

Smallpox Investigation Guideline

This guideline simply outlines information about the disease management and investigation of smallpox. The user **MUST** refer to the Kansas Biologic Incident Annex (BIA) and any supporting local standard operating guides (SOGs) for additional information managing a response to a smallpox situation.

If you suspect that you are dealing with a smallpox situation, contact the local Health Officer, on-call epidemiologist and the State Health Department immediately for assistance.

CONTENT:

VERSION DATE:

Investigation Protocol:

- Investigation Guideline 07/2012

Investigation Forms / Documentation Worksheets:

- Worksheet: Evaluating Patients for Smallpox 06/2008
- Post-event CDC Forms (in attachments) (Vs. 3.0) 11/2002

Supporting Materials found in attachments:

- Fact sheet 03/2010

Revision History:

Date	Replaced	Comments
07/2012	02/2012	Addition of notification section.
02/2012	-	Removed references to KS-EDSS.

Smallpox

Disease Management and Investigation Guidelines

CASE DEFINITION (CDC 2004)

Clinical Description for Public Health Surveillance:

An illness with acute onset of fever $\geq 101^{\circ}$ F ($\geq 38.3^{\circ}$ C) followed by a rash characterized by firm, deep seated vesicles or pustules in the same stage of development without other apparent cause. Clinically consistent cases are those presentations of smallpox that do not meet this classical clinical case definition: a) hemorrhagic type, b) flat type, and c) variola sine eruptione. (Detailed clinical description is available on the CDC web site, see URL: <http://www.bt.cdc.gov/agent/smallpox/index.asp>).

Laboratory Criteria:

- Polymerase chain reaction (PCR) identification of variola DNA in a clinical specimen, OR
- Isolation of smallpox (variola) virus from a clinical specimen (Level D laboratory only; confirmed by variola PCR).

Note: Indications for laboratory testing of patients with suspected smallpox should be followed as described in detail in Guide A of the CDC Smallpox Response Plan. Laboratory diagnostic testing for variola virus should be conducted in Level C or D laboratories only.

Case Classification *:

Confirmed: 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: A case that meets the clinical case definition, or a clinically consistent case that does not meet the clinical case definition and has an epidemiological link to a confirmed case of smallpox.

Suspected: A case with a generalized, acute vesicular or pustular rash illness with fever preceding development of rash by 1-4 days

* Exclusion Criteria: A case may be excluded as a suspect or probable smallpox case if an alternative diagnosis fully explains the illness or appropriate clinical specimens are negative for laboratory criteria for smallpox.

Note: Use the above smallpox case definition only during post-event surveillance for reporting cases to the National Notifiable Diseases Surveillance System (NNDSS). The case definition for pre-event surveillance as found in Guide A of the Smallpox Response Plan and Guidelines (Version 3) on the CDC bioterrorism preparedness website (www.bt.cdc.gov/agent/smallpox/response-plan/index.asp) includes criteria for a suspected case that is more sensitive and less specific. This pre-event case definition allows a physician to immediately assess risk, independent of the epidemiologic case classification:

- **Suspect Case (pre-event surveillance):** A case with febrile rash illness with fever preceding the development of rash by 1-4 days.

LABORATORY ANALYSIS

Notify KDHE Bureau of Epidemiology and Public Health Informatics (BEPHI) immediately at 877-427-7317 of any suspect (pre-event) smallpox case considered to be of moderate or high risk. KDHE will assist in evaluating cases and contact CDC at 770-488-7100.

The process by which patients meeting the pre-event smallpox case definition will be tested depends upon the risk assessment of the patient.

- High risk: Do not proceed with laboratory testing for other diagnoses until smallpox has been ruled out by a Bio-safety Level C or D rated laboratory.
- Moderate risk: Proceed with laboratory testing for confirmation of exclusion of varicella or any other diagnoses included in the differential diagnosis determined during an infectious disease and/or dermatology consultation.
- Low risk: If diagnosis is uncertain, test for varicella or other potential agents through standard resources. Manage as clinically indicated.

For high risk patients, Kansas Health and Environmental Laboratory (KHEL) will forward specimens to a Bio-Safety Level C or D rated laboratory for testing.

- KDHE-BEPHI must be notified at 877-427-7317.
- CDC will then be contacted to request testing and guidance.

For moderate risk patients, KHEL will perform rapid diagnostic testing for varicella and non-variola orthopox. Notify KDHE-BEPHI before sending in specimens.

- Method: Polymerase chain reaction (PCR)
- Specimen: Skin lesion (>3 good specimens) as directed by KDHE guidelines for viral specimen collection; available in attachments and on-line: www.kdheks.gov/virosero/download/Viral_Culture_Specimen_Collection_Guide.pdf
- Packaging: Refer to **Virus Shipper Guide** and **Packaging and Shipping Checklists** at www.kdheks.gov/labs/packaging_and_shipping.html.

CDC website provides the following guidance on additional laboratory testing associated to smallpox and differential diagnosis:

- Specimen Collection of Smallpox (Vaccinia) Vaccine Virus: <http://emergency.cdc.gov/agent/smallpox/vaccination/vaccinia-specimen-collection.asp>
- Specimen Collection for Suspect Monkeypox: www.cdc.gov/ncidod/monkeypox/diagspecimens.htm

For additional information and/or questions concerning isolate collection, sample transport and laboratory kits call (785) 296-1620 or refer to the online resource guide at: www.kdheks.gov/labs/lab_ref_guide.htm

EPIDEMIOLOGY

In 1980, the World Health Organization declared that smallpox had been eradicated. The last naturally occurring case occurred in Somalia in 1977 and 2 cases attributed to laboratory exposure in 1978. The United States discontinued routine childhood immunization against smallpox in 1971 and the immunization of health care workers in 1976. The United States military continued to immunize their personnel until 1990. Officially, smallpox is now only found in designated research laboratories sites in the United States and Russia.

DISEASE OVERVIEW

A. Agent:

Variola virus, a species of Orthopoxvirus. The agent is the same for variola major (classic smallpox) and variola minor (a less serious form of the disease).

B. Clinical Description:

The rash preceded by a prodromal symptoms including: high fever lasting 3-4 days, headache, malaise, muscle pain, prostration, and occasionally nausea, vomiting, and backache. The trademark of the classic smallpox is a generalized vesiculopustular rash with lesions found more densely on the face and extremities (centrifugal), including the palms and soles. All lesions on any one part of the body usually appear as a single crop with all lesions progressing from the macular to the pustular stage at about the same time. The rash progresses from sparse macules (day 1), to papules (days 2), vesicles (days 3-4), pustules (days 5-12), and scabs (days 13-18) for a total duration of 2-3 weeks. Less common presentations of the smallpox rash include flat or hemorrhagic lesions. A rash that progresses through the stages more rapidly and has fewer lesions characterizes modified smallpox, which occurs more commonly among previously vaccinated persons.

Table 1: Conditions that might be confused with small pox and clinical clues for differentiation (modified from CDC Smallpox Response Plan Guide A)

Condition	Clinical Clues
Contact dermatitis	Itching; contact with possible allergens; rash often localized in pattern suggesting external contact
Disseminated herpes simplex	Lesions indistinguishable from varicella; immunocompromised host
Disseminated herpes zoster	Rash looks like varicella, usually begins in dermatomal distribution; immunocompromised or elderly persons
Drug eruptions	Exposure to medications; rash often generalized
Enteroviruses infection (especially 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)
Erythema multiforme major (Stevens-Johnson syndrome)	Major form involves mucous membranes and conjunctivae; there may be target lesions or vesicles
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)
Impetigo (<i>Strep. pyogenes</i> , <i>Staph. aureus</i>)	Honey-colored crusted plaques with bullae but may begin as vesicles; regional non-disseminated rash; patients usually not ill
Molluscum contagiosum	May disseminate in immunosuppressed persons
Monkeypox	Recent contact with exotic animals
Scabies; insect bites	Itching is a major symptom; patient is not febrile and otherwise well
Varicella (primary infections with varicella-zoster virus)	Most common in children <10 years; children usually do not have a viral prodrome

(Detailed description is available at www.bt.cdc.gov/agent/smallpox/index.asp.)

C. Reservoirs:

Humans are the only known hosts; there are no known animal reservoirs and/or vectors. Currently, it is officially only maintained in two WHO-designated laboratories.

D. Mode(s) of Transmission:

Infection usually occurred with respiratory tract (droplet spread) or skin inoculation. The conjunctiva and placenta were occasional portals of entry.

E. Incubation Period: Range, 7-19 days; average, 10-14 days to onset of first symptoms. Skin eruption appears 2-4 days after first symptoms.

F. Period of Communicability:

From the time of development of the earliest rash lesions to disappearance of all scabs; about 3 weeks. The period of highest transmission is during the first 7-10 days after onset of rash, however, a person is considered infectious until all scabs have separated. Since the exact date of rash onset may not be reported accurately in some cases, household contacts (including those spending 3 or more hours in household during the communicable period) should be considered potentially exposed from date of the case's fever onset. Non-household members are evaluated for exposure based on date of rash onset.

G. Susceptibility and Resistance:

Susceptibility is universal among the unvaccinated. Adults vaccinated as children and military personnel vaccinated in the late 1980's are also considered susceptible. Only individuals who have been recently vaccinated or who have recovered from recent infection should be considered to be resistant.

H. Treatment

Supportive only.

I. Vaccine:

Vaccine is made from "live" vaccinia virus which is a "pox"-type virus related to smallpox. The vaccination site must be cared for carefully to prevent the virus from spreading. (Refer to [Managing Special Situations for suspect vaccinia cases.](#))

Routine smallpox vaccination among the American public stopped in 1972 after the disease was eradicated in the United States. At this time, vaccination against smallpox is recommended for laboratorians who work with orthopox viruses and public health and health care response team members. The military also has a smallpox vaccination program. Information is located on the Department of Defense (DoD) Smallpox Vaccination Program Web site at www.smallpox.mil/. The smallpox vaccine is not available to the general public, at this time.

Currently, the United States has a stockpile of smallpox vaccine to vaccinate everyone in the United States in the event of a smallpox emergency. Vaccination within a 4-day period after exposure prevents or attenuates clinical illness.

NOTIFICATION TO PUBLIC HEALTH AUTHORITIES

As a potential bioterrorism agent, all confirmed or ***suspected*** smallpox cases shall be reported within **4 hours by phone**:

1. Health care providers and hospitals: report to the local public health jurisdiction or KDHE-BEPHI (see below)
2. Local public health jurisdiction: report to KDHE-BEPHI (see below)
3. Laboratories: report to KDHE-BEPHI (see below)
4. KDHE-BEPHI will contact the local public health jurisdiction by phone within one hour of receiving any suspected smallpox report.

**Kansas Department of Health and Environment (KDHE)
Bureau of Epidemiology and Public Health Informatics (BEPHI)
Phone: 1-877-427-7317**

Further responsibilities of state and local health departments to the CDC:

As a nationally notifiable condition, smallpox cases require an IMMEDIATE, EXTREMELY URGENT report to the Center of Disease Control and Prevention (CDC).

1. Any confirmed or probable smallpox case requires **IMMEDIATE, EXTREMELY URGENT** reporting.
 - KDHE epidemiologist must call the CDC EOC at 770-488-7100 within 4 hours of a being notified of the [confirmed](#) or [probable](#) case.
 - KDHE-BEPHI will notify the **Local public health jurisdiction** immediately to coordinate on follow-up for the report information needed to complete the electronic form before the next business day.
 - KDHE-BEPHI will file an electronic case report the next business day.

INVESTIGATOR RESPONSIBILITIES

When there are no smallpox cases anywhere in the world (pre-event), the local health department, as a resource for medical providers, ensures that:

- 1) Medical providers are aware of resources available to assist with the evaluation and risk assessment of suspect smallpox patients on the CDC Smallpox Diagnosis and Evaluation web page (www.bt.cdc.gov/agent/smallpox/diagnosis/)
 - Algorithm for “Evaluating Patients for Smallpox” poster
 - Interactive risk evaluation algorithm
 - CDC’s [Worksheet: Evaluating Patients for Smallpox](#)
- 2) Appropriate infection control practices, including isolation measures, are implemented in facilities evaluating the risk of smallpox-like illness in a patient.
- 3) Resources are available or obtainable to assist with any infectious disease / dermatological consultations or digital photography.
- 4) Immediate notification occurs to KDHE-BSE for any high risk case or for a moderate risk case requiring laboratory testing at KHEL.

After a probable or confirmed case of smallpox is identified, the local health department investigator will work with KDHE to:

- 1) Assist in epidemiological investigation.
 - Conduct [contact investigation](#), tracing and surveillance to identify additional cases or contacts requiring prophylaxis.
 - Conduct a [case investigation](#) to identify potential source of infection.
 - Conducting active surveillance to identify additional cases that are classified and reported with the current case definition
- 2) Assist in formulating and implementing disease control and prevention activities ([Case Management](#) and [Contact Management](#)):
 - Identify and isolate smallpox cases to prevent disease spread.
 - Identify, vaccinate, and monitor contacts of cases and household members of the case’s contacts, to prevent secondary cases.
 - Prioritize delivery of vaccine through collected exposure histories.
- 3) Assist in investigating and reporting post-vaccination complications.
 - Establish a process for surveillance and reporting of adverse reactions.
 - Prioritize delivery of vaccinia IG for adverse vaccine reactions

The local health department will also be involved in the implementation of additional measures in response to the smallpox incident. These activities are covered in the Kansas Biological Incident Annex (BIA) and the local health department standard operating guides (SOGs), including community containment, mass dispensing, and risk communications.

The activities described below only outline the activities of a local investigator and KDHE during the investigation of initial cases of smallpox in a community. Refer to the above mentioned resources for additional implementation measures and responsibilities.

Pre-event Activities

If a patient presents with acute, severe vesicular or pustular rash illness:

- 1) Institute recommended infection control measures with patient.
- 2) Immediately notify local public health officials of any suspected smallpox case.
- 3) Assess to determine risk of smallpox:
 - Determine risk using major and minor criteria.
 - Use "[Worksheet: Evaluating Patients for Smallpox](#)".
- 4) Patient follow-up at 24-, 48-, and 72- hours may be necessary.

Risk Categories for Smallpox

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

Major Smallpox Criteria:

1. **Febrile prodrome:** 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 vesicles or all pustules)

Minor Smallpox Criteria:

1. **Centrifugal distribution:** 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**

High risk:

- Report case immediately to KDHE at 877-427-7317.
 - KDHE will re-evaluate and contact CDC for assistance.
 - KDHE will notify the state Public Health Preparedness (BT) coordinator.
- Take digital photos for consultation with experts.
- Treat patient as clinically indicated, but do not proceed with laboratory testing until smallpox has been ruled out. (Refer to [Laboratory Analysis](#).)
- Public health investigators will classify the case as probable, begin a case investigation and assist with specimen testing coordination.

Moderate risk:

- Report case immediately to KDHE at 877-427-7317 for consultations and to request rapid diagnostic testing for varicella at KHEL.
- Obtain an infectious disease and/or dermatology consultation. (Digital photos may be needed for distant consultation.)
- Proceed with laboratory testing as directed in [Laboratory Analysis](#).
- Any public health investigation will depend on results of rapid diagnostic testing for varicella and any other differential diagnoses.

Low risk: Manage as clinically indicated. No need to notify KDHE.

STANDARD CASE INVESTIGATION AND CONTROL METHODS

Case Investigation

State Health Officer will designate a state incident command system (ICS) position to coordinate the smallpox case investigation activities. Coordination will occur with the local authority responsible for surveillance and reporting.

- 1) Laboratory testing will be coordinated, as described in [Laboratory Analysis](#).
- 2) The case's medical provider will be contacted to obtain the following information (including medical records for hospitalized patients).
 - Initial information collected on the [Evaluating Patients for Smallpox Worksheet](#) will be faxed to 1-877-427-7318
 - [CDC Form 1: Post-Event Surveillance](#) will be used to record and report information related to the suspected, probable or confirmed smallpox case. (Circled numbers are minimum required fields.)
- 3) Interview the case or proxy to determine identify potential contacts:
 - [Form 2A: Case Travel/Activity Worksheet – Infectious Period](#)
 - To determine primary residence and sites/locations visited; record household contacts and primary contacts for each site on Form 2B.
 - If travel/transportation use occurred since fever onset – use Form 2C.
 - [Form 2B: Primary Contact/Site Worksheet](#) – to record listing of primary contact names or sites mentioned in case's daily activities (Form 2A)
 - First, list case's household contacts then list other primary case contacts
 - Use Form 2B to initiate Form 2D for each contact.
 - [Form 2C: Contact Transportation Worksheet – Infectious Period](#) – to record travel and transportation history since onset date of fever
 - If potential contacts are identified based on interviews, contact investigation will occur. (Refer to [Contact Investigation](#) section.)
- 4) Interview the case or proxy, to determine case's source of exposure. (This may not be necessary for all cases.):
 - [Form 3A: Case Exposure Investigation](#) – to record possible exposures (individuals and places). Sample questions included on [page 2](#) assist with the collection of information for the forms below:
 - [Form 3B: Case Travel/ Activity Worksheet – Exposure](#) – to record case's activities during exposure period to identify possible sources
 - [Form 3C: Case Transportation Worksheet - Exposure](#) – to record travel history for 19 days before date of onset of fever.

Contact Investigation

State Health Officer will designate a state ICS position to coordinate contact investigation activities (i.e. contact tracing, interviewing, arranging for vaccination and surveillance of contacts.) Coordination will occur with the local authority responsible for contact investigation to accomplish the following.

- 1) Contact tracing teams will be formed and should consist of individuals trained in all aspects of contact tracing, surveillance and follow-up who are identified based on field experience. Prior to initiating first face-to-face interview with a case or contact, personnel should be vaccinated.

- 2) Supervisors are assigned, as needed, if multiple tracing teams are involved.
- 3) Contact tracing activities continue throughout an outbreak even if widespread community or mass vaccination is offered.
 - Contact-related activities may be limited to highest priority group(s) after a review of primary contact lists ([Form 2B](#)) and available resources.
 - Complete a [Form 2D: Contact Tracing](#) for all priority contacts.
 - Household contacts should always be identified, vaccinated, and monitored.
- 4) Contact: a person who has been exposed to the risk of infection. Risk of smallpox transmission is increased with increased duration of face-to-face contact of ≤ 2 meters (≤ 6.5 feet).
 - Primary contact: individual exposed to a smallpox case during the potential infectious period and includes:
 - o Household contact: case's family member and others spending >3 hours in the case's household **since the case's onset of fever**
 - o Non-household contacts: person who does not live or work in case's household, as defined above and prioritized based on the amount of time spent at a certain distance from a **case with a rash**
 - Secondary contact: household members of all primary contacts and persons who work in the household of that primary contact
- 5) Priority categories for contacts are defined below (highest to lowest priority):
 - Household contact
 - Non-household with contact <6.5 feet with case **with rash**, for ≥ 3 hours
 - Non-household with contact <6.5 feet with case **with rash**, for <3 hours
 - Non-household with contact ≥ 6.5 feet with case **with rash**, for ≥ 3 hours
 - Non-household with contact ≥ 6.5 feet with case **with rash**, for <3 hours

Isolation, Work and Daycare Restrictions

- 1) Pre-event: For a patient with an acute, generalized rash, with vesicles or pustules that is suspected smallpox, institute airborne and contact precautions
 - Place patient in a private, negative airflow room, if available.
 - If not available, place patient in private room and keep door closed. Keep doors closed at all times, except when patient or staff must enter or exit.
 - Staff and visitors should wear properly fitted N95 or higher quality respirators, gloves, and gowns.
 - Patients should wear a surgical mask when outside the isolation room and must be gowned or wrapped in a sheet so that their rash is fully covered.
- 2) Post-event:
 - State Health Officer evaluates the event with partner organizations and makes recommendations to public health and medical authorities on quarantine, shelter-in-place, isolation or other public health measures.
 - State Health Officer designates a state ICS position to coordinate activities related to isolation/quarantine and care of known or presumed infectious individuals, contacts without rash but with fever ($\geq 101^\circ$ F (38° C) on two successive readings), asymptomatic contacts and those who were with the case 10 to 18 days before case's rash onset (possible common exposure).
- 3) For smallpox isolation, measures continue until all scabs are separated.

Case Management

- 1) Institute isolation measures as recommended by the State Health Officer and as directed in local/state plans (i.e., BIA, Community Containment SOGs)
 - Ensure adequate isolation measures are in place.
 - Ensure proper care and resources are available to those in isolation.
- 2) Coordinate activities related to isolation and care.
 - Work with medical providers to track patients in isolation.
 - Notify medical providers of additional suspect cases who may need medical treatment.
 - Report on any changes in patient status (i.e., discharge, death).

Contact Management

- 1) Institute quarantine measures as recommended by the State Health Officer and as directed in local/state plans (i.e., BIA, Community Containment SOGs).
 - Ensure adequate quarantine measures are in place.
 - Ensure proper care and resources are available to those in quarantine.
- 2) Institute vaccination measure as recommended by State Health Officer and as directed in local/state plans (i.e., BIA, Community Containment SOG, Mass Dispensing SOG). Vaccine is obtained from the Strategic National Stockpile.
 - Vaccination within 3 days of exposure will completely prevent or significantly modify smallpox in the majority of people. Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify severity disease.
 - Instruct vaccinee (i.e., household, primary contacts or household members of primary contacts) to call a specific phone number seven days after their date of vaccination to report takes and/or to call immediately, if they experience a fever ($\geq 101^{\circ}$ F (38°C) on two successive readings).
- 3) Conduct contact surveillance of primary contacts.
 - Provide [Form 2E: Case Household and Primary Contact Surveillance](#) to each household and other primary contacts to provide a diary for the case's primary contacts to record information about themselves, such as date of vaccination, date of take, daily temperature, and onset of rash or severe adverse reactions.
 - Contact the household or primary contact 7 days after the date of vaccination or earlier, if the date of vaccination is not properly reported within 3 days of when the household was given Form 2E.
- 4) Conduct surveillance of the household members of case's primary contacts.
 - Provide each non-household primary contact with [Form 2F: Case Primary Contact's Household Members Surveillance](#) to record their household members with date(s) of vaccination. Include instructions to call a specific phone number seven days after date(s) of vaccination to report takes and/or to call immediately, if they experience any severe vaccine adverse reactions shown on the Vaccination Information Sheet.
 - Contact the primary contact's household member 7 days after the date of vaccination or earlier, if the date of vaccination is not properly reported within 3 days of when the household was given Form 2F.

Environmental Measures

Refer to the CDC's Guide F—Environmental Control of Smallpox Virus.
www.bt.cdc.gov/agent/smallpox/response-plan/index.asp#guidef

Education

Refer to on-line resources and local plans (i.e., risk communication SOG).

- Frequently asked questions resources:
<http://emergency.cdc.gov/agent/smallpox/faq/>
- Smallpox vaccination for Health professionals and response teams:
www.bt.cdc.gov/agent/smallpox/vaccination/
- CDC's Guide E – Communication Plans and Activities:
www.bt.cdc.gov/agent/smallpox/response-plan/index.asp#guidee
- Factsheet for smallpox, including non-English Speakers:
 - Located in KDHE [Public Information and Communication Standard Operating Guide](#), Supporting Document F – Public Information, Biological Hazards.

MANAGING SPECIAL SITUATIONS

A. Adverse Vaccinia Reactions, Including Suspected Unintentional Transfer of Vaccinia Virus and/or Diffuse Dermatological Complications

- 1) Vaccinia adverse reactions can include:
 - Unintentional transfer of vaccinia virus from primary inoculation site to:
 - Elsewhere on vaccinee (Inadvertent autoinoculation)
 - A close contact of vaccinee (contact transmission)
 - Eyes of vaccinee or close contact (ocular vaccinia)
 - Diffuse dermatological complications, including generalized vaccinia, eczema vaccinatum and progressive vaccinia in vaccinee or contacts.
- 2) Suspected cases of these vaccinia adverse reactions should be reported to KDHE- BSE at 877-427-7317.
- 3) KDHE-BSE will assist in the coordination of laboratory testing for non-variola orthopox at KHEL and any additional testing at the CDC.
 - The following CDC website is used for specimen collection guidance:
www.emergency.cdc.gov/agent/smallpox/vaccination/vaccinia-specimen-collection.asp
- 4) The MMWR Surveillance Guidelines for Smallpox Vaccine (vaccinia) Adverse Reactions will be used to guide reporting and investigation.
www.cdc.gov/mmwr/preview/mmwrhtml/rr5501a1.htm
- 5) The event must be reported to the Vaccine Adverse Events Reporting System online (<http://vaers.hhs.gov>) or by telephone (800-822-7967).
 - In addition to the standard VAERS reporting form, a Smallpox Vaccine VAERS Report Follow-up Worksheet will be used in reporting.
 - For an event involving a contact of a vaccine recipient, the VAERS report should be submitted with information on the person experiencing the adverse event. Such reports will be coded as the result of **secondary transmission**.

- Refer to CDC's Annex 4: Vaccine Adverse-Event Reporting:
<http://emergency.cdc.gov/agent/smallpox/response-plan/files/annex-4.pdf>

B. Bioterrorism Considerations

- 1) A single confirmed case or suspect case of smallpox is an outbreak and is considered to be a bioterrorist event until proven otherwise.
- 2) CDC personnel will coordinate response efforts within the state and local health authorities and will serve as liaisons with other federal agencies (FBI, HHS, OHS, ect.).
- 3) In the event of an outbreak of smallpox, vaccine and vaccinia IG will be procured from the Strategic National Stockpile. Procurement, storage, and distribution will be coordinated through KDHE.

DATA MANAGEMENT AND REPORTING TO THE KDHE

A. Organize, collect and report data utilizing the appropriate forms.

B. Report data as directed by the KDHE-BEPHI, include:

- Form 1 – for all smallpox cases (with at least minimal data completed)
 - A case will be created in the Kansas electronic surveillance system for every Form 1 received
- Form 2B (contact listing) – use the contact feature in Kansas electronic surveillance system to create a new contact for each primary contact listed on Form 2B. Minimal entry:
 - Last and First Name to create contact
 - Page 5. Exposure information: First and Last Exposure Date and Contact Priority Category Number (under 'Nature of Exposure')
- Form 2D for all priority contacts – record in the Kansas electronic surveillance system contact tab:
 - Page 1. Partner/Cluster Info: 'Contact investigated by:'
 - Page 2. Demographics (Pregnancy recorded on Page 8. Risk Factors)
 - Page 3. Communication Attempts
 - Page 4. Occupation
 - Page 7. Disposition or Diagnosis (assignment of investigator, call back date; referral for vaccination and/or absence/presence of disease)
- Form 2E for all primary contacts or at least the available information on:
 - Date of contact's vaccination: reported in KS-WebIZ
 - Page 7. Disposition and Diagnosis: Complete and update, as needed
- Form 2F (listing of household members of primary contacts) and Form 2E
 - Date of contact's vaccination reported in WebIZ
 - Adverse vaccination events noted during call backs reported through VAERS

ADDITIONAL INFORMATION / REFERENCES

- A. Treatment / Differential Diagnosis:** Red Book: 2009 Report of the Committee on Infectious Diseases. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009:237-239.
- B. Epidemiology, Investigation and Control:** Heymann. D., ed., Control of Communicable Diseases Manual, 19th Edition. Washington, DC, American Public Health Association, 2009.
- C. Case Definitions:** CDC Division of Public Health Surveillance and Informatics, Available at: www.cdc.gov/osels/ph_surveillance/nndss/casedef/case_definitions.htm
- D. Intentional Biological Event:** Kansas Biological Incident Annex at: www.kdheks.gov/cphp/operating_guides.htm#BiologicalIncidentAnnex
- E. Chain of Custody:** KDHE Chain of Custody Standard Operating Guide, www.kdheks.gov/cphp/operating_guides.htm#coc
- F. Vaccine information:** Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book); available as a download from the main website: www.cdc.gov/vaccines/pubs/pinkbook/downloads/smallpox.pdf
- G. Specific guidance from CDC:**
- Smallpox Response Plan and Guidelines : www.bt.cdc.gov/agent/smallpox/response-plan/index.asp.
 - Smallpox Vaccination: www.bt.cdc.gov/agent/smallpox/vaccination/
 - Vaccinia (Smallpox) Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP): www.cdc.gov/mmwr/preview/mmwrhtml/rr5010a1.htm
- H. Additional Information (CDC):** www.bt.cdc.gov/agent/smallpox/

WORKSHEET: EVALUATING PATIENTS FOR SMALLPOX

Identification Number	_____
Person Completing Form	_____
Date of Contact with Case	_____
Today's Date (mo/da/yr)	_____

PATIENT INFORMATION

Name: _____

 LAST FIRST MIDDLE INITIAL

Date of Birth: ____/____/____ Age: ____ Sex: Male Female

Telephone: _____
 Home _____ Other _____

Address: _____

 CITY STATE ZIP

Race: White Black Asian Other Ethnicity: Hispanic Non-Hispanic Country of Birth: _____

Where is the patient now? Home Doctor's Office
 Emergency Room (if checked, continue below)
 Hospital (if checked, continue below)
 Other (specify) _____

Hospital Name _____
 City/State _____
 Admission Date ____/____/____ Discharge Date ____/____/____
 Hospital Telephone Number (____) _____

PROVIDER INFORMATION

Name: _____

Patient Population: Adult Peds Both

Specialty: _____

Telephone: _____
 Type _____ (____) _____
 Type _____ (____) _____

E-mail Address: _____

Name: _____

Patient Population: Adult Peds Both

Specialty: _____

Telephone: _____
 Type _____ (____) _____
 Type _____ (____) _____

E-mail Address: _____

CLINICAL INFORMATION

PRODROME / SYMPTOMS 1-4 DAYS BEFORE RASH ONSET

Did the patient have a fever and other illness 1-4 days before rash onset? Yes No Unknown

Date of prodrome onset ____/____/200__

Date of first fever ≥101° F: ____/____/____

What was the highest temperature? _____° F or _____° C

On what date? ____/____/____

Check all features of the prodrome that apply:

<input type="checkbox"/> No/Mild prodrome (<1 day)	<input type="checkbox"/> Abdominal pain
<input type="checkbox"/> Headache	<input type="checkbox"/> Sore throat*
<input type="checkbox"/> Backache	<input type="checkbox"/> Other (specify) _____
<input type="checkbox"/> Chills	
<input type="checkbox"/> Vomiting	

*In infants, this may manifest as drooling or refusing to eat or drink.

Was the patient toxic or seriously ill? Yes No Unknown

Was the patient able to do most normal activities? Yes No Unknown

RASH

Date of rash onset ____/____/200__

Was the rash acute (sudden) in onset? Yes No Unknown

Was a black scar (eschar) present before or at the time of appearance of the rash? Yes No Unknown

Is the rash *generalized* (i.e., multiple parts of the body) or *focal* (i.e., only one part of the body)? Generalized Focal

Where on the body were the first lesions noted?

<input type="checkbox"/> Face	<input type="checkbox"/> Arms
<input type="checkbox"/> Trunk	<input type="checkbox"/> Legs
<input type="checkbox"/> Inside the mouth	<input type="checkbox"/> Unknown
<input type="checkbox"/> Other (specify) _____	

Since rash onset, where on the body was the rash most dense?

<input type="checkbox"/> Trunk	<input type="checkbox"/> Equally distributed everywhere
<input type="checkbox"/> Face or scalp	<input type="checkbox"/> Other (describe) _____
<input type="checkbox"/> Distal extremities (arms, legs)	

Are there any lesions on the palms or soles? Yes No Unknown

What kind of lesions does the patient have now? (check all that apply)

<input type="checkbox"/> Macules (flat spots)	<input type="checkbox"/> Pustules (blisters filled with pus)
<input type="checkbox"/> Papules (solid bumps)	<input type="checkbox"/> Crusts
<input type="checkbox"/> Vesicles (fluid-filled blisters)	<input type="checkbox"/> Other _____

If more than one kind of lesion, which kind of lesion is now the most common? _____

Are the lesions now:

<input type="checkbox"/> Superficial (on top of the skin)
<input type="checkbox"/> Deep (feel embedded deeply in the skin)
<input type="checkbox"/> Neither (describe) _____

How many lesions are present? (in total) _____

If no precise count is available, please estimate:

<input type="checkbox"/> <20
<input type="checkbox"/> 20-50 (able to count in less than a minute)
<input type="checkbox"/> 51-499 (typically an average case of varicella has 200-400 lesions)
<input type="checkbox"/> >500 (lesions confluent in some places, can't see normal skin between)

On any one part of the body (e.g., face or arm), are all the lesions in the same state of development? Yes No Unknown

How big are most of the lesions? (Do not measure superinfected lesions.)

<input type="checkbox"/> Small (1-5 mm)
<input type="checkbox"/> Large (5-10 mm)
<input type="checkbox"/> Neither (describe) _____

Have any lesions crusted? Yes No Unknown

If Yes, how many days did it take for the first lesions to crust? _____

How itchy is the rash? Not at all Somewhat Very Unknown

Does the patient have lymphadenopathy? Yes No Unknown

If Yes, describe: _____

Is the patient toxic or moribund now? Yes No Unknown

If Yes, describe: _____

Continues

CLINICAL NOTES

SOURCE / EXPOSURE INFORMATION

Is chickenpox (varicella) occurring in the community? Yes No Unknown

Has the patient had contact with a person with chickenpox or shingles 10-21 days before rash onset? Yes No Unknown

If Yes, give date(s) and type of contact: _____

In the 3 weeks before onset of illness: *(applies to remainder of section)*

Has the patient been in contact with a person with any other rash illness? Yes No Unknown

If Yes, please specify, with date: _____

Has the patient traveled? Yes No Unknown

If Yes, please provide locations and dates of travel:
Place: _____ Dates: _____

Place: _____ Dates: _____

Has the patient had contact with mice? Yes No Unknown

Has the patient been camping, hiking, or exposed to woods before onset of illness? Yes No Unknown

If Yes, please provide details and dates:

Has the patient received insect bites? Yes No Unknown

Has the patient been exposed to ticks? Yes No Unknown

VACCINATION HISTORY

Has the patient received chickenpox (varicella) vaccine? Yes No Unknown
(Chickenpox vaccine was licensed in the United States in 1995.)

If Yes, dose #1 date ____/____/____ or age _____
dose #2 date ____/____/____ or age _____
(only persons >13 years receive a second dose)

Has the patient ever received smallpox vaccine? Yes No Unknown
(The smallpox vaccine was routinely given in the U.S. until 1972, was recommended for health care providers until 1976, was administered in the military until 1990.)

If Yes, when was the most recent vaccination? ____/____/____
or at what age? _____

MEDICAL HISTORY

Has the patient ever had chickenpox or shingles? Yes No Unknown
If Yes, when? ____/____/____ or at what age? _____

Is the patient immunocompromised? Yes No Unknown
If Yes, specify type of illness *(e.g., cancer, HIV/AIDS)* _____

Does the patient have any other serious underlying medical illnesses? *(e.g., asthma)* Yes No Unknown
If Yes, please list: _____

Is the patient sexually active? Yes No Unknown

Is the patient pregnant? Yes No Unknown

DIFFERENTIAL DIAGNOSIS

MEDICATIONS

Is the patient on medications that suppress the immune system? *(e.g., steroids, chemotherapy, radiation)* Yes No Unknown

If Yes, name of medication: _____
Dosage: _____
Method of administration: _____

Is the patient taking antiviral medications? Yes No Unknown

If Yes, name of medication: _____
Dosage: _____
Method of administration: _____

Please list all prescription and non-prescription medications that the patient has taken in the past three weeks. *(List drug, dosage, route, dates)*

Is there a history of illicit drug use? Yes No Unknown

If Yes, please specify drug, amount (if known), route, and dates:

LABORATORY

Have you tested the patient for chickenpox? Yes No Unknown
If Yes, what type of test? _____

Results of tests: _____
Date: ____/____/____

Other lab testing — Please complete last page

Other comments: _____

PLEASE LIST ALL LABORATORY TESTS ORDERED OR PERFORMED REGARDING THIS ILLNESS

Date: _____ / _____ / _____ Results: _____
Disease: _____
Test: _____
Laboratory: State _____
 Other _____

Date: _____ / _____ / _____ Results: _____
Disease: _____
Test: _____
Laboratory: State _____
 Other _____

Date: _____ / _____ / _____ Results: _____
Disease: _____
Test: _____
Laboratory: State _____
 Other _____

Date: _____ / _____ / _____ Results: _____
Disease: _____
Test: _____
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Date: _____ / _____ / _____ Results: _____
Disease: _____
Test: _____
Laboratory: State _____
 Other _____

Date: _____ / _____ / _____ Results: _____
Disease: _____
Test: _____
Laboratory: State _____
 Other _____

CDC Investigation Form(s)

Post-Event Investigation Forms are available under attachments:

CLICK HERE TO VIEW ATTACHMENTS

Then double click on the document to open.

CDC Forms and Instructions	
(Available on-line at: http://emergency.cdc.gov/agent/smallpox/response-plan/index.asp)	
Form Number and Name	Purpose
Form 1: Smallpox (Case) Post-Event Surveillance	Summarizes clinical and epi information about smallpox case patient. Report form for smallpox suspect, probable, and confirmed cases.
Form 2A: Smallpox Case Travel/Activity Worksheet – Infectious Period	Records case activities during infectious period, to help with identifying exposed contacts.
Form 2B: Smallpox Primary Contact/Site Worksheet	Lists contacts to case patient and prioritizes by risk.
Form 2C: Smallpox Case Transportation Worksheet – Infectious Period	Documents case patient travel history and modes of transportation, to identify possible exposed contacts.
Form 2D: Smallpox Contact Tracing	Documents referral for vaccination or clinical evaluation for each identified primary and secondary contact.
Form 2E: Smallpox Case Household and Primary Contact Surveillance	Documents surveillance of primary contacts for vaccine “take,” as well as fever and symptoms.
Form 2F: Smallpox Case Primary Contact Household Member Surveillance	Documents vaccine “take,” as well as fever and symptoms for all secondary contacts (household members and other close contacts of primary contact).
Form 3A: Smallpox Case Exposure Investigation	Assists in determining a common source of exposure. Records information on possible individuals and places as sources of infection. This form is not intended for use in every investigation.
Form 3B: Smallpox Case Travel/Activity Worksheet – Exposure Period	Helps identify possible sources of exposure (travel or movement during exposure period)
Form 3C: Smallpox Case Transportation Worksheet – Exposure Period	Used to record the travel history of the case for up to 19 days before his/her date of onset of fever.

Other Options to view attachments:

Go to <View>; <Navigation Pane>; <Attachments>

– OR –

Click on the “Paper Clip” icon on the left.

Supporting Materials

Fact Sheet

Supporting Materials are available under attachments:

CLICK HERE TO VIEW ATTACHMENTS

Then double click on the document to open.

Other Options to view attachments:

Go to <View>; <Navigation Pane>; <Attachments>

– OR –

Click on the “Paper Clip” icon on the left.