

Smallpox

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1. DISEASE REPORTING

A. Purpose of Reporting and Surveillance

1. To establish the smallpox diagnosis and classification;
2. to identify suspect, probable, and confirmed cases;
3. to isolate confirmed, probable, and suspected cases to facilitate medical care, minimize morbidity and prevent further disease transmission;
4. to identify contacts who need vaccination, surveillance, and prompt isolation if symptoms develop;
5. to monitor the clinical course and outcome of cases and their contacts;
6. to monitor the epidemiology of the outbreak, and evaluate effectiveness of control measures.

B. Laboratory and Physician Reporting Requirements

1. Physicians are required to report confirmed or suspected cases immediately to the local health department (LHD) or to the Oregon Acute Communicable Disease Programs (ACDP) 503-731-4024 (after hours 503-731-3040).
2. Laboratories are required to report any positive confirmed orthopox viruses, pending further identification at the reference CDC lab.

C. Local County Health Department Reporting and Follow up Responsibilities

1. Report all febrile rash illness suggestive of smallpox immediately to ACDP.
2. Consult with ACDP about strategies for enhanced surveillance and contact investigation.
3. Confirm compliance with respiratory and contact isolation procedures in medical care of case patients.
4. Assure all contacts potentially exposed to the smallpox case patient are identified, educated, and placed under adequate surveillance for the period when symptoms are most likely to arise.
5. Complete the reporting forms, surveillance and follow-up forms, and otherwise document investigation, outreach, active surveillance, and completeness of containment efforts.
6. Consult with ACDP prior to closing case and contact investigation activities for each smallpox case.

D. State Responsibilities

1. Provide consultation to LHD public health and private sector health professionals concerning:
 - a. **diagnostic evaluation, treatment, and clinical monitoring;**
 - b. required reporting and surveillance activities;
 - c. contact identification and follow-up;
 - d. facilitation of inter-jurisdictional tracking of cases and contacts who move out of county or state of Oregon jurisdiction;
 - e. development and maintenance of adequate information systems to provide needed case and contact surveillance, and assure adequacy of response activities;
 - f. provision of surge capacity if the smallpox outbreak and contact investigation overwhelm resources of the LHD.

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2. Facilitation of expert consultation with infectious disease specialists and CDC as needed;
3. Coordinate specimen collection with the LHD and Oregon State Public Health Laboratory (OSPHL), to assure confirmation of suspected smallpox cases, and early identification of disease in symptomatic contacts and others.

2. THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiological Agent

Variola virus, a DNA virus, of the genus *Orthopoxvirus*.

Variola replicates in the cytoplasm of host cells, forming inclusion bodies, unlike varicella or herpes viruses, which replicate in the nucleus. There is extensive cross-neutralization between orthopoxviruses; therefore, neutralization tests are not useful in distinguishing variola virus from other orthopoxviruses.

Variola viruses traditionally have been classified as variola major and variola minor (Alastrim). In the setting of an intentional release, use of the milder variola minor is unlikely, and the rest of the guideline will focus on variola major. See Appendix A for information on less common presentations of variola.

Environmental survival of variola virus is shortened by increased temperature and humidity. In the pre-eradication era, smallpox had a higher incidence in temperate areas during winter and spring.

B. Description of Illness

Variola major, a.k.a ordinary smallpox, is characterized by a prodrome with fever, rash onset, and progression of the rash. Variola major is the most common form. The prodrome lasts from 1 – 4 days, with symptoms of with fever >101°F (100%), headache (90%), backache (90%), chills (60%), and vomiting (50%). Following the prodrome, development and centrifugal progression of a rash occurs, through stages of macules; vesicles; firm, raised pustules; and scabs over a two-week period. Less commonly, pharyngitis and abdominal pain may occur. At least 90% of variola major cases in the pre-eradication era had the prodrome.

| Features and characteristics of <i>variola major</i> | |
|--|--|
| Feature | Characteristics |
| Incubation period* | <ul style="list-style-type: none">• 10–14 days (usually about 12 days)• May be as short as 7 days and as long as 19 days |
| Prodrome | <ul style="list-style-type: none">• Lasts 2–4 days |
| Rash | <ul style="list-style-type: none">• Enanthem on mucosa of mouth and pharynx usually begins about 24 hr before skin lesions appear (initially papular, then vesicular, then ulcerative over several days)• First few skin lesions often appear on face ("herald spots")• Lesions spread to trunk and proximal extremities and then to distal extremities• Lesions prominent on face and distal extremities, including palms and soles, in centrifugal pattern• Lesions initially maculopapular (days 1–2), then vesicular (days 3–5), then pustular (days 7–14); pustules gradually scab over by end of second week or during third week• Vesicular lesions often have central umbilication which may persist into pustular stage, but as lesions progress they gradually flatten• Pustules often described as "shotty" (i.e., like hard, round foreign |

| Features and characteristics of <i>variola major</i> | |
|--|--|
| Feature | Characteristics |
| | <p>bodies embedded in skin)</p> <ul style="list-style-type: none"> • Lesions extend deep into skin, often are painful, and pitted scarring occurs as they heal • Lesions may be discrete (relatively few in number), semiconfluent, or confluent • Lesions generally progress at same rate with relatively synchronous onset • In partially-immune persons, clinical course may be much less severe and rash may be atypical with fewer lesions and more rapid healing (i.e., "modified smallpox") |
| Complications | <ul style="list-style-type: none"> • Massive amounts of subcutaneous fluid may accumulate during vesicular and pustular stages of rash, leading to severe fluid and electrolyte disturbances, including renal failure • Massive skin desquamation can occur in cases of confluent disease; patients may clinically and metabolically resemble severe burn victims • Viral bronchitis/pneumonitis occurs relatively commonly • Other less common complications: <ul style="list-style-type: none"> ○ Corneal ulceration (about 1% of cases) and/or keratitis (about 0.25% of cases); may cause corneal scarring and blindness) ○ Secondary bacterial infections (particularly skin and pulmonary infections) ○ Encephalitis (0.2% of cases) ○ Osteomyelitis or arthritis (about 1.7% of cases; usually in children) ○ Orchitis (rare, 0.1%) |
| Case-fatality rates[§] | <ul style="list-style-type: none"> • Overall case-fatality rate for ordinary smallpox, 15%–45% • Likelihood of death varies by type of disease (i.e., confluent, semiconfluent, or discrete). • Observed case-fatality rates by type of disease among unvaccinated patients in one large series: <ul style="list-style-type: none"> ○ Overall rate, 30% ○ Confluent disease, 62% ○ Semiconfluent disease ○ Discrete disease, 9% |

[§] Case-fatality rates are based on historical data from pre-eradication era; such rates may be lower with modern medical management and intensive care.
Reference: Infectious Disease Society of America, 3/14/2003, available at http://www.idsociety.org/bt/biotemplate.cfm?template=sm_summary.htm#_Clinical_Features_of

C. Reservoirs

No natural reservoirs known. Extent of distribution of laboratory specimens is unknown, but believed to be very limited.

D. Modes of Transmission

Variola virus is predominantly transmitted person-to-person by direct exposure to and inhalation of droplet nuclei. Transmission typically occurs during close face-to-face contact with an infected patient. Smallpox is spread only from sick persons. Spread does not occur during the incubation period, but risk of transmission is high early in the course of symptomatic illness.

Nosocomial spread by the airborne route to others remote from the infectious patient, while rare, has occurred. Transmission by contaminated fomites (e.g., bedding) has been reported.

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Bioterrorist release could occur through: introduction as a spray of tiny droplets into the air (aerosol). The virus would likely be inactivated within 24 hours, and not present by time cases developed 7–17 days later; or transmission by intentionally infected persons. In this case, the origin of the virus (index case) and extent of the outbreak could potentially be tracked using standard epidemiologic and laboratory methods.

E. Incubation Period

Typically 10–14 days (range 7–17 days).

F. Period of Communicability

Variola is contagious from the onset of fever and earliest mucosal and skin lesions, until all pox lesions have crusted over (about 2–3 weeks).

G. Treatment

Supportive and symptomatic treatment includes hydration and medications for fever and pain. Currently, there is no known antiviral therapy effective for treating smallpox disease. Antibiotics could be indicated for secondary respiratory or skin infections.

3. CASE DEFINITIONS, DIAGNOSIS, AND LABORATORY SERVICES

A. Clinical Case Definition

Illness with acute onset of fever $\geq 101^{\circ}\text{F}$ followed by a rash characterized by firm, deep-seated vesicles or pustules in the same stage of development without other apparent cause. Rare clinical presentations of smallpox that would *not* meet the clinical case definition are: a) hemorrhagic type, b) flat type, and c) variola sine eruptione. For more information on less common clinical presentations of smallpox, see Appendix C.

B. Confirmed Case

A case of smallpox that is laboratory confirmed, OR
a case that meets the clinical case definition and is epidemiologically linked to a laboratory-confirmed case.

C. Probable/Presumptive Case

A case that meets the clinical case definition, but may not be laboratory confirmed, 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.

D. Suspect Case

A case with a febrile rash illness, with fever preceding development of rash by 1–4 days, OR
a case that has an atypical presentation (see Appendix C) and is not laboratory confirmed but has an epidemiological link to a confirmed or probable case of smallpox.

E. Outbreak

Discovery of any single, lab-confirmed case is defined as an outbreak and will initiate implementation of the CDC and State Smallpox Response Plans. Other criteria for implementation of the response plan:

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

F. Diagnosis Criteria

In assessing patients who may have smallpox, the CDC has outlined the major and minor diagnostic criteria regarding differential diagnosis of febrile vesicular-pustular rash illness.

1. Major Diagnostic Criteria for Smallpox

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

2. Minor Diagnostic Criteria for Smallpox

- a. Centrifugal distribution: greatest concentration of lesions on face and distal extremities;
- b. first lesions on the oral mucosa or palate, face, or forearms;
- c. severity: patient appears toxic or moribund;
- d. slow rash evolution: lesions evolved from macules to papules to pustules over days (each stage lasts 1–2 days);
- e. lesions on the palms and/or soles.

3. Distinguishing Varicella (chickenpox) and Variola (smallpox)

Because smallpox has been declared eradicated since 1980, recognition and diagnosis may be delayed. The most likely condition to consider in the possible diagnosis of smallpox is varicella (chickenpox).

| DISTINGUISHING VARICELLA (CHICKENPOX) AND VARIOLA (SMALLPOX) | | |
|---|--|---|
| | Smallpox: clinical features | Varicella: clinical features |
| Major distinguishing features | Febrile prodrome: temperature $\geq 101^{\circ}$ F and systemic symptoms (prostration, severe headache, backache, abdominal pain, or vomiting) 1–4 days <i>before</i> rash onset | No or mild prodrome before rash onset |
| | Lesions are deep, firm, well-circumscribed pustules; may be confluent or umbilicated | Lesions typically superficial vesicles |
| Other distinguishing features | Rash concentrated on face and distal extremities (centrifugal) | Rash concentrated on trunk and proximal extremities (+/- face, scalp) |
| | Rash in same stage of evolution on any one part of the body | Rash appears in crops so lesions are in different stages of evolution (papules, vesicles, crusts) on any one part of the body |
| | First lesions on oral mucosa/palate (enanthem); followed by examthem (rash) on face or forearm | First lesions on trunk (occasionally face) |
| | Lesions on palms and soles (seen in > 50%) | Lesions very uncommon on palms and soles |
| | Lesions may itch at scabbing stage | Lesions generally intensely itchy |
| | Lesions evolve from papule to pustule in days | Lesions generally evolve from macules to papules to vesicles to crusts in <24 hours |
| | Illness lasts 14–21 days | Illness lasts 4–7 days |

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4. Other conditions to consider in differential diagnosis of smallpox.

The following common conditions might be confused with smallpox and are listed with clinical clues for differentiation:

| OTHER CONDITIONS TO CONSIDER IN DIFFERENTIAL DIAGNOSIS OF SMALLPOX | |
|---|---|
| Condition | Clinical Clues |
| Disseminated herpes zoster | Immunocompromised or elderly persons; rash looks like varicella, usually begins in dermatomal distribution. Lesions are painful. |
| Impetigo (Streptococcus pyogenes, Staphylococcus aureus) | Honey-colored crusted plaques with bullae are classic but may begin as vesicles; regional not disseminated; 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, bullseye. or iris lesions; often follows recurrent herpes simplex virus infections; may involve hands and feet (incl. palms and soles). |
| Erythema multiforme major (Stevens-Johnson syndrome) | Major form involves mucous membranes and conjunctivae; there may be target lesions or vesicles |
| Enteroviruses (including 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 (including fleas) | Itching is a major symptom; patient is not febrile and is otherwise well. |
| Molluscum contagiosum | May disseminate in immunosuppressed persons. |

G. Services Available at Oregon State Public Health Laboratory (OSPHL)

Lab confirmation of smallpox occurs in Level C or D labs only. Initial confirmation is required at Level D labs, located either at CDC or USAMRIID. Level C labs will assist with testing of clinical specimens following initial confirmation of a smallpox outbreak by CDC. OSPHL will receive and facilitate shipment of specimens to Level D laboratories for confirmatory testing; OSPHL cannot perform these tests. OSPHL will provide supplies to LHDs and other providers for collection of specimens; advise regarding packaging and handling of specimens, and report all laboratory specimen results.

1. Smallpox specimen collection

- a. Call the Oregon State Public Health Lab at (503) 229-5882 to consult on collection and transporting potential smallpox specimens.
- b. Resources are also available online for specimen collection and transport at: <http://www.bt.cdc.gov/agent/smallpox/lab-testing/>. A specimen selection table is available at: <http://www.bt.cdc.gov/labissues/index.asp>.
- c. Send frozen specimens. If specimens cannot be frozen, send on wet ice within 6 hours of collection. Shipping on dry ice requires specific labeling and handling of package, as dry ice is hazardous material.
- d. If multiple cases are identified, prioritize testing of:

- i. clinical or environmental specimens that will provide information on potential sources to enhance case detection;
- ii. clinical specimens from cases with unclear presentation but who are suspected smallpox cases.

4. ROUTINE CASE INVESTIGATION

One case of smallpox is an outbreak. Smallpox outbreak investigation requires a team approach, including clinicians, law enforcement and other agencies. The highest priority of smallpox investigation and surveillance is to interrupt transmission by immediate identification and vaccination of susceptible contacts of cases, and isolating the cases while still infectious. All personnel involved must be vaccinated prior to first contact with cases or exposed contacts. Begin investigations without delay even in absence of “take” evaluation for newly-vaccinated staff members.

A. Enhanced surveillance for smallpox in Oregon

Because smallpox disease is unlikely, unless accidental laboratory or intentional bioterrorist exposure occurs, smallpox surveillance relies on two primary approaches: a highly specific case definition (and its dissemination to all clinical providers), and ability to distinguish clinical manifestations of many vesicular and pustular rash illnesses from smallpox disease. LHD staff can enhance local surveillance for febrile rash illness by monitoring measles and rubella reports and conducting syndromic surveillance for unusual numbers or presentations of febrile vesicular-pustular rash illness.

LHD smallpox surveillance includes knowledge of varicella (chickenpox). Varicella is the most common illness that will be confused with smallpox. Understand varicella epidemiology in your state or local area. Understand how varicella disease presents, especially among adults. Educate adult callers who report acute vesicular-pustular rash illness to seek immediate medical evaluation.

Other resources to help clinicians identify smallpox cases are available at:

- <http://www.cdc.gov/nip/ed/smallpox-trg/clinician-should-know/default.htm>.
- The algorithm “Evaluating Patients for Smallpox: Acute, Generalized Vesicular or Pustular Rash Illness Protocol” is a poster format that provides a standard method for evaluating patients with acute, severe rash illness. At: <http://www.bt.cdc.gov/agent/smallpox/diagnosis/evalposter.asp>.
- A related worksheet has been developed, and these documents are available at <http://www.bt.cdc.gov/agent/smallpox/diagnosis/index.asp>.

Active surveillance in local hospitals will be required during a smallpox outbreak. Each hospital in the affected jurisdiction, and other hospitals as requested by ACDP, should identify one person who will be responsible for daily active surveillance at that institution [e.g., infection control practitioner (ICP)]. Patients should be evaluated according to risk. In the event that there are no suspected smallpox patients, a report must still be sent to notify the health department that surveillance was conducted and has not yielded suspect patients (“zero reporting”). Smallpox surveillance forms will be completed on all suspect cases (**Form 1 Smallpox Post-Event Surveillance Form** – see Appendix B). Line lists should be maintained and updated daily to include both new patients and previously reported patients until smallpox is ruled out.

Whenever possible, potential cases must be seen by an infectious disease consultant, dermatologist, or smallpox consultant to clarify the diagnosis.

B. Case Surveillance and Containment

1. **Local Health Department responsibilities in surveillance**
 - a. Use CDC Form 1 “Smallpox Post-Event Surveillance Form” (See Appendix B) for collection of comprehensive information on suspect, probable, and confirmed smallpox cases, and guidance on case surveillance.
 - b. Begin **enhanced surveillance** for additional cases, once smallpox reported nationally.
 - c. Rapidly notify all public health professionals, health care facilities, and clinicians involved in patient care.

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- d. Distribute case definitions for confirmed, probable, and suspected smallpox cases.
 - e. Distribute reporting forms (consult with ACDP on use of forms)
 - f. Designate a central LHD place/person to receive smallpox reports and communicate this to community health care providers.
 - g. Actively contact major reporting sources (hospitals, ERs, major clinics) within the county, at least once daily during a smallpox outbreak to check for new cases.
- 2. Identify the source of infection and potentially exposed persons**
- a. Work with health care facilities to designate specific facilities for evaluation of febrile rash illnesses, where physicians and staff familiar with smallpox can evaluate symptomatic individuals.
 - b. Start active surveillance for cases at all health facilities.
 - c. Retrospective surveillance: attempt to identify cases admitted before the outbreak was recognized but after transmission in the community was theoretically possible. Consider retrospective screening of patients admitted with compatible syndromes (could be done by hospital or LHD personnel).
 - d. If resources are available, review records for all patients who were seen in the ER and discharged home, admitted, or transferred to another hospital.
 - e. Review charts of patients with non-lab-confirmed varicella, generalized herpes zoster, HSV, or those with diffuse vesicular or pustular rash, fever and no lab-confirmed diagnosis to determine if the illness may have been smallpox.
 - f. Encourage re-evaluation of those still in hospital; report those transferred to another facility, discharged, or expired to the local/state health department for follow-up.
- 3. Case Reporting**
- a. Review reporting procedures with health-care providers and other officials in the county.
 - b. Establish redundant reporting: fax, telephone, e-mail, and hand-carried reports in order to avoid missing cases.
 - c. Respond promptly to provider messages left at the LHD.
- 4. Case Data Management**
- The State and LHD will collaboratively gather and manage data on smallpox cases and contacts, to track the outbreak, analyze information, and plan appropriate interventions.
- 5. Isolation and transportation of cases**
- a. Facilitate, in cooperation with emergency management system (EMS) and medical personnel, the isolation and medical evaluation of all identified smallpox cases, whether suspected or confirmed.
 - b. Alternatively, in the absence of other safe transportation options, confirmed and suspected smallpox cases can be transported safely to medical evaluation and care by LHD personnel, using appropriate personal protective equipment for respiratory isolation, and other infection control precautions (See Infection Control section below).
 - c. Cases could be isolated at home or in designated health care facilities.
 - d. Facilities caring for smallpox patients are required to report on case status daily to LHD and State smallpox surveillance personnel, updating lists of suspect, probable, and confirmed cases

C. Contact Investigation and Surveillance

Identification, investigation, and appropriate follow-up care of smallpox disease contacts are priority activities for public health staff in every LHD jurisdiction. Consult immediately with

ACDP about any initial contact investigation activities following potential exposure to smallpox. If contact becomes a smallpox case, interview that new “contact-case” for his/her contacts to expand investigation and provide appropriate care for the expanded group of potentially exposed persons. *Every smallpox case started out as a contact exposed to the virus who was not discovered and treated in time to prevent disease.*

Review the investigation specifics with the Contact Supervisor and ACDP before closing the contact investigation and follow-up activities.

1. LHD Responsibilities in smallpox contact investigation

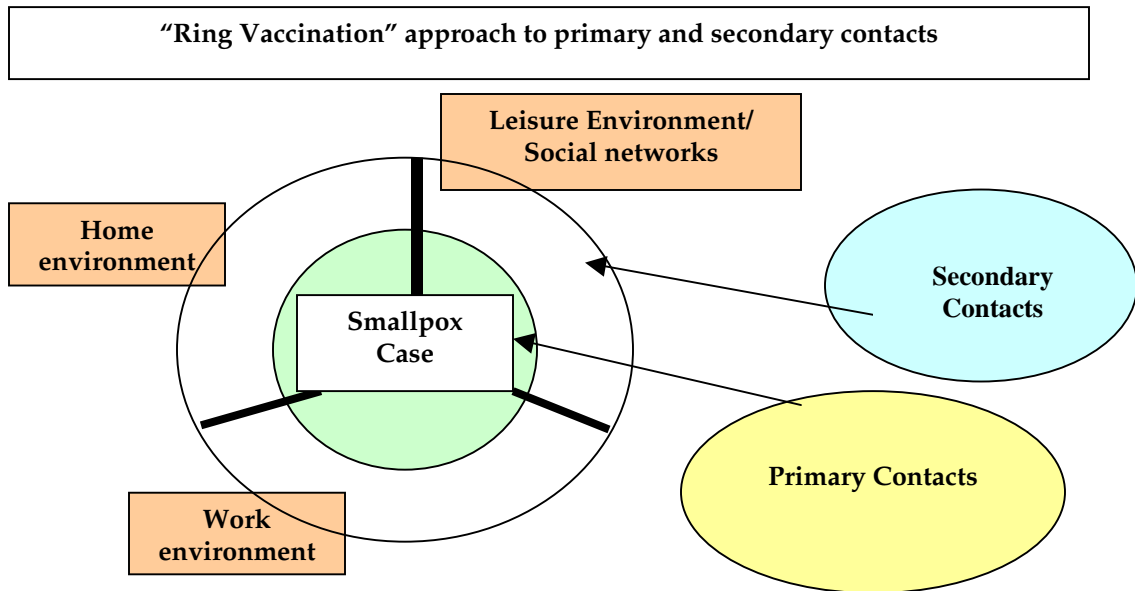
- a. Designate staff in advance (pre-smallpox outbreak) who would carry out smallpox contact investigation.
- b. Encourage appropriate training and experience with other diseases requiring field experience in contact tracing (e.g., STD, TB, HIV).
- c. Identify a contact investigation supervisor to oversee and review contact tracing information and contact surveillance activities.
- d. Ensure adequate vaccination of all staff members involved with case interviewing, contact identification and interviewing, monitoring and assessment of potentially ill contacts, or participating in vaccination, “take” monitoring, and surveillance for adverse reactions to vaccination.
- e. Identify, vaccinate, and monitor all close contacts to any suspected or confirmed smallpox case patient.
- f. Provide daily surveillance for each contact for symptoms of disease, vaccination “take”, and any adverse vaccine reactions for three weeks post-exposure.
- g. Consult with ACDP; resources may necessitate limiting activities to the highest-priority groups.

2. Definitions

- a. **Contact:** a person who has been exposed to the risk of smallpox infection.
- b. **Primary contact:** a person with close face-to-face contact (usually within a distance of 6 feet or less, for at least 4 hours with a confirmed, probable, or suspected case of smallpox during the infectious period. Investigation priority should be given to primary contacts. Primary contacts may either be:
 - i. household contacts: persons living with or working in the same household as the case patient
 - ii. non-household contacts: persons who do not live or work in the case household but share another environment closely with the case patient.
- c. **Secondary contacts:** household members of all primary, non-household contacts and persons who work in the household of a primary contact.
- d. **Contacts from highest to lowest priority:**
 - i. Case household family members and others spending ≥ 3 hours in the household since the onset of fever in the case patient.
 - ii. Non-household members with close (< 6 feet contact) for ≥ 3 hours while the case patient has rash.
 - iii. Non-household members with contact < 6 feet for < 3 hours while the case patient has rash.
 - iv. Non-household members with contact ≥ 6 feet for ≥ 3 hours, while the case patient has rash.

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- v. Non-household members with contact of ≥ 6 feet in distance for ≤ 3 hours, while the case patient has rash.



D. Case/Contact Identification

1. **Determine dates of case infectiousness**
 - a. Begin contact investigation immediately upon diagnosis (suspected, probable, and confirmed cases). Do not wait for lab confirmation.
 - b. Determine when symptoms started by reviewing the clinical information about the smallpox patient, including dates of onset of fever and rash. If the patient is too ill, verify dates of fever and rash with close family members
 - c. Calculate the dates of infectiousness to others (usually from fever onset to the day all scabs from lesions are gone).
2. **Interview the case patient in person to identify contacts**
 - a. See the smallpox case patient face-to-face, either in the hospital or at home. Two or more interviews are usually needed to get complete contact information. Plan to re-interview the patient.
 - b. Ensure privacy and be aware of the patient's comfort in the interview setting. If the case patient is very ill or a poor historian, a close family or household member must be interviewed for required information. Allow time to address questions and concerns.
 - c. Stress confidentiality, and discuss how you will assure this. Enlist the patient's help in notifying and explaining necessary follow-up to close contacts that you identify together. Note: the LDH PHN investigator is responsible to notify contacts whether or not case patient assists.
 - d. Teach the patient and all contacts about smallpox and its transmission, why contacts are at risk and required follow-up monitoring activities.
 - e. Identify all close contacts of patient (those with exposure within 6 feet distance during period of infectiousness). Inquire about close "household contacts," including those

potentially exposed in work place, school, shared transportation, leisure activities. Inquire about social network of case patient.

- f. Review the patient's daily and weekly routine to identify places he/she spends time with others. Get specific information about contacts (name, locating information, ages, relationship to patient).
- g. Ask specifically about contacts from outside the patient's county or state, and their locating information. All primary and secondary contacts from outside the LHD jurisdiction require vaccination and surveillance. Inquire about visitors from outside the area who may have had close contact while the case patient was infectious.
- h. Report to ACDP all information on contacts that have either moved or reside outside the jurisdiction where exposure occurred. ACDP will assist to coordinate appropriate follow-up.

3. Use the following forms to obtain needed information (see Appendix B)

- a. Forms for case data:
 - **Form 2A "Smallpox Case Travel/Activity Worksheet"** identifies the patient's daily activities from onset of fever.
 - **Form 2C "Smallpox Case Transportation Worksheet"** records the case patient's mobility and travel history from date of fever onset.
- b. Form/worksheet for collecting contact data from the case patient:
 - **Form 2B "Smallpox Primary Contact/Site Form"** records a line-list of primary/close contacts to the smallpox case. Each name on Form 2B must generate an individual contact record Form 2D "Contact Tracing Form – see below.

4. Tracing, locating, and interviewing contacts

- a. Use **Form 2D "Smallpox Contact Tracing Form"** to record critical information about each primary and secondary contact named by the case patient. A copy of Form 2D may serve as the individual referral form or "ticket" to a smallpox vaccination clinic site.
- b. Trace or locate each primary contact to a smallpox case. Obtain the following information for each contact: (1) exact locating information, (2) physical description, (3) priority by risk (distance from [$<$ or $>$ 6 feet] and time with [$<$ or $>$ 3 hours] the case)
- c. Identify household members of the primary contact ("secondary contacts").
- d. Outcomes or dispositions for contacts include:
 - previous successful smallpox vaccination;
 - referral for immediate vaccination;
 - clinical assessment if symptomatic;
 - hospitalized as suspected case;
 - isolation, not vaccinated, and without symptoms.
- e. Investigators may find contacts have moved or died. If unable to locate, consult with the LHD contact investigation supervisor on extent of locating efforts.

5. Contact Assessment

- a. Interview each primary contact and confirm that the individual had face-to-face contact with the case patient during the infectious period. Obtain names and locating information of all his/her close contacts (secondary contacts).
- b. Educate the contact about smallpox exposure, risk, and needed follow-up (vaccination and surveillance for one month; see section 5 below). Ensure that the contact knows what symptoms to report, and has phone number of LHD investigator.
- c. Assess the contact person for symptoms of fever or rash. Take the contact's temperature. Don't rely on self-report of fever or lack of fever.
- d. Vaccinate all contacts as soon as practical; immediately vaccinate in the field if possible. Prompt contact vaccination takes priority over transportation of a case to an isolation facility.
- e. Monitor all contacts for development of fever or rash for three weeks after exposure to infectious case patient ends, and following vaccination.

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- f. Monitor “take” of contact vaccinations; follow for development of any adverse reactions for three weeks post-vaccination.
- g. Symptomatic contacts: if primary contact is symptomatic with fever or rash, arrange for immediate vaccination and transportation to designated facility for further assessment. Report any symptomatic contact as a suspected case.
- h. Asymptomatic contacts: even if primary contact is asymptomatic, arrange for immediate vaccination.
- i. Identify and vaccinate all secondary contacts of the suspected case-contact as soon as possible.
- j. Primary contact patients are not responsible for notification and follow-up of individuals they identify. Health department staff are responsible to interrupt transmission, and must actively seek out these potentially exposed persons.

4. Contact Vaccination

Follow Oregon protocol for Smallpox Vaccination (available online at <http://www.dhs.state.or.us/publichealth/imm/provider/mso/smallpo31203.pdf>)

- a. Primary and secondary contacts of smallpox cases need vaccination as soon as possible after being identified. Vaccinate contacts immediately once located and educated about smallpox risk, in the field if possible. Otherwise, direct contacts to immediate vaccination at an appropriate clinic site. Arrange for transportation or otherwise monitor adherence.
- b. Provide adverse event surveillance of contact vaccinees, for 3–4 weeks post-vaccination (until scab falls off). Give contact vaccinees the LHD telephone number.
- c. Provide “take” evaluation appointment 6–8 days post-vaccination. “Take” evaluations should be done by a trained health professional if at all possible, not self-reported by vaccinee or other household member. If “take” appointments are not feasible, teach the contact or responsible household member to observe for and record “take.” Use visual aids.
- d. Give a time the contact may expect a follow-up telephone call by LHD staff. Arrange for visit if no telephone. Arrange for interpreter assistance for non-English-speaking persons. If vaccinated contacts do not keep “take” evaluation appointments, outreach by phone or home visit to verify immunity. If no evidence of major vaccine reaction or “take,” plan to re-vaccinate the contact as soon as possible
- e. Instruct any of the primary contact’s household members that have serious vaccine contraindications (e.g., immune deficiency) to avoid physical contact with primary contact and other vaccinated persons until all vaccinated persons in the household are noninfectious for vaccinia virus (after the scab has separated, 14–21 days post-vaccination)
- f. *Contact tracing and targeted contact vaccination activities should take precedence for staff time, even if widespread community or mass vaccination is ongoing simultaneously.*

5. Contact Surveillance and Monitoring

Primary and secondary contacts without fever or rash at the time of initial interview need a combination of active and passive surveillance and should be monitored for 3 weeks (21 days) after last exposure to the infectious case patient. (Active monitoring: LHD staff contact the primary contacts by home visit, office visit, or telephone to assess temperature and any symptoms. Passive surveillance: instruct contacts to notify LHD staff immediately if they develop fever >101°F, or any rash. Instruct vaccinated contacts to notify the LHD staff *immediately* of any possible vaccine-related adverse reactions.)

Primary and secondary contacts need surveillance for adequate vaccine “take” and for post-vaccination adverse events. For contacts with possible language barriers, review instructions with an appropriate interpreter. LHD staff must plan for 24/7 capacity to receive calls from

contacts who develop worrisome symptoms. Self-monitoring by contacts after appropriate education and return demonstration is acceptable.

a. Primary contacts

- i. Give all contacts a copy of Form 2E “Smallpox Case Household and Primary Contact Surveillance Form” as a diary for to record information about themselves, onset of any symptoms, and daily temperature reading. Teach the contact to use Form 2E to record daily temperature every morning and evening. Continue monitoring for 21 days after exposure to the case patient.
- ii. Ensure contacts have a thermometer, and know how to read it. Instruct at least one household member in use of thermometer. Ask the designated household member to demonstrate temperature-taking and recording during initial home visit. LHD may supply thermometers to households under smallpox surveillance. Plan subsequent visits to the household to assure temperatures are taken and recorded accurately, as indicated.
- iii. For contacts located in a health care facility or congregate living facility, work closely with facility staff to monitor contacts for daily temperature and any signs of illness or any vaccination adverse reaction.
- iv. Tell contacts to immediately call the designated LHD nurse investigator if temperature rises over 101° F in the post-exposure monitoring period.

b. Secondary contacts (household members and visitors with close exposure to primary contacts) need surveillance post-exposure and post-vaccination.

- i. Use **Form 2F “ Smallpox Case Primary Contact’s Household Member Surveillance Form”** to develop a line listing of vaccination information for secondary contacts.
- ii. Teach secondary contacts about smallpox disease and symptoms. Teach all contacts about normal reactions to vaccine, and signs of potential adverse reactions after vaccination that must be immediately reported to the LHD.

6. Contact activities and movement

Temperature must be monitored twice daily, regardless of other activities. Tell contacts with temperature >101° F to notify LHD immediately, and to remain at home until further evaluation can be arranged. No unvaccinated visitors or individuals should enter the home where febrile contacts may be living, or where clinical status of contacts is unclear post-exposure to a case patient.

Asymptomatic contacts may continue routine daily activities but must remain within 20 miles of their city of residence (available for surveillance monitoring by LHD).

For primary contacts with vaccination contraindications:

- a. Encourage household members with vaccine contraindications to stay outside the home, without direct contact with those persons being monitored for symptoms.
- b. Separate primary contacts who cannot be vaccinated from other at-risk persons, during the 21-day surveillance period for the specific contact household.

7. When to stop the smallpox contact investigation

Continue effort to identify contacts and evaluate them for infection as long as you are finding evidence of smallpox transmission (e.g. symptoms developing among contacts under surveillance). A decision may be made to stop contact investigation for one transmission environment (for example, a school or worksite), while simultaneously expanding the investigation in another environment, based on evidence found among exposed contacts. Review status of the investigation with the LHD contact investigation supervisor, nursing supervisor, other investigative team staff, and with ACDP in making decisions on completeness of the contact investigation.

5. CONTROLLING FURTHER SPREAD

The epidemiologic investigation often occurs simultaneously with contact identification and monitoring activities. Assure interruption of transmission. Ensure surveillance of close primary

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contacts for any evidence of smallpox disease. Confirm immunity by vaccination of all primary and secondary contacts to a smallpox case.

A. Epidemiologic Investigation

1. With consultation from ACDP, determine any source of exposure. Use CDC Forms
 - a. **Form 3A “Smallpox Case Exposure Investigation Form”**
 - b. **Form 3B “Smallpox Case Travel/Activity Worksheet – Exposure Period”**
 - c. **Form 3C “ Smallpox Case Transportation Worksheet – Exposure Period”**
2. Consult with local law enforcement to review the need for source case investigation in order to coordinate joint activities. For some groups within the community, contact investigation with law enforcement support may be appropriate.
3. With ACDP assistance, conduct analysis of information collected during contact investigation to determine:
 - a. Most likely source of initial exposure (within 24 hours of confirmed report of smallpox);
 - b. population at risk (persons exposed to intentional smallpox virus release or in other large-gathering settings will need surveillance and vaccination);
 - c. unusual presenting features, degree of morbidity, mortality, incubation period, transmission patterns, specific populations affected;
 - d. characteristics and extent of the outbreak.
4. Review and refine containment and control strategies based on continuous evaluation of contact investigation data.

B. Isolation in Smallpox Containment

1. Isolation of Cases

- a. Encourage strict isolation of hospitalized cases from 24 hours prior to rash (if admitted during prodrome) until all pox scabs have fallen off.
- b. Arrange isolation at home for non-hospitalized smallpox patients, ideally in a room alone with door closed, until all susceptible household contacts have been vaccinated or the contact with contraindications has temporarily found shelter elsewhere.
- c. For community congregate living situations, the smallpox patient should be kept in a room alone with the door closed, should avoid communal living spaces, and should wear a surgical mask if it becomes necessary to leave isolation for any reason.

2. Release from isolation

Case patients may be released from isolation after all smallpox scabs have dried and fallen off. Continue isolation if patient has any pustular or crusted skin lesions.

3. Quarantine

Quarantine is “the restriction of activities or limitation of freedom of movement of those presumed exposed to a communicable disease in such a manner as to prevent effective contact with those not so exposed.” The local public health authorities and State Public Health Officer are responsible for declaring any need for quarantine in Oregon during a smallpox outbreak. Quarantine laws may be used to detain individuals who are suspected or known to be infectious to others within a circumscribed geographic area, and to exclude healthy persons from entering the area. Notify the LHD authorities and ACDP of individuals who refuse to comply with case investigation or requested contact vaccination, who fail to cooperate with illness surveillance, or who fail to report to designated facilities for clinical assessment and care.

C. Vaccination

1. References

- a. Smallpox Immunization Protocol, Oregon DHS Immunization Program, April 14, 2003. Available online at <http://www.ohd.hr.state.or.us/imm/provider/mso/smallpo0403.pdf> or linked to DHS Immunization Home Page at <http://www.ohd.hr.state.or.us/imm/provider/stdgordr.cfm>.
- b. Smallpox Vaccination Status and Procedures – Guidelines for Grantees Using Licensed Undiluted Wyeth Dryvax® Vaccine. Centers for Disease Control, July 9, 2003. Available online at: <http://www.bt.cdc.gov/agent/smallpox/vaccination/statusprocedure.asp>

2. DHS recommendations for vaccination

a. Non- emergency situation

In the absence of disease or intentional release of variola virus, vaccination is recommended for:

- laboratory workers who directly handle cultures or animals contaminated or infected with non-highly attenuated vaccinia viruses (e.g., the NYCBOH, Temple of Heaven, Copenhagen, or Lister vaccinia strains) and recombinant vaccinia viruses derived from non-highly attenuated vaccinia strains;
- laboratory workers exposed to other orthopoxviruses that infect humans (e.g., monkeypox or cowpox);
- health care workers who come into contact with materials such as dressings that may be contaminated with vaccinia or recombinant vaccinia (clinical trials or administering the vaccine);
- consenting medical and public health response personnel approved for pre-event vaccination by local and state bioterrorism preparedness programs; and
- persons administering smallpox vaccine.

b. Emergency situation

In the event of an intentional release of variola virus, vaccination would be recommended for persons exposed to cases, either suspected or confirmed, including:

- Persons exposed to the initial release of the virus;
- close personal and household contacts, defined as face-to-face contact or within 6 feet for 3 hours or more;
- medical providers involved in assessment or treatment of suspect cases;
- public health investigators who may have contact with cases;
- persons transporting confirmed or suspect cases;
- laboratory personnel who collect or process clinical specimens from suspect cases;
- persons with risk of contact with infectious materials from suspect cases (e.g., persons handling medical waste, linen, and room waste); and
- others as identified by public health investigators.

3. Determining Prior Smallpox Vaccination Status

Factors to consider:

- Vaccination record;
- vaccination scar;
- age of the vaccinee;
- prior military service.

Consider as a revaccinee if:

- written record of vaccination, OR
- visible vaccination scar (determine if foreign born since BCG vaccine also leaves a scar), OR
- born before 1972, OR
- served in the military before 1984.
- If in the military between 1984 and 1990, must show a scar or vaccination record to be considered as revaccinee.

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Consider as a first-time (primary) vaccinee if person has none of the above factors that that would indicate revaccination status or definitive history of not having received a vaccination.

4. Vaccination procedures

For first-time (primary) vaccinees, give three vigorous insertions with potent vaccine and proper technique. If no trace of blood, without reinserting the needle into the vaccine vial, give three additional insertions in the same spot. Even if there is no trace of blood after the additional insertions, proceed with an evaluation of the reaction on day 6, 7, or 8 post vaccination.

For revaccinees, give fifteen vigorous insertions with potent vaccine and proper technique. If no trace of blood, without reinserting the needle into the vaccine vial, give three additional insertions. Even if there is no trace of blood after the additional insertions, proceed with an evaluation of the reaction on day 6, 7, or 8 post vaccination.

For both those vaccinees who were primary vaccinees or revaccinees, if no major reaction at day 6–8, repeat the vaccination by giving fifteen vigorous insertions with potent vaccine and proper technique. If no trace of blood on revaccination, give three additional insertions. Even if there is no trace of blood after the additional insertions, proceed with an evaluation of the reaction on day 6, 7, or 8 post vaccination. The repeat vaccination should be done on the same day as the take reading so as to not miss an opportunity. In addition, one can use the same arm, one to two centimeters away from the previous vaccination spot.

5. Assessing vaccination reaction

Smallpox response readiness is an on-going, long-term endeavor. It will require that all smallpox response team members maintain an up-to-date smallpox vaccination status. The appropriate interval for revaccination of response team members is currently under review by CDC and will be made available in the near future. In addition, upon confirmation of a smallpox outbreak, a repeat vaccination to boost the immune system response may be indicated for all team members to ensure their greatest protection.

The World Health Organization (WHO) has recommended that response to vaccination be evaluated on post-vaccination day 6, 7, or 8 (Fenner and Henderson, WHO 1988). These are the days of peak viral replication in primary vaccinees, and the period during which vaccination reaction should be assessed in both first-time vaccinees and re-vaccinees. If the response to vaccination is evaluated too early, <6 days post-vaccination, some equivocal responses will look reactive due to dermal hypersensitivity to vaccinia proteins. These were sometimes called "immediate reactions" but are not caused by viral replication, i.e., not successful vaccination. If the response to vaccination is evaluated too late, >8 days post-vaccination, the major reaction may be missed in those individuals with prior immunity to vaccinia who may experience a more rapid progression of the vaccination lesion. Responses in revaccinees that resolve in fewer than 6 days are not successful vaccinations. (See Appendix D for normal "take" reaction and normal post-vaccination symptoms).

a. 6–8 days after vaccination

Vaccination site reactions are classified into two categories, "major reactions" and "equivocal reactions." A major reaction indicates a successful vaccination, and is characterized by a pustular lesion or an area of definite induration or congestion surrounding a central lesion, which might be a scab or an ulcer. All other responses are equivocal reactions and are not successful vaccinations. Equivocal reactions may be due to poor vaccination technique, use of subpotent vaccine, or residual vaccinia immunity in previously-vaccinated individuals. Persons with an initial equivocal reaction cannot be presumed to be immune to smallpox and revaccination is recommended. If a second equivocal reaction occurs after revaccination with fresh vaccine and vigorous technique, if a revaccinee, the vaccinee can be considered immune; if a first-time

vaccinee, a third vaccination should be given. (See criteria for considering a vaccinated person immune for persons with two consecutive equivocal reactions below.)

b. More than 8 days after vaccination

If a vaccinee is not seen at 6–8 days post vaccination for an assessment of his/her vaccination site, but shows up at a later time, visually observing that the vaccination site reaction is at that time characteristic of a major reaction (pustule, and/or scab or ulcer surrounded by definitive induration or congestion) confirms it to be a successful vaccination. At even a much later time, if the vaccination site has a scar and the receipt and date of the pertinent dose of vaccine can be documented through the vaccinee's vaccination card, clinic record or PVS, the observer may confirm a successful vaccination. The observer should rely on his/her direct visual observation and not on the vaccinee's history of the evolution of the vaccination site reaction.

6. Criteria for Considering a Vaccinated Person Immune

Smallpox response readiness is an on-going, long-term endeavor. It will require that all smallpox response team members maintain an up-to-date smallpox vaccination status. The appropriate interval for revaccination of response team members is currently under review and will be made available in the near future. In addition, upon confirmation of a smallpox outbreak, a repeat vaccination to boost the immune system response may be indicated for all team members to ensure their greatest protection.

a. Revaccinees

If a revaccinee has some degree of visible or palpable erythema or induration and there is an indication of a central lesion at day 6, 7, or 8, it is a major reaction and the vaccinee should be considered immune. If a revaccinee has had 2 additional vaccinations, both with equivocal reactions, consider that person immune. This person may serve on a smallpox response team.

b. Primary Vaccinees

If a first-time vaccinee (primary vaccinee) has not had a successful vaccination (major reaction) after two vaccinations (the first with 3 insertions; the 2nd with 15 insertions), a third vaccination should be given with 15 insertions using fresh vaccine and vigorous technique. If the third vaccination is not successful, the vaccinee may not have been a true first-time vaccinee. If it can be confirmed that the individual actually was vaccinated prior to the recent vaccinations, this person can be considered immune and can serve on a smallpox response team. However, if it can't be confirmed that the individual is actually a re-vaccinee, then this person should not be considered immune and should not serve on a smallpox response team in a capacity in which exposure to smallpox might occur.

7. Contraindications to Smallpox Vaccination

Persons with the following conditions or whose household members or close contacts have such conditions should not be vaccinated, *unless exposed to a suspected or confirmed smallpox patient during a smallpox emergency.*

a. History or Presence of Eczema or Other Skin Conditions

Because of the increased risk for eczema vaccinatum in persons with a history of eczema or atopic dermatitis, smallpox vaccine should not be administered to persons with these conditions or a history of them, nor those whose household or close contacts have active eczema, or a history of eczema or atopic dermatitis. Persons with other acute, chronic, or exfoliative skin conditions that cause breaks in the skin, such as burns, zoster, psoriasis, severe acne, impetigo, or herpes might also be at higher risk for eczema vaccinatum.

b. Immunosuppression

Replication of vaccinia virus can be increased among persons with conditions associated with decreased immunity, including HIV infection, leukemia, lymphoma, generalized malignancy, solid organ transplantation, cellular or humoral immunity disorders, or those receiving therapy with alkylating agents, antimetabolites or radiation.

c. Corticosteroid therapy and steroid drops

Delay immunization of persons taking high-dose corticosteroid therapy (≥ 2 mg/kg body weight or 20 mg/day of prednisone for ≥ 2 weeks) for at least 3 months after the last dose. Also included

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in this risk group are hematopoietic stem-cell transplant recipients who are <24 months post-transplant, and hematopoietic stem-cell transplant recipients who are ≥24 months post-transplant but who have graft-versus-host disease or disease relapse. Anyone using steroid drops in his or her eyes for any reason should not get the smallpox vaccine until medication is finished.

d. Pregnancy and Breastfeeding

Smallpox vaccine is contraindicated for individuals who are pregnant or whose household contacts are pregnant. Pregnancy should be avoided for at least one month after vaccination. Women who are breastfeeding should not get the vaccine. This applies to women who are breastfeeding as well as pumping and then bottle-feeding breast milk. Breastfeeding by a close contact is not a contraindication.

e. Age <18 years

Before eradication, smallpox vaccine was administered routinely during childhood. However, smallpox vaccination is no longer indicated for infants or children <18 years of age in non-emergency situations.

f. Allergies to Vaccine Components

The currently available vaccinia vaccine (Dryvax[®]) contains trace amounts of polymyxin B sulfate, streptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate. Persons who have experienced anaphylactic reactions (i.e., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) to any of these antibiotics or to a previous dose of smallpox vaccine should not be vaccinated. The vaccine does not contain penicillin.

g. Moderate or Severe Short Term Illness

Anyone moderately or severely ill (including illness with fever) should defer vaccination until illness is resolved.

h. Heart Problems or known coronary disease, including:

- Previous myocardial infarction (heart attack);
- angina (chest pain caused by lack of blood flow to heart);
- congestive heart disease;
- myocarditis (heart muscle becomes inflamed);
- cardiomyopathy;
- stroke or transient ischemic attack (“mini-stroke” causing stroke-like symptoms but no lasting damage).
- chest pain or shortness of breath with activity (e.g., walking upstairs);
- other heart conditions under care of doctor.

i. Heart related risk factors: (3 or more of these 5 contraindicate smallpox vaccine)

- Been told by a doctor that you have high blood pressure;
- been told by a doctor that you have high blood cholesterol;
- been told by a doctor that you have diabetes or high blood sugar;
- have a first degree relative (mother, father, brother, or sister) who had a heart condition before the age of 50;
- smoke cigarettes now.

| CONTRAINDICATIONS TO SMALLPOX VACCINE | |
|---|---|
| Non-emergency use | During smallpox emergency |
| <ul style="list-style-type: none"> • History or presence of atopic dermatitis or eczema or close/household contacts with these conditions • Other acute, chronic, or exfoliative skin conditions that are active at the time of proposed vaccination or close/household contacts with these conditions • Immunosuppression or close/household contact who is immunocompromised • Pregnancy or pregnant household members • Age <18 yrs • Serious vaccine component allergy • Breastfeeding • Moderate or severe short term illness • Use of steroid eye drops • Diagnosed by a doctor as having a heart condition with or without symptoms • Three or more heart related risk factors | <p><i>There are NO contraindications to smallpox vaccine if exposure to smallpox virus is suspected or confirmed. Anyone directly exposed to smallpox virus should be vaccinated, regardless of age, allergies, pregnancy or medical condition.</i></p> <p>If no exposure is suspected, follow the contraindications for non-emergency use.</p> |
| <p>These may be temporary exclusions and may change as more information is gathered. (source: CDC Smallpox Vaccine Information Statement (VIS) 3/31/03; Smallpox Vaccine and Heart Problems)</p> | |

8. Vaccine Administration

- Reconstitute smallpox vaccine according to manufacturer package insert.
- Secure vial of vaccine to eliminate possibility of a spill.
- Cleanse the skin only if grossly contaminated with soap and water. Allow skin to dry thoroughly. Do not use alcohol; alcohol inactivates the vaccine.
- Dip bifurcated needle into the reconstituted vaccine causing a droplet of vaccine to adhere between the prongs of the needle. Hold perpendicular to the vial to allow any excess vaccine to drop from the needle. Do not shake the needle. The droplet contains the recommended dose of vaccine, and its presence within the prongs of the bifurcated needle should be confirmed visually. If no vaccine is seen between the prongs of the needle, and the needle has not touched the skin of the vaccinee, it may be dipped again.
- Pull the skin over the deltoid muscle of the non-dominant arm, taut with one gloved hand. Hold bifurcated needle perpendicular to the skin with the other gloved hand while resting wrist on the patient's arm. Rapidly puncture the skin 3 times for a primary vaccinee and 15 times for a secondary vaccinee in an area 5 mm in diameter. Use strokes vigorous enough to allow a trace of blood to appear after 15 to 20 seconds. If no trace of blood is visible, an additional 3 punctures should be made using the same bifurcated needle without reinserting the needle into the vaccine vial.
- Absorb excess vaccine gently with sterile gauze and discard gauze in a biohazard waste receptacle.
- Cover the vaccination site with a single layer of sterile gauze and secure with tape. If vaccinee is a health care worker, cover the gauze with a semipermeable dressing (e.g., Opsite®).

9. Post Vaccination Site Care

Vaccinia virus can be cultured from vaccination site from time the initial papule forms (2–5 days post-vaccination) until the scab separates from the skin, as long as 21 days after the vaccination. During this time, attention is necessary to prevent spread of the virus to another area of the body or to another person.

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DO'S:

- COVER vaccination site and change cover frequently to allow site to breathe.
- When working in a health care setting, cover vaccination site loosely with gauze, using first aid adhesive tape to hold in place. Then cover gauze with a semipermeable dressing (e.g., OpSite[®]). Change bandage at least every 3–5 days in order to prevent build-up of fluids and irritation of the site. Wear a shirt to cover the bandaged site as additional barrier to spreading virus to other areas of body or to other people.
- When not working in a health care setting, cover vaccination site loosely with gauze and tape. Change gauze bandage every 1–3 days and wear a shirt that covers the site. This is particularly important in situations of close physical contact.
- Keep vaccination site dry. Change bandage or gauze if it gets wet. Bathe as normal by covering vaccination site with a water-resistant bandage (e.g., plastic wrap) during bath or shower. Do not scrub site while bathing. Do not touch site and then touch another area of body (such as genitals or eyes). Replace water-proof covering with regular dressing as soon as area has dried.
- Handle contaminated materials safely. Place used bandages and gauze in a plastic zipper bag before throwing away. Do the same with scab when it falls off. Dispose of bags in regular trash. Use normal laundering (warm or hot water with bleach or detergent) to wash clothing, towels, washcloths, or sheets that have touched the vaccination site.
- WASH HANDS with soap and water after touching the vaccine site or other things that have touched the site like bandages or clothing.

DON'TS:

- Don't use a bandage that blocks all air from vaccination site. This may cause skin to soften and wear away.
- Don't put salves or ointments on the site.
- Don't scratch site.
- Don't forget to wash hands.
- Don't let persons who haven't been vaccinated touch the vaccination site or things that have touched the vaccination site, such as bandages or clothes.

10. Adverse Event Reporting

The State of Oregon DHS Immunization Program will track reports of adverse reactions to the smallpox vaccine. Serious and life-threatening reactions to the smallpox vaccination are uncommon.

All adverse events following smallpox immunization should be reported by all providers to the DHS Immunization Program, using a Vaccine Adverse Events Reporting System (VAERS) form by fax. Life-threatening events must be reported within 24 hours and all other events within 7 days. Completed forms should be FAXED (preferable, due to timeliness) to 503-731-3095. If faxing is not possible, please mail completed forms to the DHS Immunization Program, PO Box 14450, Portland, OR 97214-9929. If there are questions about the VAERS program or reporting, please call the Immunization Program at 503-731-4020. All VAERS reports received by the state will be forwarded to the VAERS program in Rockville, MD.

If clinical consultation is needed, or VIG or Cidofovir is indicated, contact the ACDP epidemiologist on call at 503-731-4024 (business hours) or 503-731-4030 (after hours).

a. Serious Reactions That Need Evaluation for Medical Attention

- Accidental implantation — a vaccinia rash or outbreak of sores limited to one area distant from the vaccination site. It usually occurs on the genitals or face, and can

include the eyes, where it can damage sight or lead to blindness. Note: If the eyes are affected, seek immediate medical attention.

- Generalized Vaccinia — a widespread vaccinia rash. The virus spreads from the vaccination site, probably through the blood.
- Erythema multiforme — an allergic rash in response to the vaccine. This can take various forms such as red spots, bumps, or hives.
- Red streaks coming out from the vaccination site are most likely a normal reaction, but could be an infection and should be checked.

b. Life-Threatening Reactions That Need Immediate Attention

- Eczema vaccinatum — widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis; it can lead to scarring, severe systemic illness, or death.
- Progressive vaccinia or vaccinia necrosum — an ongoing infection of skin at the vaccination site with tissue destruction. It can cause scarring, spread to other organs, or lead to death.
- Post-vaccinial encephalitis — Inflammation of the brain. This can lead to disability or death.

For more information, see Appendix D, consult with your health officer, bioterrorism coordinator, ACDP medical epidemiologists, or go to the CDC website, <http://www.bt.cdc.gov> or www.cdc.gov/smallpox for current fact sheets on smallpox vaccinations; CDC Smallpox Pre-Vaccination Information Packet, updated 11/15/03, available online at <http://www.bt.cdc.gov/agent/smallpox/vaccination/infopacket.asp>; MMWR, 6/22/01, Vol 50, RR-10, *Vaccinia (Smallpox) Vaccine; Epidemiology and Prevention of Vaccine-Preventable Diseases*, 7th Edition, January 2002; Smallpox Vaccine Administration Video Transcript, 12/2002; Dryvax® (smallpox vaccine) package insert. Also contact DHS Immunization Program 503-731-4020, or visit our website at <http://www.healthoregon.org/imm>. To request this material in an alternate format (e.g., Braille), please call 503-731-4020.

11. Other Considerations

a. Simultaneous Administration With Other Vaccines

To avoid confusion in ascertaining which vaccine might have caused post vaccination skin lesions or other adverse events, varicella vaccine and smallpox vaccine should only be administered ≥ 4 weeks apart.

To minimize potential risk for interference, live vaccines (e.g., smallpox, MMR) not administered on the same day should be administered ≥ 4 weeks apart. If live vaccines are separated by < 4 weeks, the vaccine administered second should not be counted as a valid dose and should be repeated. The repeat dose should be administered ≥ 4 weeks after the last, invalid dose.

Persons scheduled to receive an annual PPD (tuberculin) skin test should not receive the skin test for 1 month after the smallpox vaccination to prevent a possible false-negative reaction.

b. Vaccination and Blood Donation

The Food and Drug Administration (FDA) has recommended that smallpox vaccinees be deferred from donating blood for 21 days or until the scab has separated. Contacts of vaccinees who have inadvertently contracted vaccinia also should be deferred from donating blood for 14 days after complete resolution of their complications.

c. Vaccine and Heart Problems

If you have received the smallpox vaccine, you should see a health care provider right away if you develop chest pain, shortness of breath, or other symptoms of cardiac disease.

D. Infection Control Measures

1. Infection Control in the Community Setting

Historically, secondary transmission of infection has been limited to susceptible contacts in the immediate vicinity of the symptomatic patient. Prevention of the spread of smallpox virus from patients to others is a critical part of the overall control strategy.

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- Use both contact and respiratory precautions when working with any person with suspected smallpox infection.
- Teach contacts of the ill person about respiratory and contact precautions.
- Keep patient in an isolation room with the door closed, with ventilation to outside air, not the inside of the home.
- Minimize close contact with ill person from fever onset until pox scabs fall off.
- Limit visits and wear a surgical mask when within 6 feet of patient.
- Ensure all persons in contact with patient are vaccinated with evidence of “take.”
- Ensure patient wears a mask and covers skin lesions if leaving isolation for any reason.
- Recommend gloves for direct-contact care with patient.
- Recommend thorough hand washing with soap and warm water after any direct contact with patient.
- Keep personal patient care items within the room.
- Recommend cleaning of any surface in contact with patient secretions or scab material with disinfectant or dilute bleach.
- Recommend disposal of gloves before leaving the patient isolation room by placing in a plastic bag.
- For home laundering of contaminated clothing and bed linens, wash using the hot water cycle at the highest possible temperature, with detergent, followed by hot air drying. Chlorine bleach may or may not be added as an additional measure. Coldwater washing is not recommended but if no other option exists, use detergent and additives formulated for cold water washing, and dry with hot air dryer.

2. Infection control in the hospital setting

Infection control of smallpox includes strategies at several levels to reduce transmission of infectious material. Use administrative controls and personal protective equipment (PPE) to avoid transmission of disease. Use a checklist to standardize all infection control procedures.

Ensure vigilant respiratory isolation procedures. Droplet precautions minimize the risk of exposure from a suspected or confirmed smallpox patient. Although respirators and masks are not needed once health care staff demonstrate adequate “take” post-vaccination, the safest policy to prevent inadvertent exposures is to require respiratory protection for all who enter smallpox patient rooms. Use personal respiratory protection (fit-tested N95 respirators) when providing care to smallpox patients. Use of disposable personal protective equipment should be confined to the isolation room. Discard disposable PPE after use, using current infectious medical waste guidelines. Use physical contact precautions. Keep patients isolated: beware of infectious smallpox lesion secretions and dried scabs.

Use airborne precautions: airborne spread of smallpox in health care facilities and laboratories has been documented. Patients with the most severe forms of disease have increased shedding of virus, increasing risk of airborne virus. Re-aerosolized virus may be transmitted from fabric or bedding. Factors that enhance potential airborne spread of smallpox virus are viral shedding from oro-pharyngeal lesions prior to diagnosis and poorly-engineered ventilation of rooms.

- Immunize caregivers as soon as possible.
- Minimize exposure of vulnerable persons. Limit visitors and assure all visitors wear a surgical mask when within 6 feet of the patient.
- Ensure all persons providing direct care to smallpox patients have active immunity to the disease (vaccinated, with evidence of “take”).
- All staff involved with care of the patient or his/her immediate environment need vaccination, including those in medical, nursing, dietary, and housekeeping roles within health care facilities.

- Isolate possible or suspected or confirmed smallpox cases from onset of fever until all scabs from lesions separate and fall off.
- Place the smallpox patient in a private room with negative pressure relative to other rooms. Monitor pressure regularly. Ensure 6–12 room air changes per hour.
- If a negative pressure room is not available, keep the room door closed, open a window to the outside air, and use a fan to blow air away from the hallway.
- If private room is not available, place the patient in a room or ward with other smallpox patients.
- Wear PPE when within 6 feet of the patient; use either a fit-tested N95 respirator or surgical mask.
- Confine use of PPE to the patient isolation room.
- Wear gloves when entering the isolation room. Change gloves after any contact with the patient or infectious materials. Observe strict hand hygiene when providing direct care.
- Wear a leak-proof gown when in contact with the patient or any body fluids.
- Discard of PPE using infectious medical waste guidelines.
- Dispose of gowns and gloves before leaving the patient isolation room, by placing in a biohazard bag.
- Keep personal patient care items within the enclosed patient room.
- Assure surfaces are cleaned daily.
- Dedicate use of monitoring equipment and other items to remain in the smallpox patient's isolation room.
- If an infectious patient is transported from isolation, place a mask on the patient to prevent droplet spread and avoid crowded areas. Cover all skin lesions completely while away from negative pressure isolation.
- Isolate the patient alone in a room when waiting for care.
- Reduce transmission by fomites by reducing transmission from contaminated fabrics, clothing, and bedding.
- Textiles and clothing should be bagged or contained at the point of use.
- Do not sort laundry from areas of smallpox patient care prior to laundering, wet items should be bagged, and placed in leak-proof containers when transported.
- Reusable laundry bags should be laundered with the contaminated laundry.
- Handle all clothing, bedding, and laundry from smallpox care areas with a minimal of agitation, to prevent introducing virus into the air.
- Separate contaminated laundry from all other clean laundry during washing, drying, folding, or transporting.
- Use routine procedures for laundry, including hot water (>160° F), washing with detergent and bleach, and hot air drying. No other special laundering protocols are needed.
- For home laundering of contaminated clothing and bed linens, wash using the hot water cycle at the highest possible temperature, with detergent, followed by hot air drying. Chlorine bleach may or may not be added as an additional measure. Coldwater washing is not recommended but if no other option exists, use detergent and additives formulated for cold water washing, and dry with hot air dryer.
- Contain, treat, and dispose of medical waste properly. All currently approved methods of medical waste management can be expected to inactivate the variola virus.
- Contain deceased smallpox bodies in leak-proof body bags for transport. For disposal of anatomical and pathological waste, incineration is an option. Current mortuary practices of barrier protection are expected to prevent transmission.
- See CDC Guide C for further information on infection control during smallpox emergency, available online at <http://www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-c-part-1.pdf>

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3. Decontamination and disinfection measures

Variola virus is particularly sensitive to chemical disinfection. No specific disinfectants have been formulated or tested for inactivation of variola virus on surfaces. Viruses with biophysical properties similar to smallpox, such as vaccinia, are readily inactivated by a variety of agents found in EPA-approved chemical germicides.

a. Medical instruments

Current disinfectants and liquid chemical sterilants approved by U.S. Food and Drug Administration (FDA) are effective for inactivating vaccinia and variola virus from medical instruments and devices. However, use of such disinfectant on large environmental surfaces (table tops, floors, walls) is not indicated. Use disposable medical instruments and patient-care devices if possible. Discard as medical waste. Reusable instruments should either be sterilized or subjected to high-level disinfection. Reusable medical equipment should be cleaned and then disinfected with EPA-registered chemical germicide, using current protocols

b. Environmental surfaces

There is no evidence of transmission of variola virus from non-porous surfaces. Manufacturer-recommended concentrations of EPA-registered germicides are considered adequate for cleaning and disinfecting environmental surfaces in smallpox care areas. There is no need to clean or disinfect interior surfaces of ambulances, other vehicles, or spaces occupied by smallpox patients. Fumigation of air is not needed. Large housekeeping surfaces such as floors and tables can be cleaned using EPA-registered detergent disinfectant. Use a vacuum cleaner with high efficiency particulate air filter (HEPA) for cleaning carpets or upholstered furniture and discard vacuum bags as routine waste.

For further information on environmental control of smallpox virus, see CDC Guide F, available online at <http://www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-f.pdf>

6. OTHER SPECIAL CONSIDERATIONS

A. Smallpox Virus as a Bioterrorist Weapon

Intentional release of smallpox could occur through airborne dispersions or intentionally infecting persons who could expose groups of others to the disease. If airborne dispersion should occur, smallpox virus would be inactivated within 24 hours, and would not be present before first cases were detected 7–17 days later. If spread by intentionally-infected persons, the source of the outbreak could likely be tracked down using epidemiologic methods

B. Legal Issues in Smallpox Containment

Consent for release of information is not necessary to discuss the patient's care with medical professionals, lab, radiology, or other health care agency staff involved in *direct care* of the patient or contacts who are potentially infected. Consult with LHD administrators and LHD Health Officer concerning extent of information to be shared with law enforcement, emergency management personnel, and others. Oregon Administrative Rules mandate investigation of communicable diseases of public health significance (see OAR 333-019-0000 at <http://www.ohd.hr.state.or.us/acd/oars/div19.cfm>), and give Health Officers power to institute measures to control communicable disease outbreaks.

Confidentiality refers to protection of all private information about a patient, and preventing unauthorized persons from learning information shared in confidence. Ensuring confidentiality while caring for smallpox patients is a professional obligation as well as a legal requirement. Adequate contact investigation depends on establishing trust in the health care providers involved with the patient.

Do not discuss the smallpox patient's status with family members, patient's co-workers or supervisor, or any "worried well" contacts who may seek care. Guard confidential records when

on home visits, and ensure phone or faxed messages about the patient will reach only intended providers. When working with interpreters, assure that the interpreter understands and consider obtaining written agreement from interpreters to guard all information about the patient or contact.

Reference: Awareness of HIPAA requirements in public health settings (see <http://www.cdc.gov/mmwr/PDF/wk/su5201.pdf>, or for Oregon, see <http://www.dhs.state.or.us/admin/hipaa/>)

C. Delegation to Outreach Workers

LHD smallpox contact investigation and surveillance staff should be aware of standards of nursing practice within Oregon, and delegate activities to paraprofessional outreach staff that are consistent with the Board of Nursing guidelines. The local health department administrators, health officer and nursing supervisors are the authority for decisions, and must be consulted, concerning “surge capacity” needs during a smallpox emergency, which would require paraprofessionals to perform duties beyond their usual roles.

D. Inter-jurisdictional Transfers and Coordination of Care

Maintain good communication with other counties, tribal health agencies, correctional health agencies, and states to minimize any hazards from patients and at-risk contacts who move. Notify the receiving jurisdiction smallpox patients and contacts who move outside your LHD jurisdiction. Telephone nurses and health officers who will continue the patient and contact surveillance and vaccination. Fax all appropriate patient information obtained prior to the relocation, or as soon as a new location for patients under surveillance is known. Complete reporting forms generated in the initial investigation, and forward copies to ACDP and to any jurisdiction involved. Contact ACDP at (503) 731-4024 to report any smallpox case or contact who moves out of the LHD jurisdiction while under investigation or surveillance.

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Appendix A. Less Common Clinical Presentations of Smallpox

- 1. Flat-type (or malignant) smallpox** accounted for about 6% of cases in the pre-eradication era.
 - Cases occurred most commonly in children; illness was usually fatal
 - The rash seen in flat-type smallpox involves flattened, confluent lesions rather than the characteristic firm pustules seen with ordinary smallpox.
 - Flat-type smallpox is thought to be associated with a deficient cellular immune response to the virus, although immunologic data are generally lacking.
 - The rash illness is characterized by lesions which develop slowly, rarely progress to pustular stage but remain soft and flattened, and may be “velvety” to touch.
 - If patient survives, lesions gradually disappear without forming scabs and without scarring.
 - Skin peeling or desquamation may occur as lesions heal.
 - Case-fatality rate 97% in one series involving 236 patients.
- 2. Hemorrhagic smallpox** was rare and accounted for between 2% and 3% of cases in the pre-eradication era. For example, in one series, 200 cases occurred out of 6,942 hospitalized smallpox patients.
 - Illness was more common in adults, and pregnant women appeared to be at greater risk.
 - Early onset of prodrome was noted with this form of disease, with sudden onset of illness, with high fever, severe headache and backache, and toxemia; hemorrhages often noted by day 2
 - Hemorrhagic smallpox involved hemorrhages into the skin and/or mucous membranes. Early-onset and late-onset forms were described.
 - The rash illness demonstrated either early-onset of generalized dusky erythema, petechiae, and ecchymoses occur soon after illness started, or later-onset of lesions which begin as macules and develop into pustules; bleeding at base of skin. In both forms, bleeding may occur from mucosal surfaces.
 - Features in one series of nine patients with early-onset form included subconjunctival hemorrhage (67%), hematuria (56%), epistaxis (33%), hematemesis and/or melena (33%), hemoptysis (33%), and bleeding from gums (33%).
 - The pathologic features of hemorrhagic smallpox are consistent with disseminated intravascular coagulation
 - As with malignant smallpox, a defective immune response is suspected as the cause. Several studies have found lower antibody responses among patients with hemorrhagic disease compared with those with ordinary disease Case fatality rates were over 96% in one study, with death usually within the first week of illness
- 3. Modified smallpox** was like ordinary smallpox but had an accelerated course and was a milder illness with fewer skin lesions and a low case-fatality rate; it was more likely to occur in persons with some immunity from past vaccination.
- 4. Variola sine eruptione** occurred in vaccinated contacts of cases and was characterized by sudden onset of fever, headache, and backache. Illness resolved in 1 to 2 days without development of a rash.

Death from smallpox most commonly results from overwhelming toxemia, probably associated with circulating immune complexes. Case-fatality rates in the pre-eradication era for the various types of smallpox were high; however, such rates may be lower with modern medical management and intensive care.

For more information on clinical presentations of smallpox, see: Infectious Disease Society of America Medical Summary, available at http://www.idsociety.org/bt/biotemplate.cfm?template=sm_summary.htm

Center for Disease Control and Prevention, Clinical and Epidemiologic Features (D.A. Henderson), available at <http://www.cdc.gov/ncidod/EID/vol5no4/henderson.htm>

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