



Diphtheria

Investigation Guideline

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Revision History:

Date	Replaced	Comments
05/2019	05/2018	Updated case definition. Added link to CDC contact management worksheet (Investigator Responsibilities and Contact Investigation.) Updated DAT request process to begin with contacting KDHE before contacting CDC (Notification and Case Management Sections). Formatted Laboratory Analysis section. Removed statement that cutaneous diphtheria is not be reported to CDC in Data Management. Updated Investigator Responsibilities and Case Investigation with statement that "Immediate action...until shown not to be caused by toxigenic <i>C. diphtheriae</i> ."
05/2018	12/2014	Notification Section and Isolation...Restriction Section modified with requirements of revised regulations. Additional guidance provided on management of cutaneous case and contact management. Epidemiology section updated. Guidance added in data management on classification of cutaneous cases and asymptomatic (carrier) cases.
12/2014	02/2012	Updated Laboratory and Case Management Section. More details added to Investigators Responsibilities and Data Management. Reformatted Standard Case Investigation section to assist with EpiTrax system data entry. Reformatted fact sheet.
02/2012	03/2009	Revised format. Added diphtheria worksheet. Replaced BSE with BEPHI. Added notification section. Removed references to KS-EDSS. Revised case definition with CDC 2010 version.

Diphtheria

Disease Management and Investigative Guidelines

CASE DEFINITION (CDC 2019)

Clinical Criteria

- Upper respiratory tract illness with an adherent membrane of the nose, pharynx, tonsils, or larynx **OR**
- Infection of a non-respiratory anatomical site (e.g., skin, wound, conjunctiva, ear, genital mucosa)

Laboratory Criteria for Diagnosis

Confirmatory laboratory evidence:

- Isolation of *C. diphtheriae* from any site **AND**
- Confirmation of toxin-production by Elek test or by another validated test capable of confirming toxin-production

Supportive laboratory evidence:

- Histopathologic diagnosis

Epidemiologic Linkage

Direct contact with a laboratory-confirmed case of diphtheria.

Criteria to Distinguish a New Case from an Existing Case

Individuals without evidence of clinical criteria as described by the diphtheria surveillance case definition but for whom toxin-producing *Corynebacterium diphtheriae* is confirmed via laboratory testing (isolation and toxigenicity testing by modified Elek test or other validated test capable of confirming toxin-production) should not be classified as cases. These individuals are considered carriers of the bacteria and are not reportable.

Case Classification

Suspected

- In the absence of a more likely diagnosis, an upper respiratory tract illness with each of the following:
 - an adherent membrane of the nose, pharynx, tonsils, or larynx **AND**
 - absence of laboratory confirmation **AND**
 - lack of epidemiologic linkage to a laboratory-confirmed case of diphtheria.
- OR**
- Histopathologic diagnosis

Confirmed

- An upper respiratory tract illness with an adherent membrane of the nose, pharynx, tonsils, or larynx and any of the following:
 - isolation of toxin-producing *Corynebacterium diphtheriae* from the nose or throat **OR**
 - epidemiologic linkage to a laboratory-confirmed case of diphtheria.
- OR**
- An infection at a non-respiratory anatomical site (e.g., skin, wound, conjunctiva, ear, genital mucosa) with isolation of toxin-producing *C. diphtheriae* from that site

Case Classification Comments

- Cases of laboratory-confirmed, non-toxin-producing *C. diphtheriae* should not be reported to CDC as diphtheria cases.
- PCR and MALDI-TOF diagnostics for *C. diphtheriae*, when used alone, do not confirm toxin production. Always combine these tests with a test that confirms toxin production, such as the Elek test.
- Negative laboratory results may rule-out a diagnosis of diphtheria; however, clinicians should carefully consider all lab results in the context of the patient's vaccination status, antimicrobial treatment, and other risk factors.

LABORATORY ANALYSIS

Commercially available tests to confirm diphtheria include: *C. diphtheriae* culture and Elek testing of isolates for diphtheria toxin production. Commercially available MALDI-TOF (matrix assisted laser desorption/ionization-time of flight mass spectrometry) and the CDC provided polymerase chain reaction (PCR) diagnostics do not confirm toxin production. The measurement of the patient's serum antibodies to diphtheria toxin may assist in assessing the probability of diphtheria.

The Kansas Health and Environmental Laboratories (KHEL) is not equipped to test for *C. diphtheriae*, but will assist in the forwarding of isolates and specimens to the CDC Diphtheria Laboratory for testing:

- KHEL will contact the CDC Diphtheria Laboratory and arrange for testing.
- CDC will perform culture, toxigenicity testing, and polymerase chain reaction (PCR) tests on specimens approved and forwarded by KHEL.
 - CDC does not test sera for antibodies to *C. diphtheriae*.
- KHEL Will only forward specimens to CDC that have been approved by the KDHE Infectious Disease and Epidemiology Response (IDER) unit.

Because respiratory diphtheria is very uncommon in the US, the medical provider must first review the attached [Checklist for Assessing a Patient with Suspected Diphtheria](#) and consider other agents in the differential diagnosis.

Other biological disease agents which may cause a membranous pharyngitis:

1. Group A β -hemolytic *Streptococcus*
2. *Staphylococcus aureus*
3. *Arcanobacter hemolyticum*
4. *Candida albicans*
5. *Borellia vincenti* (Vincent's angina caused by a fusiform bacteria)
6. *H. influenzae* (acute epiglottitis)
7. Viruses – EBV (Infectious mononucleosis), adenovirus, Herpes simplex
8. *Toxoplasma*
9. Other agents:
 - Anti-neoplastic agents use may cause pharyngeal membrane formation.
 - Long-term use of corticosteroids can cause oral candidiasis.

If diphtheria is still suspected, the medical provider should contact KDHE-IDER at 1-877-427-7317, and:

- Institute strict isolation.
- Perform antibody testing for diphtheria toxin through a commercial laboratory.
- Perform *C. diphtheriae* culture, and toxigenicity testing of any isolates, through a commercial laboratory.
 - Both nasal and pharyngeal swabs should be obtained for culture for pharyngeal diphtheria.
 - If a commercial laboratory cannot assist with the culture and toxigenicity testing, work with KDHE- IDER for forwarding to the CDC's Diphtheria Laboratory for testing.
- Consider treatment with diphtheria toxin (DAT).
 - *Suspect cases of pharyngeal diphtheria should receive diphtheria antitoxin (DAT) immediately after bacteriologic specimens are taken without waiting for lab results.* Refer to guidance in the:
 - [Case Management](#) section of this document and
 - [CDC's Use of DAT for Suspected Diphtheria Cases— Protocol](#)
 - If DAT is requested for pharyngeal diphtheria, work with KDHE-IDER to arrange PCR testing at CDC.
 - Obtain additional clinical specimens for PCR testing when specimens are obtained for culture.
 - Ship specimens to KHEL for forwarding to CDC.
 - CDC will not perform *C. diphtheriae* PCR unless diphtheria anti-toxin (DAT) has been requested to treat a patient.

Additional notes on Laboratory Testing:

- **Testing of isolates:** For *C. diphtheriae* and any other diphtheria toxin-producing *Corynebacterium* species (*C. ulcerans* or *C. pseudotuberculosis*), **CDC requests that all isolates of these types be sent to the CDC Diphtheria Laboratory.**
- **Serology:** Measurement of serum antibodies to diphtheria toxin before administration of antitoxin helps to assess the probability of diphtheria.
 - <0.01 IU/ml, immunity is likely to be absent
 - >0.1 IU/ml, considered protective and diphtheria is unlikely the cause
 - Levels between 0.01 IU/ml to 0.09 IU/ml, indicate the presence of some or limited immunity
- **PCR:** If a patient has received antibiotics, PCR can still be used to detect the toxin production gene (dtxR) and the toxin gene (tox). It does not confirm a case for surveillance as the test does not show toxin is being actively produced.

For additional information on laboratory testing for confirmation of diphtheria, see:

- CDC's Diphtheria Laboratory web page: www.cdc.gov/diphtheria/laboratory.html
- CDC's Manual for the Surveillance of Vaccine-Preventable Diseases, [Chapter 22: "Laboratory Support for the Surveillance of Vaccine-Preventable Diseases."](#)

EPIDEMIOLOGY

Diphtheria occurs worldwide, particularly in tropical countries. It is a rare disease in industrialized countries with active immunization programs. In the U.S., from 1995 to 2015, 14 cases were reported; the median age was 28 years (range: 8 months–86 years) and most of cases (92%) were among persons 15 years of age or older.

Diphtheria epidemics can occur in susceptible populations. Contributing factors include increased susceptibility among adults due to waning of vaccine-induced immunity; and failure fully to immunize children because of unwarranted contraindications, anti-vaccine movements, and declining socioeconomic conditions. Outbreak control is achieved through mass immunization campaigns.

While rarely developing into systemic disease or being transmitted to others, cutaneous diphtheria still has the potential to result in respiratory or cutaneous infections in other susceptible hosts. While more common in tropical climates, it is associated with homeless persons or those with poor hygiene in the U.S.

DISEASE OVERVIEW

A. Agent:

Diphtheria is caused by toxin-producing biotypes of *C. diphtheriae*, a gram-positive bacillus. The 4 biotypes, in order of likelihood of producing toxin, are: *gravis*, *mitis*, *intermedius*, and *belfanti*.

B. Clinical Description:

A toxin mediated, upper respiratory tract illness characterized by sore throat, low-grade fever, and an adherent grayish membrane of the tonsil(s), pharynx, and/or nose. Symptoms also include large tender cervical lymph nodes and marked swelling and edema of neck ("bull neck"). Upper airway obstructions may be caused by extensive membrane formation. Late effects of the toxin include cranial and peripheral motor and sensory nerve palsies, myocarditis, and nephropathy. Cutaneous diphtheria usually appears as a localized ulcer that is non-healing.

C. Reservoirs:

Humans are the only reservoir of *C. diphtheria*.

D. Mode(s) of Transmission:

Person-to-person transmission by respiratory droplets or direct contact with respiratory secretions, discharges from skin lesions or, rarely, fomites. Raw milk may serve as a vehicle of transmission.

E. Incubation Period:

Average, 2-5 days (range 1-10 days).

F. Period of Communicability:

Transmission may occur as long as virulent bacilli are present in discharges and lesions. Usually < 2 weeks and rarely > 1 month. Effective antibiotic therapy can reduce communicability to < 4 days. Carriers may shed organisms for ≥ 6 months.

G. Susceptibility and Resistance:

Infants born of immune mothers are relatively immune; protection is usually lost before the 6th month. Lifelong immunity is usually, but not always, acquired after infection. Prolonged active immunity can be induced by toxoid.

H. Treatment: **

- Suspect cases of pharyngeal diphtheria should receive diphtheria antitoxin (DAT) immediately after bacteriologic specimens are taken without waiting for lab results. Appropriate antibiotic therapy with erythromycin or penicillin should then be given in conjunction with antitoxin to eradicate the organism and reduce the period of communicability.
 - Antibiotics are not substitutes for antitoxin which is the primary treatment.
- Suspect cases of cutaneous diphtheria should receive appropriate antibiotic therapy with erythromycin or penicillin immediately after bacteriologic specimens are taken prior to lab results.

NOTIFICATION TO PUBLIC HEALTH AUTHORITIES

All confirmed or **suspected** diphtheria cases shall be reported within **4 hours by phone** **:

1. Health care providers and hospitals: report to local health jurisdiction
2. Laboratories: report to KDHE - BEPHI
3. Local health jurisdiction: report to KDHE - BEPHI

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

**** Suspected cases of respiratory diphtheria should be reported promptly by telephone to CDC so that diphtheria antitoxin (DAT) can be obtained.**

- Kansas physicians caring for patients with suspected respiratory diphtheria:
 1. Contact KDHE at 1-877-427-7317 to report the suspected case and discuss need for antitoxin. [Epidemiologic and clinical data](#) will need to be provided to meet the requirements of using DAT as an Investigational New Drug (IND) protocol
 2. After consultation with KDHE, physicians should contact CDC's Emergency Operations Center at 770-488-7100 to request diphtheria antitoxin and assistance for its transport.

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

As a nationally notifiable condition, all respiratory diphtheria cases even before classification require an IMMEDIATELY NOTIFIABLE, URGENT report to the Center of Disease Control and Prevention (CDC).

1. *IMMEDIATELY NOTIFIABLE, URGENT* reporting requires a KDHE epidemiologist to call the CDC EOC at 770-488-7100 within 24 hours of a case meeting the notification criteria, followed by submission of an electronic case notification in next regularly scheduled electronic transmission.
 - KDHE-BEPHI will notify the CDC immediately by phone of all confirmed or suspected cases and will file electronic reports weekly with CDC.
2. **Local public health jurisdiction** will report information requested on the supplemental form as soon as possible, completing the form within 3 days of receiving a notification of a report.

INVESTIGATOR RESPONSIBILITIES

- 1) [Report](#) all suspected or confirmed diphtheria cases to the KDHE.
- 2) Initiate the case investigation within 1 day of notification of a report.
 - Complete the investigation within 3 days of the notification.
 - Use the [CDC Diphtheria Worksheet](#) as a guide for data collection.
- 3) Contact medical provider to collect additional information and confirm diagnosis using the current case definition.
 - Collect all information requested in [Step 1](#)) of case investigation.
 - Verify that [laboratory testing](#) has occurred or is underway for a of *C. diphtheriae* culture and serology for antibodies to diphtheria toxin
 - Ensure [isolates](#) of any toxin-producing *Corynebacterium species* are sent KHEL for transport to CDC.
 - For pharyngeal diphtheria, what is the status of [DAT release](#).
 - Ensure patient [isolation](#) and antimicrobial therapy has begun.
 - Ensure that the patient is aware of his/her diagnosis.
- 4) Conduct a [case investigation](#) to determine the individual's risks of exposure and potential geographical location of exposure.
 - If there is no known exposure (low suspicion) and no high-risk transmission setting (unvaccinated contacts), wait for laboratory results to confirm and a final diagnosis prior to starting the contact investigation.
 - If there is a possible exposure (high suspicion) or a potential high-risk transmission setting (unvaccinated contacts), the investigator should immediately start the contact investigation.
- 5) Situations of high suspicion or potential high-risk situations include:
 - Suspected case is reported from a group objecting to vaccination.
 - Suspected case traveled internationally within his/her exposure period.
 - Suspected case was exposed to a diphtheria case or carrier or to an international traveler or immigrant.
 - Suspected case interacted with unimmunized or under-immunized individuals during his/her infectious period or a healthcare setting, school/daycare or food facility is involved.
- 6) Conduct [contact investigation](#) to locate additional cases and/or contacts.
 - Use the [CDC Diphtheria Contact Investigation Worksheet](#) as needed.
- 7) Control and prevention measures will include [case management](#) and [contact management](#) with [Restrictions](#) on activity, collecting of specimens for culture, antibiotic treatment, and vaccinations.
 - Contacts of cutaneous cases require no restrictions, unless they are later identified as diphtheria carriers or cases.
 - Non-toxicogenic infections require no contact management.
- 8) [Record](#) data, collected during the investigation, in the KS EpiTrax system under the data's associated [\[tab\]](#) in the case morbidity report (CMR).
- 9) As appropriate, use the disease [fact sheet](#) to notify individuals or groups.

STANDARD CASE INVESTIGATION AND CONTROL METHODS

Case Investigation

- 1) Contact the medical provider who ordered testing and obtain the following information. (This includes medical records for hospitalized patients.)
 - Collect patient's demographics and contacting information (address, birth date, gender, race/ethnicity, primary language, and phone number(s)).
[Demographic]
 - Obtain clinical information on:
 - Date of illness onset. [Clinical]
 - Date diagnosed-presumptive [Clinical]
 - Date of final diagnosis, what was diagnosed, and how was the final diagnosis confirmed. [Clinical]
 - Symptoms & signs: type of wound (if present), fever, sore throat, difficulty swallowing, change in voice, shortness of breath, weakness, fatigue, membrane present (specify anatomical site of membrane), soft tissue swelling around membrane, neck edema (specify: bilateral or side of swelling and extent of swelling), stridor, wheezing, palatal weakness, tachycardia, and EKG abnormalities). [Investigation-Symptoms]
 - Complications and date of complication onset for pharyngeal symptoms: airway obstruction, myocarditis, polyneuritis, or other (describe).
[Investigation-Complications]
 - Examine the laboratory testing that was done, especially:
 - Culture, biotype and toxigenicity test*, PCR, molecular typing.
 - Determine if further laboratory testing is needed.
 - If not yet done, coordinate testing for symptomatic, highly suspected cases.
 - Record treatment, including: [Clinical]
 - Antibiotics prescribed, date started and duration of therapy. [Clinical]
 - DAT administration, including amount antitoxin. [Investigation-Follow Up]
 - Request history of immunization against diphtheria, post-vaccine antibody titers, or information on why the patient, if less than 18 years of age, is not immunized or fully immunized. [Investigation-Vaccination History]
 - If not available from the medical records, attempt to collect the information from another credible source.
 - Record hospitalizations: location, duration of stay, and reason. [Clinical]
 - Record outcomes: "Recovered, no residual", "Recovered, residual", or Death (with date of death). [Clinical]

** Immediate action on all highly suspect cases is warranted until they are shown not to be caused by toxigenic C. diphtheriae. (Pink Book, 2015)*

- 2) Interview the patient to determine source, risk factors and transmission settings.
 - Travel History:
 - If not US resident, record date of US arrival. [Investigation-Exposure]
 - Record any travel outside of Kansas 14 days before illness began; specify whether travel was inside the US and/or international (include dates and locations). [Investigation-Exposure]
 - Noting travel dates and locations record where the infection was most likely imported from. (Indigenous / out-of-county, state, or U.S.) [Epidemiological]
 - Investigate potential exposures: [Investigation-Exposure]
 - Exposure to diphtheria case or carrier; include dates and locations.
 - Exposure to international travelers; include dates and locations.
 - Exposure to immigrants; include dates and locations.
 - Examine potential transmission settings, include:
 - Patient’s occupation: food handler, health care worker, group living, day care attendee / worker, or school attendee / employee; specifically list patient’s occupation. [Epidemiological]
 - Obtain name of school and grade of patient (if applicable).
 - Examining occupation, record any Place Exposure(s) (where illness could have been transmitted). [Epidemiological]
- 3) Examine the epidemiological information, record where the infection was most likely imported from. (Indigenous or out-of-county, state, or U.S.). [Epidemiological]
- 4) Collect information from case for the [Contact Investigation](#). (See below).
- 5) Investigate epi-links among cases (clusters, household, co-workers, etc).
 - If the patient had contact with person(s) who have/had diphtheria, determine if the other “cases” have been reported to the state:
 - Search the state electronic surveillance for the possible case.
 - If found, record the previously reported record number in the record of the case you are investigating. [Notes]
 - Highly suspected illness in persons that have not previously been reported should be investigated as a suspect case and [reported](#) to KDHE-BEPHI:
 - Enter the symptomatic contact of the case on the [Contact] Tab of the CMR and save.
 - After the CMR has updated successfully, click ‘Show’ beside the contact on the listing.
 - With the **View Contact** open in show mode, select ‘Promote to CMR’; update, as needed.
 - For suspected [Outbreaks](#) refer to Managing Special Situations section.

Contact Investigation

- 1) Review the patient's occupation and activities collected during the [case investigation](#) and recorded on [\[Epidemiological\]](#) and [\[Investigation-Exposure\]](#) tabs:
 - Examine activities from onset date to 2 weeks after onset. (The period can be shortened to 4 days after the completion of antibiotic therapy if therapy was considered effective.)
 - Verify patient's household address and telephone number(s). [\[Demographics\]](#)
 - Verify addresses of places of exposure, dates the patient was at the location, and ways to identify potential contacts at the locations. [\[Epidemiological\]](#)
 - Consider the locations the patient sought medical care. [\[Clinical\]](#)
- 2) Consider the following types of contacts during the contact investigation:
 - Household members or those who regularly visit the home.
 - Other persons with a history of close direct contact with a case-patient in manner that would have allowed exposure to oral or respiratory secretions for pharyngeal case or lesion discharge for cutaneous. (e.g. caretakers)
 - Close contact with oral or respiratory secretions are those persons within large droplet range of 3 feet including those who shared food, drink or eating utensils.
 - Medical staff exposed to oral or respiratory secretions of a case-patient.
- 3) Create a line listing of contacts. [\[Contact\]](#)
 - [CDC Diphtheria Contact Investigation Worksheet](#) can be used.
 - Obtain name, address, and telephone of contacts.
 - Collect contact's immunization status and note any diphtheria symptoms
 - Collect information on the contact's occupation.
 - Note any school or daycare attendance. (Include facility name and location.)
 - Note any healthcare associations. (Include facility name and location)
 - Note any high-risk situations or medical conditions.
- 4) Follow-up symptomatic contacts as suspect cases.
 - Report and manage as diphtheria case and refer for medical care.
(On the [\[Contact\]](#) Tab of the CMR, click 'Show' beside the contact on the listing. When View Contact Event opens in show mode, select 'Promote to CMR'.)
 - A contact meeting the clinical case definition is considered a confirmed case if epi-linked to a laboratory confirmed case.
 - If a symptomatic contact is laboratory confirmed – the primary case that was not laboratory confirmed is confirmed based on the epi-link.
- 5) [Institute control measures](#) for infected persons and close contacts.
 - Contacts of cutaneous diphtheria may require a vaccine booster and monitoring, but no work or daycare restrictions are required.
- 6) Follow-up close contacts as recommended under [Contact Management](#).
 - [Cutaneous](#) cases resulting from [non-toxigenic](#) strains require no further contact management. (Pink Book, 2015)

Isolation, Work and Daycare Restrictions

K.A.R 28-1-6 for Diphtheria:

Control of Cases with Cutaneous Diphtheria

- For each person hospitalized with a case, contact precautions shall be followed until:
 - Two consecutive negative cultures from lesion specimens are obtained at least 24 hours apart and at least 24 hours after completion of appropriate antimicrobial therapy, **OR**
 - Two sequential pairs of cultures are obtained after symptoms resolve and greater than 14 days after onset of symptoms if appropriate antimicrobial therapy is not followed.
- Each person with a case shall remain in home isolation until:
 - Two consecutive negative cultures from lesion specimens are obtained at least 24 hours apart and at least 24 hours after completion of appropriate antimicrobial therapy, **OR**
 - Two sequential pairs of cultures are obtained after symptoms resolve and greater than 14 days after onset of symptoms if appropriate antimicrobial therapy is not followed.

Control of cases with Pharyngeal Diphtheria

- For each person hospitalized with a case, droplet precautions shall be followed until:
 - Two consecutive negative cultures are obtained from both nose and throat specimens collected at least 24 hours apart and at least 24 hours following completion of appropriate antimicrobial therapy, **OR**
 - Two sequential pairs of cultures are obtained after symptoms resolve and greater than 14 days after onset of symptoms if appropriate antimicrobial therapy is not followed.
- Each person with a case shall remain in home isolation until:
 - Two consecutive negative cultures from both nose and throat specimens are attained at least 24 hours apart and at least 24 hours after completion of antimicrobial therapy, **OR**
 - Two sequential pairs of cultures shall be obtained after symptoms resolve and greater than 14 days after onset of symptoms if appropriate antimicrobial therapy is not followed.

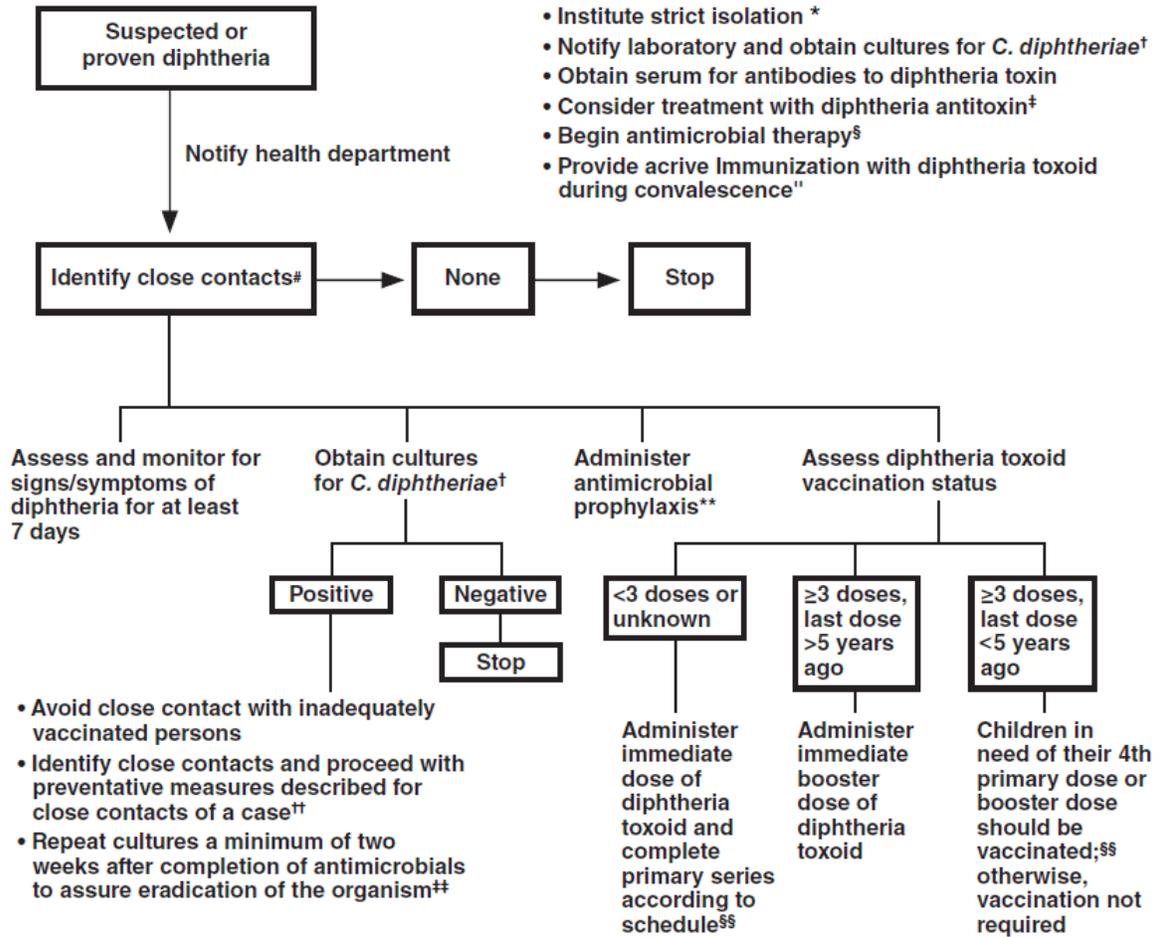
Control of Contacts of Pharyngeal Diphtheria

- All contacts, regardless of their immunization status, shall be monitored for seven days for evidence of disease and shall have specimens collected from both nose and throat for culture.
- Each contact found to be a carrier shall be considered a person with a case and shall be kept in isolation until requirements in control of cases are met.
- Each contact shall be excluded from working as a food employee, health care worker, and attending or working in a child care facility and attending or working in a school, child care facility, or adult day care:
 - For 28 days from the last exposure to a case, **OR**
 - Until treated with appropriate antimicrobial therapy and two consecutive negative cultures are obtained from both nose and throat specimens collected at least 24 hours apart and at least 24 hours following completion of any antimicrobial therapy.

Case Management

- 1) Prompt administration of DAT is needed for pharyngeal diphtheria.
 - DAT is currently available only through the CDC under an FDA-approved Investigational New Drug protocol; important epidemiologic and clinical data are needed prior to DAT release.
 - Contact KDHE at 1-877-427-7317 to report the suspected case and discuss need for antitoxin.
 - [Epidemiologic and clinical data](#) will be collected.
 - KDHE-IDER and KHEL will assist with any [laboratory specimens](#) needed to be sent to CDC.
 - After consultation with KDHE, physicians should contact CDC's Emergency Operations Center at 770-488-7100 to request diphtheria antitoxin and assistance for its transport.
 - The diphtheria duty officer will discuss the case and protocol for DAT release with the physician.
 - Patients should be tested for sensitivity to horse serum and, if necessary, desensitized before administration of the antitoxin.
 - The recommended dosage and route of administration depends on the extent and duration of disease; refer to the package insert.
 - Antimicrobial therapy (penicillin or erythromycin) is not a substitute for antitoxin treatment but is administered to eradicate the organism, prevent further production of toxin and decrease chance of further transmission.
- 2) Strict isolation continues until two sequential pairs of negative cultures are obtained (lesion swab for cutaneous, or nose and throat swabs for pharyngeal).
 - Swabs are to be collected >24 hours apart and ≥ 24 hours from the completion of antimicrobial therapy.
 - If illness onset was ≥ 2 weeks prior and symptoms have resolved without antimicrobial therapy, collect the first specimens for culture immediately.
- 3) If a repeat culture is positive, an additional 10-day course of oral erythromycin is administered with follow-up cultures again repeated as described above.
- 4) Provide active immunization with diphtheria toxoid during convalescence, as disease does not confer immunity.
- 5) Record whether DAT was administered. [Investigation-Exposure]
- 6) Conduct a follow-up as needed to assure compliance with [control measures](#).
- 7) Conduct a follow-up interview to determine outcome of illness. [Clinical]
- 8) As an additional reference, see [Figure 1](#) for pharyngeal diphtheria.

Figure 1. Diphtheria: Recommendations for Case Management and Investigation of Close Contacts



* Maintain isolation until elimination of the organism is demonstrated by negative cultures of two samples obtained at least 24 hours apart after the completion of antimicrobial therapy.

† Both nasal and pharyngeal swabs should be obtained for culture.

‡ Contact the state health department to make arrangements for antitoxin from the CDC.

§ Antimicrobial therapy is not a substitute for antitoxin treatment in clinical diphtheria but may eliminate the organism. Procaine penicillin G or parenteral erythromycin is used until patient can swallow comfortably, and then oral erythromycin or oral penicillin V is used.

" Vaccination is required because clinical diphtheria does not necessarily confer immunity.

Close contacts include household members and other persons with a history of direct contact with a case-patient (e.g. caretakers, relatives, or regular visitors to home) and medical staff exposed to oral or respiratory secretions of the case-patient.

** Prophylaxis includes a single dose of benzathine penicillin G or a 7- to 10- day course of oral erythromycin.

†† Preventive measures may extend to close contacts of carriers but should be a lower priority than control measures for contacts of a case.

‡‡ Persons who continue to harbor the organism after treatment with either penicillin or erythromycin should receive an additional 10-day course of oral erythromycin and should submit samples for follow-up cultures.

§§ Refer to published recommendations for the schedule for routine administration of DTP.

(Source: [Appendix 2](#) of the CDC Manual for the Surveillance of Vaccine-Preventable Diseases)

Contact Management

- 1) Maintain [notes](#) on all contacts: symptoms screenings, immunization histories, culture results, prophylaxis recommended/completed (antibiotics and booster doses), and the disposition of the contact after 10 days of active surveillance, including any missing or gone explanations (MOGE). [[Contact- 'Edit Contact'](#)]
 - 2) Refer to [Figure 1](#) and complete the following steps for all pharyngeal close contacts and for those cutaneous close contacts of toxigenic strains.
 - Obtain nose and throat swabs for culture.
 - Initiate antibiotic prophylaxis of contacts regardless of immunization status:
 - After specimens for culture are collected.
 - Recommend a single dose of benzathine penicillin or a 7-10-day course of erythromycin.
 - Single penicillin dose is used when the contact's compliance in doubt.
 - Assess diphtheria toxoid vaccination status and vaccinate as needed.
 - Previously immunized contacts should receive a booster dose of diphtheria toxoid if >5 years have elapsed since their last dose.
 - Non-immunized contacts (those with <3 doses or unknown histories) should begin and/or continue with a primary series according to published recommendations for routine immunizations.
 - Report any adverse event that occurs after the administration of a vaccine to Vaccine Adverse Events Reporting System at <https://vaers.hhs.gov/index.html>
 - 3) Carryout work, school, and daycare restrictions of pharyngeal contacts only as instructed in [K.A.R. 28-1-6](#).
 - 4) Assess and monitor contacts (active surveillance) for signs and symptoms of diphtheria for 10 days after last contact with an infectious case.
 - Symptomatic contacts are treated as cases and reported to the National Notifiable Disease Surveillance System (NNDSS)
 - Asymptomatic contacts that are culture-positive are carriers, not reportable cases to NNDSS but are managed as cases.
 - 5) Management of culture-positive secondary cases and carriers:
 - Treat and manage as described in [Case Management](#), including the strict isolation for two weeks or until two consecutive sets of nose and throat swabs, collected >24 hours apart, are culture negative for *C. diphtheriae*.
 - Close contacts of carriers are [managed as close contacts](#) of cases but:
 - Assign close contacts of persons with clinical diphtheria highest priority.
 - Contacts of carriers should be given secondary priority.
- Note:** *The risk of developing diphtheria is sevenfold higher after household exposure to clinical diphtheria case than after household exposure to a carrier.*
- 6) Initiate active surveillance for suspect cases in the affected settings for at least 2 maximum incubation periods (a total of 20 days).

Environmental

- Disinfect fomites and discharges from lesions.
- Use pasteurized milk.

Education

- 1) Provide education that includes basic information about the disease and its complications and ways to treat and prevent transmission of illness.
- 2) Instruct cases on the necessary isolation.
- 3) Cases, carriers and contacts should be instructed to pay strict attention to personal hygiene by:
 - Covering nose and mouth with tissue when coughing.
 - Placing all contaminated tissues directly into garbage containers.
 - Washing hands with soap and water every time there is contact with respiratory secretions or infected wounds.
- 4) Instruct cases and contacts to be aware of the high risk that infection poses to certain individuals, especially unvaccinated or inadequately vaccinated persons, such as infants under 2 months of age.
- 5) Counsel contacts to watch for signs or symptoms for 10 days after exposure.
 - Should symptoms develop, medical care should be sought promptly, and appropriate specimens taken. Treatment should be considered for persons with any of the signs or symptoms that are compatible with pertussis.

MANAGING SPECIAL SITUATIONS

A. Outbreak Investigation:

- A single case of suspected diphtheria should be treated with urgency.
- Notify KDHE immediately, 1-877-427-7317.
- Active case finding will be an important part of any investigation; especially when there is no history of international travel or contact with visitors who have been to an area endemic for diphtheria.
- All epidemiologic data will be reported and managed through the Kansas electronic surveillance system.
- Recommendations will be made based on the [CDC's Manual for the Surveillance of Vaccine-Preventable Diseases](#).

DATA MANAGEMENT AND REPORTING TO THE KDHE

- A. Accept the case assigned to the LHD and record the date the LHD investigation was started on the [\[Administrative\]](#) tab.
- B. Organize and collect data, using appropriate questionnaires, case listings (spreadsheets), and investigation forms, including the [Diphtheria Investigation Worksheet](#) and [Diphtheria Contact Investigation Worksheet](#).
- Investigators can collect and enter all required information directly into EpiTrax [\[Investigation\]](#), [\[Clinical\]](#), [\[Demographics\]](#), and [\[Epidemiological\]](#) tabs without using the paper forms.
 - During outbreak investigations, refer to guidance from a KDHE epidemiologist for appropriate collection tools.
- C. Report data collected during the investigation via EpiTrax.
- Verify that all data requested on the applicable forms has been recorded on an appropriate EpiTrax [\[tab\]](#), or that actions are completed for a case lost to follow-up as outlined below.
 - Some data that cannot be reported on an EpiTrax [\[tab\]](#) may need to be recorded in [\[Notes\]](#) or scanned and attached to the record.
 - Paper report forms do not need to be sent to KDHE after the information is recorded in EpiTrax. The forms should be handled as directed by local administrative practices.
- D. If a case is lost to follow-up, after the appropriate attempts to contact the case have been made:
- Indicate 'lost to follow-up' on the [\[Investigation\]](#) tab with the number of attempts to contact the case recorded.
 - Record at least the information that was collected from the medical records.
 - Record a reason for 'lost to follow-up' in [\[Notes\]](#).
- E. After the requirements listed under [Case Investigation](#) have been completed, record the "Date LHD investigation completed" field located on the [\[Administrative\]](#) tab.
- Record the date even if the local investigator's [Case](#) or [Contact Management](#) for the contact is not "Complete".
- F. Once the entire investigation is completed, the LHD investigator will click the "Complete" button on the [\[Administrative\]](#) tab. This will trigger an alert to the LHD Administrator, so they can review the case before sending to the state.
- The LHD Administrator will then "Approve" or "Reject" the CMR.
 - Once a case is "Approved" by the LHD Administrator, BEPHI staff will review the case to ensure completion before closing the case.

Notes on case classification of **Diphtheria (*Corynebacterium diphtheriae*)**:

- Case investigation and management is required for toxin-producing *C. diphtheriae* carriers, but the events are not nationally notifiable disease events to CDC.
- Cases in EpiTrax that are identified as culture positive and toxin producing, asymptomatic cases will be closed as "Not a case" for data reporting purposes.

ADDITIONAL INFORMATION / REFERENCES

- A. Treatment / Differential Diagnosis:** American Academy of Pediatrics. Red Book: Report of the Committee on Infectious Disease, 29th Edition. Illinois, Academy of Pediatrics, 2014.
- B. Epidemiology, Investigation and Control:** Heymann, D., ed., Control of Communicable Diseases Manual, Washington, DC, American Public Health Association, 2010.
- C. Case Definitions:** wwwn.cdc.gov/nndss/
- D. Quarantine and Isolation:** Kansas Community Containment Isolation/ Quarantine Toolbox Section III, Guidelines and Sample Legal Orders www.kdheks.gov/cphp/operating_guides.htm#coc
- E. Kansas Regulations/Statutes Related to Infectious Disease:** www.kdheks.gov/epi/regulations.htm
- F. Pink Book:** Epidemiology and Prevention of Vaccine-Preventable Diseases. Available at: www.cdc.gov/vaccines/pubs/pinkbook/index.html
- G. Manual for the Surveillance of Vaccine-Preventable Diseases:** Available at: www.cdc.gov/vaccines/pubs/surv-manual/index.html.
- H. Additional Information (CDC):** www.cdc.gov/health/default.htm

ATTACHMENTS

To view attachments in the electronic version:

1. Go to <View>; <Navigation Pane>; <Attachments> – OR – Click on the “Paper Clip”  icon at the left.
2. Double click on the document to open.

CDC Diphtheria Worksheet

PATIENT INFORMATION	Date of Request <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>		Name (Last, First)					
	Birth Date <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>		Age <input type="text"/> <input type="text"/> <small>Unk = 999</small>	Age Type <input type="checkbox"/> 0 = 0-120 years <input type="checkbox"/> 1 = 0-11 months <input type="checkbox"/> 2 = 0-52 weeks <input type="checkbox"/> 3 = 0-28 days <input type="checkbox"/> 9 = Age unknown	Sex <input type="checkbox"/> M = Male <input type="checkbox"/> F = Female <input type="checkbox"/> U = Unknown	Pregnant? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown	Race <input type="checkbox"/> N = Native Amer./Alaskan Native <input type="checkbox"/> A = Asian/Pacific Islander <input type="checkbox"/> B = African American <input type="checkbox"/> W = White <input type="checkbox"/> O = Other <input type="checkbox"/> U = Unknown	Ethnicity <input type="checkbox"/> H = Hispanic <input type="checkbox"/> N = Not Hispanic <input type="checkbox"/> U = Unknown
	Address (Street and No.)			County		State	Zip	Phone
	Date Symptom Onset <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>	Date First Diagnosis <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>	Date Hospitalized <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>	History of Immunization Against Diphtheria Childhood Primary Series? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown		If < 18 Years Old, Number of Doses <input type="text"/>	Boosters as Adult? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown	Date of Last Dose <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> <small>Month Day Year OR U = Unk</small>
Description of Clinical Picture							Outcome <input type="checkbox"/> N = Recovered, No Residua <input type="checkbox"/> R = Recovered, Residua <input type="checkbox"/> D = Died <input type="checkbox"/> U = Unknown	

CLINICAL INFORMATION	<i>Enter Y = Yes, N = No, or U = Unknown in the Boxes Below Unless Otherwise Indicated</i>						
	Symptoms Fever? <input type="checkbox"/> Sore Throat? <input type="checkbox"/> Difficulty Swallowing? <input type="checkbox"/> Change in Voice? <input type="checkbox"/> Shortness of Breath? <input type="checkbox"/> Weakness? <input type="checkbox"/> Fatigue? <input type="checkbox"/> Other? <input type="checkbox"/>		Signs Fever? <input type="checkbox"/> If Yes, Temp <input type="text"/> <input type="text"/> <input type="text"/> °C Membrane? <input type="checkbox"/> If Yes, Site(s) <input type="text"/> Tonsils <input type="checkbox"/> Soft Palate <input type="checkbox"/> Hard Palate <input type="checkbox"/> Larynx <input type="checkbox"/> Nares <input type="checkbox"/> Nasopharynx <input type="checkbox"/> Conjunctiva <input type="checkbox"/> Skin <input type="checkbox"/>		Signs Soft Tissue Swelling? <input type="checkbox"/> <small>(Around Membrane)</small> Neck Edema? <input type="checkbox"/> If Yes <input type="checkbox"/> B = Bilateral <input type="checkbox"/> L = Left Side Only <input type="checkbox"/> R = Right Side Only If Yes, Extent <input type="checkbox"/> S = Submandibular Only <input type="checkbox"/> M = Midway to Clavicle <input type="checkbox"/> C = To Clavicle <input type="checkbox"/> B = Below Clavicle Stridor? <input type="checkbox"/> Wheezing? <input type="checkbox"/> Palatal Weakness? <input type="checkbox"/> Tachycardia? <input type="checkbox"/> EKG Abnormalities? <input type="checkbox"/>		Complications Complications? <input type="checkbox"/> Airway Obstruction? <input type="checkbox"/> Date of Onset <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small> Intubation Required? <input type="checkbox"/> Myocarditis? <input type="checkbox"/> Date of Onset <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small> (Poly)neuritis? <input type="checkbox"/> Date of Onset <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small> Other? <input type="checkbox"/> Describe:

LABORATORY	Specimen for Diphtheria Culture Obtained? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown	If Yes, Obtained on <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> <small>Month Day Year OR U = Unknown</small>	Culture Result <input type="checkbox"/> P = Positive <input type="checkbox"/> N = Negative <input type="checkbox"/> U = Unknown	Specify Lab Performing Culture:	If Culture Positive, Biotype <input type="checkbox"/> M = Mitis <input type="checkbox"/> G = Gravis <input type="checkbox"/> I = Intermedius <input type="checkbox"/> B = Belfanti
	If Culture Positive, Results of Toxicogenicity Testing <input type="checkbox"/> X = Not Done <input type="checkbox"/> P = Positive <input type="checkbox"/> N = Negative <input type="checkbox"/> U = Unknown	Specimen Sent to CDC Diphtheria Lab for Confirmation/Molecular Typing? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> W = Will be Sent	Type of Specimen (Check All That Apply) <input type="checkbox"/> Clinical Swab <input type="checkbox"/> Piece of Membrane <input type="checkbox"/> C. diphtheria Isolate	Serum Specimen for Diphtheria Antitoxin Antibodies Obtained? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> W = Will be Obtained Prior to DAT	PCR Result <input type="checkbox"/> P = Positive <input type="checkbox"/> N = Negative <input type="checkbox"/> U = Unknown <input type="checkbox"/> X = Not Done

ANTIBIOTICS	Treated with Antibiotics? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No	As an Outpatient If Yes, Date Initiated <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>	Antibiotic <input type="checkbox"/> <small>See Codes Below</small>	Duration of Therapy <input type="text"/> <input type="text"/> <small>Days</small>	Antibiotic Therapy in Hospital? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No	As an Inpatient If Yes, Date Initiated <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>	Antibiotic <input type="checkbox"/> <small>See Codes Below</small>	Duration of Therapy <input type="text"/> <input type="text"/> <small>Days</small>
	Were Antibiotics Given in the 24 Hours Before Culture? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown	1 = Erythromycin (Incl. Pediazole, Ilosone)	5 = Cotrimoxazole (Bactrim/Septtra)	2 = Penicillin (Bicillin, Pfizerpen-AS, Wycillin)	6 = Tetracycline/Doxycycline	3 = Amoxicillin/Ampicillin/Augmentin/Ceclor/Cefixime	7 = Other	4 = Clarithromycin/azithromycin

EXPOSURE	Country of Residence <input type="checkbox"/> U = US <input type="checkbox"/> O = Other		If Other, Country Name: _____		Date of US Arrival <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> <small>Month Day Year U = Unknown</small>																														
	History of International Travel? (2 Weeks Prior to Onset) <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown	Country(s) Visited <table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="border: none;"></th> <th colspan="3" style="border: none;">From</th> <th colspan="3" style="border: none;">To</th> </tr> <tr> <th style="border: none;"></th> <th style="border: none;">Month</th> <th style="border: none;">Day</th> <th style="border: none;">Year</th> <th style="border: none;">Month</th> <th style="border: none;">Day</th> <th style="border: none;">Year</th> </tr> </thead> <tbody> <tr> <td style="border: none;">_____</td> <td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td> <td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td> </tr> <tr> <td style="border: none;">_____</td> <td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td> <td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td> </tr> </tbody> </table>							From			To				Month	Day	Year	Month	Day	Year	_____	<input type="text"/>	_____	<input type="text"/>										
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Known Exposure to Diphtheria Case or Carrier? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown	Known Exposure to International Travelers? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown		Known Exposure to Immigrants? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown																																

REPORTING INFORMATION	Has This Suspected Case Been Reported to The State or Local Health Department? <input type="checkbox"/> Y = Yes <input type="checkbox"/> N = No <input type="checkbox"/> U = Unknown		Date Reported to State or Local Health Department <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>			
	Person Informed:	Phone <input type="text"/> - <input type="text"/> - <input type="text"/>	Fax <input type="text"/> - <input type="text"/> - <input type="text"/>			
	Reporting Physician:	Phone <input type="text"/> - <input type="text"/> - <input type="text"/>	Fax <input type="text"/> - <input type="text"/> - <input type="text"/>			

REQUESTING PHYSICIAN	Name					
	Institution					
	Street					
	City				State	Zip
	Phone <input type="text"/> - <input type="text"/> - <input type="text"/>			Fax <input type="text"/> - <input type="text"/> - <input type="text"/>		
	Name of Investigator Under the IND (If Different From Requesting Physician)			Phone <input type="text"/> - <input type="text"/> - <input type="text"/>		Fax <input type="text"/> - <input type="text"/> - <input type="text"/>

SEND DRUG TO	Name					
	Attn.					
	Institution					
	Street					
	City				State	Zip
	Phone <input type="text"/> - <input type="text"/> - <input type="text"/>			Fax <input type="text"/> - <input type="text"/> - <input type="text"/>		

DOSE	Amount of DAT Administered: <input type="text"/> <input type="text"/> , <input type="text"/> <input type="text"/> IU DAT
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DISPOSITION	Final Diagnosis: _____	How Was the Final Diagnosis Confirmed? _____	Final Case Disposition <input type="checkbox"/> C = Confirmed <input type="checkbox"/> P = Probable <input type="checkbox"/> N = Not a Case
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