorities with jurisdiction in the area where the case or cases were identified should initiate immediate active and enhanced passive surveillance for additional suspected and confirmed cases. Specific mechanisms and logistics for surveillance may differ between jurisdictional areas. However, the general guidelines outlined in this section should be followed.

The following surveillance activities are outlined for use in an outbreak of smallpox. Since smallpox no longer exists as a naturally occurring disease, an outbreak of smallpox is defined as a single laboratory confirmed case. Activities and actions described within this section may be altered depending upon the size and characteristics of the outbreak. If this occurs, information regarding the new procedures or actions will be communicated to health department personnel by the state health officer, other state health office personnel, or federal health authorities.

Table 3. List of Appendices for Guide A

Form Number and Name	Purpose	Appendix Number
Forms Overview for Smallpox Response Plan Guide A	Summarize the purpose of the forms designed for smallpox surveillance and case reporting; contact identification, tracing, vaccination, and surveillance; and epidemiologic investigation	4
Form 1: Post-Event Surveillance	Smallpox surveillance and case reporting	5
Form 2a: Case Travel/Activity Worksheet—Infectious Period	Records case's activities during infectious period for contact identification	6
Form 2b: Primary Contact/Site Worksheet	Contact identification & prioritization and site identification	7
Form 2c: Contact Transportation Worksheet—Infectious Period	Contact and site identification	8
Form 2d: Contact Tracing	Contact identification, referral for vaccination and evaluation	9
Form 2e: Case Household and Primary Contact Surveillance	Contact surveillance for vaccine take, as well as fever and symptoms	10
Form 2f: Case Primary Contact's Household Members Surveillance	Contact surveillance for vaccine take, as well as fever and symptoms	11
Form 3a: Case Exposure Investigation	Identify exposure source	12
Form 3b: Case Travel/Activity Worksheet—Exposure Period	Identify exposure source (exposure period)	13
Form 3c Case Transportation Worksheet—Exposure Period	Identify exposure source (exposure period)	14

A single, laboratory confirmed case will initiate implementation of the CDC and state smallpox response plans. Other criteria for implementation of the response plan include:

- A large outbreak of a clinically compatible illness pending etiologic confirmation;

- Reports of suspected or probable cases once an outbreak has been identified elsewhere in the country; and
- Confirmation of smallpox virus in an environmental sample, package, or device associated with human exposure.

Surveillance, outbreak investigation and control activities including contact identification, tracing, vaccination and surveillance will need to be prioritized once smallpox is confirmed in a local jurisdiction. Following the confirmation of a smallpox case, especially if it is the first case confirmed in the United States, an epidemiological investigation will need to occur in collaboration with law enforcement and state and federal authorities. If a smallpox case is confirmed anywhere in the United States or in the world, enhanced surveillance for smallpox should be initiated and decisions on vaccination will be made in collaboration with state and federal authorities.

1. Strategies for post-event enhanced smallpox surveillance include:
 - a. Making smallpox and varicella reportable if they are not already reportable.
 - b. Establishing active surveillance for smallpox cases from designated smallpox facilities, other hospitals, ERs, and laboratories.
 - c. Establishing enhanced passive surveillance from all health care providers.
 - d. Establishing enhanced passive surveillance from institutions such as schools, child care centers, homeless shelters, correctional facilities, and other institutions.
 - e. Establishing a protocol for active surveillance for fatal cases by reviewing all deaths from rash illnesses each week; deaths due to hemorrhagic conditions and unexplained deaths should be included.
 - f. Establishing worksite or event-specific surveillance where the initial smallpox attack or exposures may have occurred.
 - g. Designating staff at all hospitals (e.g., infection control practitioner) to review current and newly admitted hospitalized patients for confirmed, probable and suspect cases.
 - h. Reviewing and following up on reported varicella cases.
 - i. Establishing targeted surveillance, depending on the epidemiology of the outbreak, to ensure appropriate case ascertainment in hard-to-reach populations (e.g., homeless, migrant workers).
 - j. Establishing mechanisms to allow for retrospective surveillance, in order to identify the earliest cases that may have occurred before the smallpox outbreak was recognized.
2. In addition to the recommendations in this Guide, steps for managing large numbers of reports of suspected cases for smallpox include:
 - a. Establishing procedures and referral facilities for management, isolation, and evaluation of suspect cases.

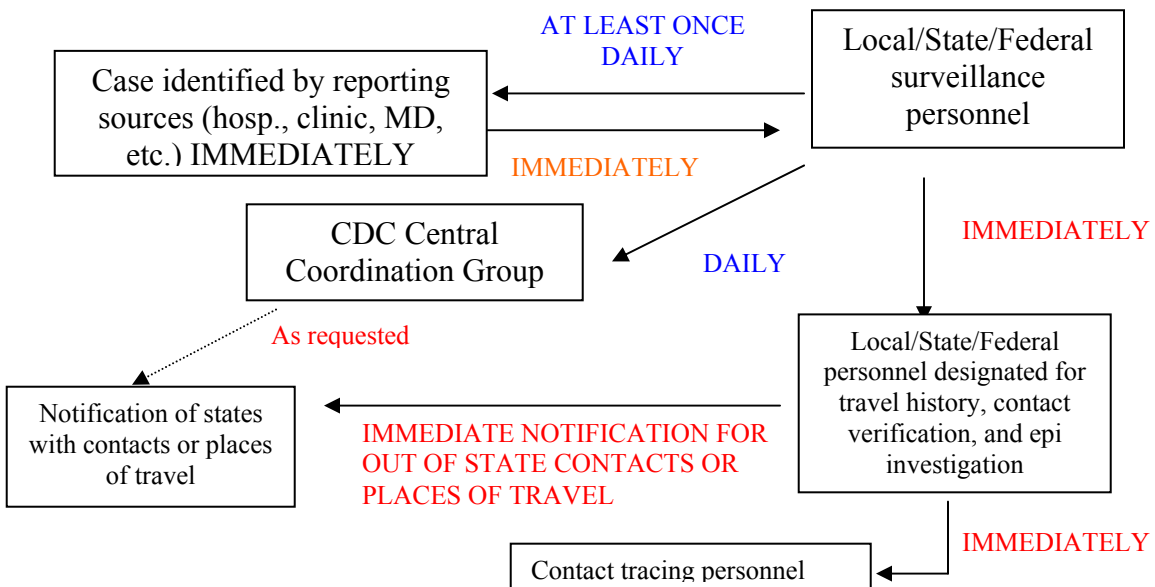
- b. Providing appropriate communication with the public regarding steps to take with suspected smallpox.
- c. Implementation of the recommendations in Guide B for vaccination guidelines for state and local health agencies.
- d. Implementation of the recommendations in Guide C for infection control measures for healthcare and community settings and quarantine
- e. Implementation of the recommendations in Guide D for specimen collection and transport.
- f. Implementation of the recommendations in Guide E for communication plans and activities.

B. Surveillance and Case Reporting

1. Case Reporting

Figure 1 describes reporting and information flow for post-event smallpox surveillance. Single cases of suspect, probable, and/or confirmed smallpox should be reported immediately (by telephone) from reporting health care providers. Smallpox facilities should report smallpox cases daily, updating the list of suspect, probable, and confirmed cases.

Figure 1. Surveillance Reporting and Information Flow



Each jurisdiction should establish multiple mechanisms for reporting confirmed, probable, and suspected cases to public health surveillance personnel and should communicate these mechanisms to all reporting sources (hospitals, clinics, private physician offices, etc.). Designated smallpox facilities (types C and X) should have daily communication with public health authorities, to report and update lists of confirmed, probable, and suspect cases. Redundant systems may be required due to potential communication problems. Such mechanisms for reporting may include:

- a. Secured fax,
- b. Secured Web-based reporting,
- c. Database transmission via modem to health department server,
- d. Direct telephone reporting (provide a telephone hotline for reporting cases),
- e. E-mail transmission,
- f. Hand-carried reports, and
- g. Other traditional methods of disease reporting that are timely

[Form 1 \(Appendix 5\)](#), the “Smallpox Post-Event Surveillance Form,” has been developed to provide guidance for the surveillance and reporting of suspect, probable, or confirmed cases of smallpox.

Smallpox surveillance forms (Form 1, Appendix 5) should be distributed to all reporting sources. In addition, the clinical case definition and case classifications should be distributed to all reporting sources, including public health staff; hospitals; emergency rooms; clinics; and other health care providers. Reporting sources in the community, such as correctional facilities, schools, homeless shelters, and child care centers should also receive forms and instructions.

Public health officials should encourage reporting of all suspected, probable and confirmed cases and should coordinate with designated staff to ensure appropriate isolation, management, and surveillance of cases in specially designated facilities. These facilities may include Type C, Type X, Type R, and/or even the case’s or contact’s home (e.g., suspect cases that are not ill with no epidemiological link to a case). See [Guide C — Infection Control Measures for Healthcare and Community Settings and Quarantine Guidelines](#), for additional assistance. (*note: this section will be harmonized with Guide C as it is revised*).

All reported probable and suspect cases and their contacts should be immediately vaccinated (see Guide B — Vaccination Guidelines for State and Local Health Agencies, [part 1](#), [part 2](#), and [part 3](#)), pending laboratory test results for other diagnoses or clinical progression of disease.

Laboratory reporting should be strengthened, including variola, vaccinia and generic orthopox testing. Reporting from designated laboratories is essential for confirmation of other causes of rash illness, most importantly varicella zoster virus (VZV) infections.

2. Data Collection

While Form 1 is designed to provide complete surveillance and reporting information for each case, the size of the outbreak may require reprioritization of resources from extensive data collection. For those situations, a list of the data of highest priority has been identified (circled variables on Form 1). These data should be collected by the reporting source and reported to surveillance personnel for each suspected, probable, and/or confirmed case. The minimum data include:

- a. State,
- b. Case ID,
- c. Name of person reporting case,
- d. Contact telephone number for person reporting case,
- e. Date case reported,
- f. Last name, first name and alias or nickname of suspected/probable/confirmed case,
- g. Home address of case ,
- h. Telephone number of case,
- i. Date of birth,
- j. Gender,
- k. Smallpox vaccination ever (yes/no),
- l. Date of smallpox vaccination,
- m. Date of fever onset,
- n. Date of rash onset,
- o. Clinical type of smallpox,
- p. Known exposure to suspected/confirmed or probable case (yes/no),
- q. Name of first hospital or isolation center where case was admitted,
- r. Outcome (complications, death),
- s. Lab confirmation, and
- t. Case status (confirmed, probable, or suspected).

If time/personnel constraints permit, additional information to be collected includes:

- a. Timing of smallpox vaccination and recording of take,
- b. Pre-existing medical conditions and medications,
- c. Pregnancy status, if female,
- d. Details on clinical illness including prodromal symptoms, lesion distribution,
- e. Treatment, including anti-viral therapy,
- f. Laboratory test results, and
- g. Transmission setting.

Out-of-state contacts or places of travel should be immediately reported to other states through existing state-to-state reporting mechanisms. The reports may also be forwarded to the CDC coordination group, especially in the early stages of the first case investigations to facilitate interstate communication.

3. Data Management

Post-event surveillance and case reporting will be enhanced by data management systems designed to address the challenges of smallpox. [Appendix 15](#) presents a flow diagram of the forms' physical workflow, as well as the data system designed to capture the data collected on the forms (Appendices 5-14).

Each jurisdiction should establish a centralized place and dedicated telephone numbers for receiving telephoned and faxed reports. In addition, dedicated computers for accepting electronic reports should be identified.

A database with the collected surveillance information should be established and maintained for all confirmed, probable, and suspected cases. Links to establish electronic laboratory reporting will enhance data management. Surveillance data should be reported on a daily basis to the CDC Coordination Group. This group will be responsible for maintaining the national surveillance database, reporting national data to DHHS and helping with notification for out-of-state contacts, if requested by a state.

C. Contact identification, tracing, vaccination, and surveillance

A single person should be designated by the state health officer to coordinate tracing, interviewing, arranging for vaccination, and surveillance of contacts. Additional personnel should be provided from state resources as needed. All contact information obtained by the case interviewers and the related forms should be given to the designated supervisor to coordinate contact tracing activities. Vaccination of contacts and their contacts (search and containment, also known as ring vaccination) is the primary strategy for outbreak control. Contact tracing activities should continue throughout an outbreak even if widespread community or mass vaccination is offered. After review of contact priority lists and available resources, a decision may be made by state authorities to limit contact-related activities to the highest priority group(s) only. In all situations, however, household contacts should be identified, vaccinated, and monitored.

Contact identification, tracing, vaccination, and surveillance will require significant personnel resources. It is likely that even in a small to moderate outbreak of disease, dozens to hundreds of personnel need to be trained and involved in all aspects of contact tracing, surveillance, and follow-up. The personnel working on these activities should be those identified with field experience with contact tracing (e.g., from STD, TB or HIV

control programs). In addition, all personnel designated for case interviews or contact tracing activities should be vaccinated prior to initiating their first face-to-face interview with a suspected, probable, or confirmed case or contact tracing activities.

Forms 2 A – F were designed to provide guidance for contact identification, tracing, vaccination, and surveillance. Forms 2 A – C allow the interviewer to record information about the case and contacts during the infectious period, to facilitate contact identification. Form 2 D is for contact tracing, form 2 E provides a form for the primary contacts to record relevant information about themselves, and 2 F provides a form for secondary contacts to record vaccination information.

Forms dedicated to identifying contacts include name, contact information, and travel history, all of which must also be obtained from the case or next of kin. Names and contact numbers for face-to-face contacts from the onset of the case's fever until presentation for evaluation. This information is collected in order to identify individuals who may have been exposed to an infectious case. Tracing contacts following onset of fever allows a time buffer for cases where date of rash onset, and thus "time of infectiousness," may have not have been clearly recognized by the case. This information, including places visited (in daily activities) and travel history since onset of symptoms (fever), allows the interviewer to identify potential unrecognized contacts.

1. Identification, tracing, and vaccination of contacts

A supervisor for the contact tracing team should be identified. Personnel assigned to trace contacts will receive names and any known address, telephone number(s), or other locating information for the primary contacts from the supervisor. The number of contacts for each case may require a very large number of personnel to be identified, trained, and made available for contact tracing and follow-up activities. [Appendix 16](#), "Using Forms and Worksheets for Contact Identification, Tracing, Vaccination, and Surveillance" provides additional details about the use and interrelationship of the forms and data management.

Contact: a person who has been exposed to the risk of infection

Primary contact: person with contact with a confirmed, probable, or suspected case of smallpox during the infectious period. Primary contacts include both household and nonhousehold contacts. Risk of smallpox transmission is increased with increased duration of face-to-face contact of ≤ 2 meters (≤ 6.5 feet). Priority categories for contacts, from highest priority to lowest, are as follows:

- a. Case household family members and others spending 3 or more hours in the household since the case's onset of fever.
- b. Nonhousehold members with contact ≤ 2 meters (≤ 6.5 feet) with case with rash for 3 or more hours.

- c. Nonhousehold members with contact ≤ 2 meters (≤ 6.5 feet) with case with rash for fewer than 3 hours.
- d. Nonhousehold members with contact ≤ 2 meters (≤ 6.5 feet) or more with case with rash for 3 or more hours.
- e. Nonhousehold members with contact ≤ 2 meters (≤ 6.5 feet) or more with case with rash for fewer than 3 hours.

Household contact: person who lives or works in the same household as the case
Nonhousehold contact: person who does not live or work in the case household

Secondary contact: household members of all primary, non-household contacts and persons who work in the household of a primary contact

Contact tracing personnel should:

- a. Trace each contact whose name, address and/or telephone number is given to them.
- b. Use work and school contact numbers, telephone directories, voting lists, neighborhood interviews, site visits, "hangouts," etc. to trace contacts when contact information is unknown or incomplete. If contacts cannot be found through these mechanisms, other sources for notification of potential contacts (such as media announcements) may have to be considered.
- c. Locate and interview each primary contact to confirm contact with the suspected, probable, or confirmed smallpox case, the presence or absence of symptoms in the contact (fever and/or rash) and to identify additional contacts that may not have been listed by the case.
- d. Identify household contacts of the primary contact of the smallpox case (secondary contacts).
- e. Arrange for immediate vaccination of the primary contact and his/her household contacts (secondary contacts). Either vaccinate contacts in the household (if this is feasible with vaccine supply, security issues, and resources) or provide a vaccination ticket with identifying information and designate a vaccination facility for the contact(s) to attend as soon as possible. *It is extremely important for smallpox outbreak control to vaccinate contacts as an urgent priority. In the past, when vaccination was done in the household, this task was given priority over transportation of a case to an isolation facility.*
- f. If the primary contact is symptomatic with fever or rash,

arrangements should be made for prompt vaccination and transportation of the contact to a Type C facility or other designated evaluation site for medical evaluation to rule out smallpox. Contacts with symptoms should be counseled, interviewed and reported as a suspected case using the appropriate smallpox surveillance (case reporting) form and his/her contacts should be identified, interviewed, and vaccinated as soon as possible.

- g. If the primary contact does not have fever or rash, vaccinate or arrange for prompt vaccination and place the contact under surveillance so that if the contact develops fever or rash he or she is immediately isolated and evaluated and does not expose other persons to smallpox (see below).
- h. 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).
- i. Each household contact should be provided with a vaccination ticket (this may be with his/her form 2d number according to current draft forms) and instructed to attend a designated vaccination clinic site as soon as possible.
- j. If they discover that any contacts have left the state, the contact tracers should notify the supervisor responsible for out-of-state contacts. The supervisor will then notify the appropriate authorities.

2. Surveillance (monitoring) of health status and vaccine “take” of contacts

Surveillance is conducted for early signs of smallpox disease (fever on 2 consecutive days and/or rash) and for vaccine “take.” Contacts are provided with a health department phone number to call if they develop any of the severe vaccine adverse reactions shown on the Vaccine Information Statement. Ideally, and if resources are available, primary contacts who do not have fever or rash at the time of interview should remain under active surveillance for 21 days after their last contact with the smallpox case, or 14 days following successful vaccination. [Appendix 16](#), “Using Forms and Worksheets for Contact Identification, Tracing, Vaccination, and Surveillance” provides additional details about the use and interrelationship of the forms and data management.

D. Epidemiological investigation

Following identification of a smallpox case or cases in a community, especially the first case(s) confirmed in the United States, a criminal investigation will be conducted to determine the source of introduction of smallpox virus. The state epidemiologist or his/her designee should coordinate the epidemiological investigation in collaboration with federal health authorities. The lead state and federal staff will coordinate all aspects of the investigation with other relevant state and federal authorities including the Federal Bureau of Investigation (FBI), police, quarantine officials, and others. If indicated, the epidemiological investigation may be performed in conjunction with contact identification and verification activities. An estimate of the number and kind of personnel necessary for performing these functions should be made and additional assistance requested as needed.

1. Smallpox occurrence

Epidemiologic investigation should consider that because smallpox no longer occurs as a naturally-acquired infection, there are two most likely causes for smallpox initial reappearance into the human population, including:

- a. Infection caused by exposure of a nonimmune person to smallpox as a result of accidental release or inoculation during approved laboratory research involving the virus or exposure to inadequately sterilized material generated during laboratory research involving the virus. Currently there are only two WHO-approved smallpox virus research and repository laboratories which include the CDC in Atlanta, Georgia and the Institute of Virus Preparations in Moscow, Russia (both laboratories have undergone frequent WHO inspections and have stringent safety and security procedures in place).
- b. Infection caused by exposure of a nonimmune person to smallpox as a result of accidental release or inoculation during non-approved laboratory research involving the virus or exposure to inadequately sterilized material generated during non-approved laboratory research involving the virus
- c. Infection caused by an intentional release of the smallpox virus into the population either by infecting a person or by releasing smallpox virus via an aerosol or other device.

2. Data collection

Much of the epidemiological investigation may be performed in conjunction with identification and evaluation of potential smallpox cases including contact identification and followup. However, because of the urgency of the outbreak,

adequate personnel must be available to collect and analyze data that would allow rapid:

- a. Identification of the most likely source of initial exposure (hopefully within 24 hours of the first confirmation of smallpox). *This may require extensive trace-back capabilities if the initial recognition and confirmation of smallpox occurred later than the first generation of disease in the outbreak.*
 - b. Identification or estimation of the population at risk. To the extent possible, the population at risk should be identified. Exposure could be due to an infected person present at a specified location; use of a specified mode of transportation; or presence at a location of suspected smallpox virus release. These persons should be placed under surveillance. Public health actions to consider would include offering smallpox vaccine to the exposed population and to their household contacts.
 - c. Identification of any unexpected epidemiological features of the outbreak (e.g., unusual presentation, morbidity, mortality, incubation period, transmission, and affected population).
 - d. Evaluation of characteristics and extent of the outbreak to develop the most effective containment strategies.
3. Expected epidemiological features of smallpox (*Note: historical experience may not apply if the smallpox virus is genetically altered*)
- a. Incubation period is about 12 days (range 7 to 17 days).
 - b. Person-to-person spread by droplet transmission (most common), contact with material from pustules/rash lesions or contaminated clothing or bedding (less common), or small particle aerosol (least common).
 - c. Smallpox cases are generally not infectious to others until the onset of rash (approximately 7 to 17 days after exposure). However, since exact date of rash onset may not be noted accurately and because of the infectious enanthem which may precede rash onset by 1 to 2 days, cases should be considered potentially infectious from date of fever onset.
 - d. Period of highest transmissibility is during the first 7 to 10 days after onset of rash. However, a person is considered infectious until all scabs have separated. The risk of contracting disease increases with duration and intensity of exposure.
 - e. Persons at greatest risk for disease are household members and persons who have had face-to-face contact with a case after the onset of rash.

- f. During the smallpox era, the seasonal transmission of disease was highest during winter and early spring.
- g. Cases are likely to occur in all age groups due to the lack of population immunity in the United States. Cases may be less severe among adults > 30 years who may have received one or more smallpox vaccination in the past. Childhood vaccinations were halted in the United States in 1972.
- h. Historically, up to 30% of unvaccinated smallpox cases resulted in death. The case-fatality ratio (CFR) may be greater because of a:
 - Lack of natural immunity,
 - High percentage of non-vaccinated persons in the U.S. population, and
 - Larger immunocompromised population compared to the smallpox era.

The CFR may be lower because of:

- Better intensive care and medical treatment options than were available 30 years ago and
 - Partial immunity among the adult population.
- i. Historically, the secondary attack rate among susceptible household contacts was approximately 58% (range 38% to 88%).
 - j. The outbreak experience in Europe suggested that in a susceptible population, a single case of smallpox would be expected to result in 5-7 secondary cases, which is lower than observed for some other vaccine-preventable diseases (e.g., measles, pertussis). The relatively low transmission of smallpox resulted from the severe initial prostration of persons with smallpox and the prolonged contact required for transmission in most instances.

4. Information Systems Management

[Appendix 15](#) of this Guide provides a flow diagram describing the information management for post-event smallpox surveillance and case reporting; contact identification, tracing, vaccination, and surveillance; and epidemiologic investigation.

Guide A: List of Appendices

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