Toledo-Lucas County Health Department Standard Operating Procedure

Infectious Disease SOP— Anthrax

Original Effective Date:	Review / Revision Date:	Environmental Health Procedure:
8/2008	7/20/17	2017.07.002

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*	7-20-17 *Date*
☒	*Health Commissioner*	07-20-2 *Date*
☒	*Director of Environmental Health & Community Services*	7/20/2017 *Date*

Infectious Disease SOP— Anthrax

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 procedure/process establishes guidelines for anthrax investigations. Per the Ohio Administrative Code (OAC) 3701-3, anthrax 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.

III. Purpose

This procedure/process establishes guidelines for anthrax investigations. Per the Ohio Administrative Code (OAC) 3701-3, anthrax 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

Bacillus anthracis, a Gram-positive, encapsulated, spore-forming, non-motile rod. This organism is found in a vegetative state in humans and animals. When exposed to air, it forms spores which are highly resistant to physical and chemical agents. The spores live for years in contaminated soils.

Cutaneous anthrax is the most common form. The mortality rate is 5%-20% in untreated patients. Inhalation anthrax can present as respiratory distress with fever and shock. The mortality rate in inhalation anthrax is 80%-100%. Intestinal anthrax rarely occurs, but when it does, it usually manifests as explosive outbreaks of violent gastroenteritis with vomiting and bloody stools. The mortality rate is 25%-75%.

V. Case Definition

A. Clinical Description

1. Cutaneous Anthrax: An acute illness or post-mortem examination revealing a painless skin lesion developing over 2 to 6 days from a papular through a vesicular stage into a depressed black eschar with surrounding edema. Fever, malaise and lymphadenopathy may accompany the lesion.
2. Inhalation Anthrax: An acute illness or post-mortem examination revealing a prodrome resembling a viral respiratory illness, followed by hypoxia, dyspnea or acute respiratory distress with resulting cyanosis and shock. Radiological evidence of mediastinal widening or pleural effusion is common.

3. Gastrointestinal Anthrax: An acute illness or post-mortem examination revealing severe abdominal pain and tenderness, nausea, vomiting, hematemesis, bloody diarrhea, anorexia, fever, abdominal swelling and septicemia.
4. Oropharyngeal Anthrax: An acute illness or post-mortem examination revealing a painless mucosal lesion in the oral cavity or oropharynx, with cervical adenopathy, edema, pharyngitis, fever, and possibly septicemia.
5. Meningeal Anthrax: An acute illness or post-mortem examination revealing fever, convulsions, coma, or meningeal signs. Signs of another form will likely be evident as this syndrome is usually secondary to the above syndromes.
6. Injection Anthrax: Recently, another type of anthrax infection has been identified in heroin-injecting drug users in northern Europe. This type of infection has never been reported in the United States. Symptoms may be similar to those of cutaneous anthrax, but there may be infection deep under the skin or in the muscle where the drug was injected. Injection anthrax can spread throughout the body faster and be harder to recognize and treat.

B. <u>Diagnosis</u>

All specimens are sent to the ODH Laboratory, which will then forward them to the Centers for Disease Control and Prevention (CDC), as necessary.

1. Serology
   a. Electrophoretic-immunotransblot (EITB) is available through the CDC. This requires 2 cc serum. Acute serum may be submitted singly or acute and convalescent sera (taken two weeks apart) may be submitted paired.
2. Culture and Isolation
   a. Isolation of the organism from lesions, blood or discharges. Organism isolation and polymerase chain reaction (PCR) testing can be done at ODH Laboratory.
   b. Immunofluorescence studies are done at CDC. For blood isolation, collect 10 cc of blood in a sterile red-topped tube. For cutaneous lesions use two dry sterile swabs. Soak both swabs in the clear serous fluid of the lesion or ring of lesions. If the lesion has a black eschar, slightly moisten both swabs in sterile saline or broth and rotate carefully under the edge of the eschar to avoid its detachment from the skin.
      i. Swab 1 - Immediately prepare a smear for gram stain and another for DFA. Airdry both smears and gently heat-fix both.
      ii. Swab 2 - Place in a dry sterile tube or silica gel pack (as is used for strep).
      iii. **Transport all specimens by messenger at ambient temperatures to ODHL.**

For further details, in the Infectious Disease Control Manual, see Microbiology Client Services Manual, Section 4 (see Select Agent/Biothreat Agent (Clinical specimens), and Appendix N: Biothreat Agent Submission Information for Clinical Samples).

VI. Case Classification

A. Suspect:

1. An illness suggestive of one of the known anthrax clinical forms. No definitive, presumptive, or suggestive laboratory evidence of B. anthracis, or epidemiologic evidence relating it to anthrax.

B. Probable:

1. A clinically compatible illness that does not meet the confirmed case definition, but with one of the following:
    a. Epidemiological link to a documented anthrax environmental exposure;
    b. Evidence of B. anthracis DNA (for example, by LRN-validated polymerase chain reaction) in clinical specimens collected from a normally sterile site (such as blood or CSF) or lesion of other affected tissue (skin, pulmonary, reticuloendothelial, or gastrointestinal);
    c. Positive result on testing of clinical serum specimens using the Quick ELISA Anthrax-PA kit;
    d. Detection of Lethal Factor (LF) in clinical serum specimens by LF mass spectrometry
    e. Positive result on testing of culture from clinical specimens with eh RedLine Alert test

C. Confirmed:

1. A clinically compatible illness with one of the following:
    a. Culture and identification of B. anthracis from clinical specimens by the Laboratory Response Network (LRN);
    b. Demonstration of B. anthracis antigens in tissues by immunohistochemical staining using both B. anthracis cell wall and capsule monoclonal antibodies;
    c. Evidence of a four-fold rise in antibodies to protective antigen between acute and convalescent sera or a fourfold change in antibodies to protective antigen in paired convalescent sera using Centers for Disease Control and Prevention (CDC) quantitative anti-PA IgG ELISA testing;
    d. Documented anthrax environmental exposure AND evidence of B. anthracis DNA (for example, by LRN-validated polymerase chain reaction) in clinical specimens collected from a normally sterile site (such as blood or CSF) or lesion of other affected tissue (skin, pulmonary, reticuloendothelial, or gastrointestinal).

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. 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.

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, pertinent test results, and travel history.
      i. Search for history of exposure to infected animals, contact or employment in industry working with hides, pelts, bone meal or other animal products, or heroin injection.
      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/anthrax.pdf. This information is also located in S:\CSRP\SOGs\Anthrax.
         1) If no one answers, leave a message requesting a call back.
         2) Mail an informational letter requesting a callback.
         3) Continue to attempt phone contact with the patient for three more times in the span of 48 hours after the informational letter was sent.
         4) Travel history for the week prior to symptom onset to an endemic area is important data to elicit. Toledo Lucas County HD progress notes will be utilized to record the necessary information and travel activity.
         5) 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 anthrax 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. Ciprofloxacin is recommended. If the isolate is susceptible, doxycycline and amoxicillin are acceptable alternatives.
   b. From the: Summary of Notifiable Infectious Diseases and Conditions — United States, 2014; October 14, 2016 / 63(54);1-152:

      The U.S. Food and Drug Administration (FDA) has approved two antitoxin treatments for inhalation anthrax: anthrax immune globulin intravenous (human) (i.e., Anthrasil) and raxibacumab. These therapeutics are held in the Strategic National Stockpile, and requests for use must be made to CDC. Antitoxins, in combination with antimicrobials and supportive therapies, are recommended for treatment of systemic anthrax. In addition, anthrax vaccine adsorbed (i.e., BioThrax) is FDA approved as a 3-dose post-exposure prophylaxis

(PEP) series, along with antimicrobials, to prevent anthrax in adults exposed to Bacillus anthracis. PEP and treatment recommendations exist for multiple populations, including children, pregnant and postpartum women, and adults for conventional and mass casualty settings.

c. Consult the CDC anthrax website for up-to-date information on treatment protocols.

4. Isolation/Follow Up Specimens
    a. There is no isolation requirement. The convalescent serum specimen should be drawn 14 -35 days after the acute specimen.
5. Prophylaxis
    a. Person-to-person transmission is not common.
    b. Important to identify source, if possible, as others may have similar contact (work or home) and may also contract disease.
    c. Spores remain viable for decades in soil. If bioterrorism is suspected, postexposure prophylaxis may be recommended for persons who may have been exposed to the spores. Post-exposure prophylaxis would include antimicrobials (such as ciprofloxacin or doxycycline) and possibly anthrax vaccine.
    d. Please note that there is an existing standing medical order issued by the Director of the Ohio Department of Health for Ohio local health departments in an emergency situation to dispense prophylactic antibiotics and to provide anthrax vaccine to persons with known or suspected exposure to *Bacillus anthracis.* For further details, see www.odh.ohio.gov/pdf/idcm/btstandorders.pdf.
6. Contacts (Exclusion)
    a. Depending on the type of anthrax case (cutaneous, pulmonary, intestinal, oropharyngeal, or injection) and case history, look for others with similar exposure in family, co-workers, or community.
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.

C. Documentation

1. Enter information into ODRS as it is obtained.
2. 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.

3. Include a note for each occupation, activity, or other notification and any actions taken.

D. Closing a case

1. 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.

VIII. Appendices

None

IX. Reference/Investigation Forms

A. Anthrax Factsheet is located in S:\CSRP\SOGs\Anthrax.

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

X. 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