Toledo-Lucas County Health Department Standard Operating Procedure

Infectious Disease SOP— Smallpox

Original Effective Date:	Review / Revision Date:	Environmental Health Procedure:
8/2008	7/20/2017	2017.07.014

Maintenance Steward: Epidemiology Supervisor History: ☐ New ☒ Revised ☐ Archived

Organizational Scope:

☐ Full Agency ☒ Administration ☒ Community Services ☒ Environmental Health ☐ Health Services

Frequency of Review:

☐ Annually ☒ Biennially ☐ 5 Years ☒ As Needed ☐ Other:

Location:

S-Drive: S: → Users → Common → Policies & Procedures

Website: www.lucascountyhealth.com/employee-login/

Hardcopy: Environmental Health and Community Services Director's Office

Archived Version(s): S:\CSRP\SOGs\Archives

Requisite Signatures

☒	*Medical Director*	*Date* 7-28-17
☒	*Health Commissioner*	*Date* 07-20-17
☒	*Director of Environmental Health & Community Services*	*Date* 7/20/2017

Infectious Disease SOP— Smallpox

I. Policy

It is the policy of the Toledo-Lucas County Health Department (TLCHD) to adhere to all state, federal, and local statutes governing the management and case investigation of individual communicable disease cases and outbreaks within Lucas County.

II. Scope

This standard procedure applies to the Infectious Disease Program when investigating one case of smallpox. When an outbreak occurs, call ODH ORBIT. In an outbreak, refer to the "Epi and Surveillance OB Procedure."

III. Purpose

This procedure/process establishes guidelines for smallpox investigations. Per the Ohio Administrative Code (OAC) 3701-3, smallpox is a Class A disease and must be reported immediately via telephone according to 3701-3-02, 3701-3-03, 3701-3-04, and 3701-3-05 of the Administrative Code.

IV. Background

Smallpox is caused by Variola virus, a species of Orthopoxvirus. Humans are the only known reservoir although laboratory specimens are the only ones that remain now. This disease is currently eradicated worldwide, with the last naturally acquired case in the world located in Somalia in 1977. The disease is transmitted person-to-person through contact with the respiratory discharges and the skin lesions of the patients. Although droplet spread is the major mode of person-to-person smallpox transmission, airborne transmission through fine particle aerosol can also occur. Smallpox can also be transmitted by contact with items that have been recently contaminated by respiratory secretions or smallpox skin lesions. The period of communicability is estimated to be from a few days before the lesions appear until disappearance of all scabs, which usually occurs about three weeks after the onset of the rash. After exposure, it takes 7-19 days for symptoms of smallpox to appear with an average of 12-14 days.

V. Case Definition

A. Clinical Description

1. Smallpox is an illness with acute onset fever of ≥101.0°F (≥38.3°C) followed by a rash characterized by firm, deep seated vesicles or pustules in the same stage of development without other apparent cause.

B. Laboratory Criteria for Diagnosis

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

NOTE: Laboratory diagnostic testing for variola virus should be conducted in Level C or D laboratories only. Specimen collection, packaging, and transport to CDC should be coordinated with the ODH Laboratory. A chain of custody form should accompany the specimen(s). Contact the ODH laboratory at (614)728-0544 (M-F; 8AM-5PM) for CDC Specimen submission criteria.

VI. Case Classification

A. Suspected:

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

B. Probable:

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

C. Confirmed:

1. 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

D. Not a case:

1. This status is not generally used when reporting a case, but may be used to reclassify a report if investigation revealed it was not a case.

VII. Exclusion criteria:

A. 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.

VIII. Procedure

The procedure/process of the Infectious Disease Program is to ensure that all cases are investigated in the same format.

When a report is received, a member of the ID team will complete an interview of the contact using the CDC Worksheet for Evaluating Patients for Smallpox, which can be found in S:\CSRP\SOGs\Smallpox.

A. Outbreak Response

1. Call ODH ORBIT at 614-995-5599 for guidance

B. Public Health Investigation Process

1. ODRS:
    a. Check to see if the patient is entered into ODRS. If not, enter the patient into ODRS
    b. Key fields for ODRS reporting include:
        i. Import status
        ii. Date of illness onset

iii. All fields in the Epidemiology module

2. Investigation
    a. Case investigation should start as soon as possible following notification.
    b. Contact the patient's provider and/or hospital to obtain demographic information, symptoms, date of onset of symptoms, and travel history. The health department staff will consult with ODH and/or CDC to determine if the laboratory results and /or clinical symptoms indicate a case.
        i. Additional blood work for may be requested through the physician to confirm the case.
        ii. If there are multiple cases, consider terrorist activity.
            1) Call JTTF/FBI Immediately if terrorist activity is suspected
                a) Local FBI Contact: Louie Espinosa—419-779-6600 or lespinosa@fbi.gov
    c. Once the provider and/or hospital ICP has been contacted call the patient/parent and complete the interview.
        i. Provide education from the fact sheet on the IDCM website at http://www.odh.ohio.gov/pdf/IDCM/smallpx.pdf. This information is also located in S:\CSRP\SOGs\Smallpox.
        ii. If no one answers, leave a message requesting a call back.
        iii. Mail an informational letter requesting a callback.
        iv. Continue to attempt phone contact with the patient for three more times in the span of 48 hours after the informational letter was sent.
        v. After interview is completed, ask the patient/parent whether they would like more information. If they express an interest, ask what the best method to deliver the information would be (e.g. e-mail, mail, etc.)
    d. Once information is obtained about case, inform the following agencies, as smallpox is a select agent reportable under 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73:
        i. Local FBI Contact: Louie Espinosa—419-779-6600 or lespinosa@fbi.gov
3. Treatment
    a. There is no proven treatment for smallpox, but research to evaluate new antiviral agents is ongoing.
    b. Early results from laboratory studies suggest that the drug cidofovir may fight against the smallpox virus
    c. Patients with smallpox can benefit from supportive therapy and antibiotics for secondary bacterial infections that may occur.
4. Isolation/Follow Up Specimens
    a. Ohio Administrative Code (OAC) 3701-3-13 (Y) states: "a person with suspected or confirmed smallpox shall be placed in airborne isolation in a facility designated by the director. The patient's release from the facility can occur when all scabs have fallen off."
    b. Follow-up stool specimens should be obtained no earlier than 48 hours following the completion of antibiotic therapy. Collect the remaining specimen(s) not less than 24 hours apart.
5. Prophylaxis
    a. Vaccine no longer commercially available

6. Contacts (Exclusion)
    a. All face-to-face contacts should be vaccinated and placed in quarantine for 19 days after their last contact with a smallpox case.
    b. In a large outbreak due to bioterrorism, exposed persons could be placed under surveillance in their home. These persons will be isolated until a smallpox diagnosis is confirmed or ruled out.
7. Notification
    a. Notify TLCHD contacts immediately after investigation with patient (in sequential order)
        i. Supervisor of Epidemiology
        ii. Director of Community Services and Environmental Health
        iii. Medical Director
        iv. Health Commissioner
    b. Public health recommendations and interventions will be shared with the public by the PIO or to specific individuals within 6 hours of identification of the agent as determined by ODH and supervisory staff at the local health department. An OPHCS alert will be distributed within 12 hours of a positive test result as determined by supervisory local health department staff and ODH.
8. Documentation
    a. Enter information into ODRS as it is obtained.
    Include a note documenting investigation, education, and intervention.
    Sample: Spoke with mother by phone on [date]. EDUCATION: Reviewed disease facts, transmission, and symptoms. DISEASE COURSE: Client has history of [medical conditions] and started [symptoms] on [date]. Started [treatment] on [date]. HOUSEHOLD: HH contacts include [relationships]. All are [asymptomatic/symptomatic] [Include information about sensitive settings for HH contacts]. OCCUPATION: [job] TRAVEL HISTORY: [Include information about travel history within the past 2-3 weeks]. MAILING: Mailed fact sheet and cover letter to home address.
    b. Include a note for each occupation, activity, or other notification and any actions taken.
9. Closing a case
    a. Ensure that all available information is entered into ODRS before closing. Close case and print record. Staple with investigation sheet and any related documents and file in the appropriate file drawer for the current year located in the CSRP office.

IX. Appendices

None

X. Reference/Investigation Forms

A. Smallpox Disease Factsheet is located in G:\CSRP\SOGs\Smallpox

B. For additional information please refer to the ODH IDCM at http://www.odh.ohio.gov/pdf/IDCM/smallpox.pdf

XI. Maintenance

A. Review

1. The Infectious Disease standard operating procedures are to be reviewed every other year or as needed to ensure compliance with both agency and accreditation standards.

2. If guidance/recommendations from the Centers for Disease Control, Ohio Department of Health or law changes regarding this infectious disease, TLCHD will follow the most up-to-date guidance and adjust the SOP(s) as needed.

B. Revision

1. All changes made to this SOP are to be noted on the **Record of Change.** Substantial changes will require renewed signatures from all applicable parties. This includes changes to the intent, scope, procedures, or policy statement.

2. Changes in style, format, grammar or minor error correction will not require renewed signatures but must be indicated on the Record of Change.

Record of Change

(Required for all procedures)

Date of Change	Changes Made By	Changes Made/Notes	Approved By