Kansas
Department of Health and Environment
Division of Health

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.

Contents

Attachments can be accessed through the Adobe Reader's navigation panel for attachments. Throughout this document attachment links are indicated by this symbol ; when the link is activated in Adobe Reader it will open the attachments navigation panel. The link may not work when using PDF readers other than Adobe.

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Revision History:

Date	Replaced	Comments
05/2018	07/2012	Updated Notification sections and Isolation, Work and Daycare Restrictions sections with updated regulations. Updated all investigation responsibilities, investigations, and management sections with updated guidance from CDC. Removed case reporting and contact tracing forms that are no longer supported.
07/2012	02/2012	Addition of notification section.

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Smallpox
Disease Management and Investigation Guidelines

CASE DEFINITION (CDC 2004)

Clinical Description for Public Health Surveillance:

An illness with acute onset of fever ≥101º F (≥38.3º 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 classical 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 on the Enhanced Surveillance website (https://www.cdc.gov/smallpox/bioterrorism-response-planning/public-health/enhanced-surveillance-case-reporting.html) 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:

- Info for Lab Personnel: https://www.cdc.gov/smallpox/lab-personnel/index.html
- Suspect Monkeypox: https://www.cdc.gov/poxvirus/monkeypox/index.html

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 (*Strep. pyogenes, Staph. aureus*)	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

Additional resources are at: www.cdc.gov/smallpox/clinicians/algorithm-protocol.html

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) at https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Smallpox.

The smallpox vaccine is not available to the general public. Currently, the United States has a stockpile of smallpox vaccine 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 on the CDC Smallpox Diagnosis and Evaluation web page (www.cdc.gov/smallpox/clinicians/diagnosis-evaluation.html)
   - Algorithm for "Evaluating Patients for Smallpox" poster
   - 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 "Evaluating Patients for Smallpox Algorithm".
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:** Fever ≥101ºF (38.3ºC), 1-4 days prior to rash onset with at least prostration, headache, backache, chills, vomiting or severe abdominal pain
2. **Classic smallpox lesions:** Deep-seated, firm/hard, round well-circumscribed vesicles or pustules; lesions may umbilicate or become confluent.
3. **Lesions in the same stage of development:** On any one part of the body all lesions in same stage of development.

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 evolution of lesions** from macule, to papule, to vesicle (1-2 days each stage)
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 as described on Evaluating Patients for Smallpox Worksheet will be faxed to 1-877-427-7318
   - Epidemiologist should work with medical provider to monitor the outcome of patient with confirmed smallpox and work to collect aggregate data.
3) Interview the case or proxy to determine identify potential contacts:
   - **The interviewers should be vaccinated prior to, or within 72 hours (preferably within 24 hours), of their first contact with the patient and wear appropriate personal protective equipment (PPE).**
   - If there is suspicion the smallpox emergency is the result of a deliberate release of the virus, the Federal Bureau of Investigation (FBI) and law enforcement agencies may need to collaborate on these interviews.
   - Review the patient's travel and activity history for the previous 2 to 3 weeks.
     – If more people are diagnosed with smallpox, this information will help determine a common source of exposure.
     – Identifying the source of exposure will help to estimate the number of people at risk for illness.
   - Identify other people the patient has had close contact with since their symptoms began (when the patient became infectious).
   - Institute control measures as indicated under Isolation, Work and Daycare Restrictions and Case Management.
   - If potential contacts are identified based on interviews, start contact tracing activities as soon as possible after a patient has been diagnosed with smallpox. (Refer to Contact Investigation section.)

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) A contact of a smallpox patient as:
   - Household family members of the smallpox patient
   - Others spending ≥3 hours in the household since the patient's onset of fever
   - Non-household members with ≥3 hours of contact <2 meters (<6.5 feet) from a patient with a rash
2) Review the patient's occupation and activities collected during the case investigation.

3) Identify contacts of the patient and their own close household contacts.
   - Interview and assess contacts for symptoms.
   - If any show symptoms of smallpox, arrange for their transport to the healthcare facility in the community designated to care for suspected smallpox cases.
   - As long as those being interviewed do not show symptoms or have a fever, interviewing personnel do not need to wear PPE.
4) Depending on the number of contacts, contact tracing teams may need to be used with supervisors assigned if multiple tracing teams are involved.
   - Teams should consist of individuals trained in all aspects of contact tracing, surveillance and follow-up who are identified based on field experience.
5) Contact tracing activities continue throughout an outbreak even if widespread community or mass vaccination is offered.
6) Vaccinate and monitor contacts as outlined in Contact Management.

Isolation, Work and Daycare Restrictions

***K.A.R 28-1-6* for Smallpox**:

Control of Cases

- For each person hospitalized with a case, contact and airborne precautions shall be followed for the duration of acute illness and until all scabs have crusted and separated.
- Each person with a case shall remain in home isolation for the duration of the acute illness and until all scabs have crusted and separated, except when seeking medical care.

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 (≥101º F (38ºC) 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).

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.
   - Ring vaccination strategies will be employed with contacts of confirmed small pox patients being vaccinated.
   - 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.
   - Give all contacts and their respective close household contacts information about where and when they can get the smallpox vaccination.
   - Arrange for transportation to the place to receive the vaccination, if necessary.
   - Provide a time and place for a vaccine "take" reading 6 to 8 days after vaccination.
   - Provide vaccinated contacts with a way to report their temperatures to designated public health officials and provide a phone number to call immediately, if they experience a fever (≥101º F (38ºC)).
3) Monitoring of contacts:
   - Administration of fever surveillance.
     - Fever surveillance: Contacts without symptoms should take their temperatures twice every day (every 12 hours) for 18 days after their last contact with the smallpox patient, and 14 days after being vaccinated
     - Establish a dedicated phone line or other method for contacts (vaccinated and unvaccinated) to report their temperature readings each day (fever surveillance).

- If a contact develops a fever ≥101°F (38.3°C) for 2 successive readings, they should notify health department personnel and remain at home until transportation to the healthcare facility in the community designated to care for suspected smallpox cases can be arranged.
- Designate personnel to follow up with contacts who do not report regularly.

- Vaccinated contacts, additional notes:
  - Monitored for 18 days after exposure to smallpox and 14 days after vaccination.
  - Provide contacts information about how to seek care for and report adverse events to vaccination.
- Unvaccinated contacts, additional notes:
  - Monitored until 18 days after exposure to smallpox, and
  - Remain at home for 18 days after their last exposure to smallpox virus.

4) Additional vaccination measures as described by the CDC Bioterrorism Response Planning includes Community-wide (Mass Vaccination)

Environmental Measures

Refer to the CDC's https://www.cdc.gov/smallpox/bioterrorism-response-planning/healthcare-facility/prevent-spread-disease.html

Education

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

1) Public Health Response Activities (Smallpox): Communications: https://www.cdc.gov/smallpox/bioterrorism-response-planning/public-health/communication.html
2) CDC Smallpox web page: https://www.cdc.gov/smallpox/index.html

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 at 877-427-7317.
3) KDHE will assist in coordinating a consultation with CDC, if requested, and can assist with the coordination of laboratory testing for non-variola orthopox at KHEL and any additional testing at the CDC.
   - Medical management: www.cdc.gov/smallpox/clinicians/vaccine-medical-management6.html
4) The MMWR Surveillance Guidelines for Smallpox Vaccine (vaccinia) Adverse Reactions (2006) will 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.**

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.

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: wwwn.cdc.gov/nndss/

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
- Vaccinia (Smallpox) Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP): www.cdc.gov/mmwr/preview/mmwrhtml/rr5010a1.htm

G. Additional Information (CDC):

- www.cdc.gov/smallpox/index.html
- https://www.cdc.gov/smallpox/bioterrorism-response-planning/index.html

3/04/2002 5:30pm

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

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 ( )

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

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:
☐ No/Mild prodrome (<1 day)
☐ Headache
☐ Backache
☐ Chills
☐ Vomiting
☐ Abdominal pain
☐ Sore throat*
☐ Other *(specify)* _____

*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?
☐ Face
☐ Trunk
☐ Inside the mouth
☐ Other *(specify)* _____
☐ Arms
☐ Legs
☐ Unknown

Since rash onset, where on the body was the rash most dense?
☐ Trunk
☐ Face or scalp
☐ Distal extremities (arms, legs)
☐ Equally distributed everywhere
☐ Other *(describe)* _____

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)*
☐ Macules (flat spots)
☐ Papules (solid bumps)
☐ Vesicles (fluid-filled blisters)
☐ Pustules (blisters filled with pus)
☐ Crusts
☐ Other _____

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

Are the lesions now:
☐ Superficial (on top of the skin)
☐ Deep (feel embedded deeply in the skin)
☐ Neither *(describe)* _____

How many lesions are present? (in total) _____

If no precise count is available, please estimate:
☐ <20
☐ 20-50 (able to count in less than a minute)
☐ 51-499 (typically an average case of varicella has 200-400 lesions)
☐ >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.)*
☐ Small (1-5 mm)
☐ Large (5-10 mm)
☐ 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:

_____ Dates: _____

_____ 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

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:

DIFFERENTIAL DIAGNOSIS

LABORATORY

Other lab testing — Please complete last page

Have you tested the patient for chickenpox? ☐ Yes ☐ No ☐ Unknown

If *Yes*, what type of test? _____

Results of tests: _____

Date: ____/____/____

Other comments: _____

DISPOSITION

Risk of smallpox
using CDC criteria (available at www.cdc.gov/nip/smallpox):

☐ **Low** ☐ **Moderate** ☐ **High*** ☐ **Unknown**
**If checked, see contact checklist below in Immediate Response Information*

IMMEDIATE RESPONSE INFORMATION

☐ Institute airborne and contact precautions
☐ Alert infection control
☐ Take digital photographs of rash
☐ Consult ID and/or dermatology

IF THE PATIENT IS AT HIGH RISK:

☐ Contact local health department

Name: _____ Phone: _____

E-mail: _____ Phone: _____

☐ Contact state epidemiologist

Name: _____ Phone: _____

E-mail: _____ Phone: _____

☐ Contact state BT coordinator

Name: _____ Phone: _____

E-mail: _____ Phone: _____

☐ Contact CDC BT coordinator

Name: _____ Phone: _____

E-mail: _____ Phone: _____

24-HOUR FOLLOW-UP INFORMATION

Date of follow -up: ____/____/____

Person making follow-up: _____

Condition of patient: _____

Risk of smallpox 24 hours later: ☐ Low ☐ Moderate ☐ High ☐ Unkn

Action taken: _____

Diagnosis: _____

Was diagnosis confirmed? ☐ Yes ☐ No ☐ Unknown

How was diagnosis confirmed? _____

48-HOUR FOLLOW-UP INFORMATION

Date of follow -up: ____/____/____

Person making follow-up: _____

Condition of patient: _____

Risk of smallpox 48 hours later: ☐ Low ☐ Moderate ☐ High ☐ Unkn

Action taken: _____

Diagnosis: _____

Was diagnosis confirmed? ☐ Yes ☐ No ☐ Unknown

How was diagnosis confirmed? _____

72-HOUR FOLLOW-UP INFORMATION

Date of follow -up: ____/____/____

Person making follow-up: _____

Condition of patient: _____

Risk of smallpox 72 hours later: ☐ Low ☐ Moderate ☐ High ☐ Unkn

Action taken:

Diagnosis: _____

Was diagnosis confirmed? ☐ Yes ☐ No ☐ Unknown

How was diagnosis confirmed? _____

www.cdc.gov/smallpox

CLINICAL NOTES

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: ____________________
Laboratory: ☐ State
☐ Other ____________

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: ____________________
Laboratory: ☐ State
☐ Other ____________

Date: ______/______/______ Results: ____________________
Disease: ____________________
Test: ____________________
Laboratory: ☐ State
☐ Other ____________

Date: ______/______/______ Results: ____________________
Disease: ____________________
Test: ____________________
Laboratory: ☐ State
☐ Other ____________