

24-ID-07

Committee: Infectious Disease

Title: Update to Public Health Reporting and National Notification for Leptospirosis

☒ Check this box if this position statement is an update to an existing standardized surveillance case definition and include the most recent position statement number here: 12-ID-02.

Synopsis:

- This position statement updates the standardized surveillance case definition for leptospirosis (previous position statement 12-ID-02) to address the previous clinical criteria being overly specific, resource intensive, and requiring either (1) patient interview/recall or (2) medical chart review.
- Updates include:
 - Simplification of the clinical case classification criteria based on nationally reported case data to the Centers for Disease Control and Prevention (CDC) and to align more closely with the World Health Organization (WHO) clinical criteria. The update drops the second tier of clinical findings from the 2013 position statement and requires only one or more signs and symptoms for leptospirosis case classification. The update simplifies the clinical criteria for leptospirosis case identification and characterization, especially useful during large scale public health emergencies or periods of increased transmission in endemic jurisdictions.

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I. Statement of the Problem

The leptospirosis clinical criteria contained in position statement 12-ID-02 are overly specific, resource intensive, and require either (1) patient interview/recall or (2) medical chart review. Based on an analysis by the Centers for Disease Control and Prevention (CDC) Bacterial Special Pathogens Branch Epidemiology Team of supplemental case report data sent to CDC from 2013-2023, only 70% of reported cases that met the laboratory criteria needed for probable case classification included the required history of “fever within the past two weeks.” This position statement updates the clinical criteria to reduce the burden of case ascertainment and to more closely align the national CSTE case definition with the WHO leptospirosis case definition. Simplifying case classification to improve case ascertainment is especially pertinent in jurisdictions where leptospirosis is endemic and that may have to respond to frequent outbreaks related to widescale flooding and do not want to create event-specific case classification criteria.

II. Background and Justification

Leptospirosis is a zoonotic disease identified globally, with most cases occurring in tropical climates. Human infection may occur following direct contact with urine or other body fluids from an infected animal, or indirectly through contact with contaminated water, soil, or food. *Leptospira* bacteria may enter the body through mucous membranes or abraded skin (1, 2). CSTE approved a position statement in 2012 (12-ID-02) that was implemented in 2013, making leptospirosis a nationally notifiable condition (3).

Since the implementation of 12-ID-02, there have been several natural disasters in endemic jurisdictions in the United States (U.S.) and its territories that have resulted in increased leptospirosis incidence and highlighted the need for improved case identification and classification (4, 5, 6, 7). In endemic settings, during public health emergencies and routine surveillance periods, the current clinical classification criteria are overly cumbersome and result in the undercounting of cases. Due to a broad spectrum of disease and a bi-phasic clinical progression, leptospirosis cases are frequently reported with limited clinical data, subsequently requiring significant resources for case investigation for collection of clinical and exposure criteria to support laboratory criteria.

Overly specific clinical criteria for case ascertainment and classification may also exclude probable cases and impede a jurisdiction’s ability to quickly identify cases and enact public health measures to reduce the burden of disease. After analyzing nationally reported leptospirosis data submitted to CDC between 2013-2023 from U.S. jurisdictions, only 70% of probable cases reported any fever. Based upon current (12-ID-02) clinical criteria, 65% (n=383) of probable cases who met the presumptive laboratory criteria also met current clinical criteria. In the newly proposed criteria, 95% (n=560) of probable cases who met the presumptive laboratory criteria would meet the clinical criteria with at least one of the compatible signs or symptoms.

The current (12-ID-02) clinical criteria for case classification are also not closely aligned with the WHO clinical case definition, which is broader in its clinical criteria inclusion. The two-tiered CSTE clinical criteria requires clinical presentation of history of fever within the past two weeks and either (a) at least two of the following clinical findings: myalgia, headache, jaundice, conjunctival suffusion without purulent discharge, or purulent discharge, or rash (i.e. maculopapular or petechial); OR (b) at least one of the following clinical findings: aseptic meningitis, gastrointestinal symptoms (e.g., abdominal pain, nausea, vomiting, diarrhea), pulmonary complications (e.g., cough, breathlessness, hemoptysis), cardiac arrhythmias or ECG abnormalities, renal insufficiency (e.g., anuria, oliguria), hemorrhage (e.g., intestinal, pulmonary, hematuria, hematemesis), jaundice with acute renal failure.

This update to the leptospirosis position statement proposes simplification and broadening of the clinical criteria for case classification and streamlined case ascertainment. An analysis of clinical presentation and laboratory testing data submitted to CDC from 2013-2023 justifies these new streamlined clinical criteria, which is more closely aligned with the WHO clinical case definition: abrupt onset of fever, chills, conjunctival suffusion, headache, myalgia, jaundice, cardiac or renal failure, and pulmonary hemorrhage (8). The proposed additions to the clinical signs and symptoms reflect nationally reported data to the CDC (see Appendix 1) and include chills, vomiting, nausea, diarrhea, abdominal pain, and respiratory insufficiency. Lastly, this updated case definition is simplified to include the need for just one clinical sign or symptom consistent with leptospirosis.

III. Statement of the Desired Action(s) to be Taken

CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for **leptospirosis**.
 - A. Utilize recommended reporting* sources for case ascertainment for **leptospirosis**. Surveillance for **leptospirosis** should use the recommended sources of data to the extent of coverage presented in Section V.
 - B. Utilize standardized criteria for case ascertainment for **leptospirosis** presented in Section VI and Table VI in Technical Supplement.
 - C. Utilize standardized criteria for case classification for **leptospirosis** presented in Section VII and Table VII in Technical Supplement.
2. Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement) for **leptospirosis** and **update** leptospirosis on the *Nationally Notifiable Condition List* using the following notification** timeframe:
 - ☐ Immediately notifiable, extremely urgent (within 4 hours)
 - ☐ Immediately notifiable, urgent (within 24 hours)
 - ☒ Routinely notifiable
 - ☐ No longer notifiable
3. CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g., States and Territories) conducting surveillance (according to these methods) should submit case notifications to CDC.
4. CSTE recommends that all jurisdictions (e.g., States, Localities, or Territories) with legal authority should conduct public health surveillance and use the case classifications included in this standardized surveillance position statement.
5. Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: the National Notifiable Diseases Surveillance System (NNDSS) is transitioning to HL7-based messages for case notifications; the specifications for these messages are presented in MMGs. When CSTE recommends a new condition be made nationally notifiable, CDC must obtain Office of Management and Budget Paperwork Reduction Act (OMB PRA) approval prior to accepting case notifications for the new condition. Under anticipated timelines, notification using the Generic V2 MMG would support transmission of the basic demographic and epidemiologic information common to all cases and could begin with the new MMWR year following the CSTE annual conference. Input from CDC programs and CSTE would prioritize development of a disease-specific MMG for the new condition among other conditions waiting for MMGs.
6. CDC should publish data on leptospirosis as appropriate (see Section IX). CSTE recommends the following case statuses be included in the CDC Print Criteria:
 - ☒ Confirmed
 - ☒ Probable
 - ☐ Suspect
 - ☐ Unknown
 - Annual case data on leptospirosis is also summarized in the annual Summary of Notifiable Diseases.
 - State-specific compiled data will be published in the weekly reports and annual MMWR Surveillance Summaries.
 - The frequency of release of additional publications of these data will be dependent on the current epidemiologic situation in the country. These publications might include annual epidemiologic summaries in the MMWR or manuscripts in peer-reviewed journals.
 - Aggregate case data will be shared with WHO as requested.

* *Reporting: process of a healthcare provider, laboratory, or other entity submitting a report (case information) of a condition under public health surveillance to local, state, or territorial public health.*

** *Notification is the process of a local, state, or territorial public health authority submitting a report (case information) of a condition on the Nationally Notifiable Conditions List to CDC.*

IV. Goals of Surveillance

To characterize the temporal, geographic, and demographic occurrence of leptospirosis to facilitate its prevention and control.

V. Recommended Data Sources and Methods for Surveillance

Surveillance for leptospirosis should use the following recommended sources of data and/or methodologies and the extent of coverage listed in Table V.

Leptospirosis has been nationally notifiable since CSTE approval in 2012. Case ascertainment should be supported through the following surveillance reporting sources: clinicians, laboratories, hospitals, death registries, and hospital discharge or outpatient records (Table V). Jurisdictions where leptospirosis is endemic may consider integrating active or sentinel surveillance to augment situational awareness during public health emergencies or other disasters where routine sources may be incapacitated.

Table V. Recommended Sources of Data, Surveillance Methods, and Extent of Coverage for Ascertainment of Cases of Leptospirosis.

Source of Data/Methodology for Case Ascertainment	Coverage	
	Population-Wide	Sentinel Sites
Clinician reporting	X	
Laboratory reporting	X	
Reporting by other entities, specify:		
Death certificates	X	
Hospital discharge or outpatient records	X	
Data from electronic medical records	X	
Telephone or online survey		
School-based survey		
Other, specify: N/A		

VI. Criteria for Case Ascertainment

Case ascertainment is the process through which public health identifies potential cases of a disease or condition using data reported or provided to public health by healthcare, laboratories, and other reporting entities. This public health reporting is triggered by the case ascertainment criteria (a single criterion or a combination of criteria) included in this position statement, and each initial report sent to public health should include common data elements and disease-specific data elements. Case ascertainment criteria are not intended to be used for clinical diagnosis purposes.

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition and recommended reporting procedures.

Diagnostic testing should be requested for patients with whom there is a high index of suspicion for leptospirosis, based either on signs and symptoms, or on occupational, recreational, or vocational exposure to animals or environments contaminated with animal urine.

Reporting should be ongoing and routine. Timeliness of reporting should follow the jurisdiction health department's routine reporting schedule.

Report to public health authorities any of the following:

- Any person who meets laboratory criteria for reporting, **OR**
- Any person who meets the epidemiologic linkage criteria for reporting AND who meets clinical criteria for reporting, **OR**
- Any person who meets the vital records criteria for reporting, **OR**
- Any person who meets the healthcare record criteria for reporting.

A1. Clinical Criteria for Reporting*

- An illness characterized by fever, headache, chills, myalgia, vomiting, nausea, diarrhea, abdominal pain, conjunctival suffusion, renal insufficiency, jaundice, respiratory insufficiency, meningitis, or rash. Symptoms may be biphasic.

** Clinical criteria for reporting must be paired with epidemiologic linkage criteria for reporting to trigger a report to public health.*

A2. Laboratory Criteria for Reporting

- Isolation of *Leptospira* from a clinical specimen,
OR
- Demonstration of *Leptospira* in tissue by direct immunofluorescence,
OR
- A positive *Leptospira* total agglutination titer by Microscopic Agglutination Test (MAT) in one or more serum specimens,
OR
- Detection of pathogenic (P1 clade) or intermediate (P2 clade) *Leptospira* DNA (e.g., by PCR) from a clinical specimen,
OR
- Demonstration of anti-*Leptospira* antibodies in a clinical specimen by indirect immunofluorescence,
OR
- Demonstration of *Leptospira* in a clinical specimen by darkfield microscopy,
OR
- Detection of IgM antibodies against *Leptospira* in an acute phase serum specimen.

A3. Epidemiologic Linkage Criteria for Reporting***

- Involvement in an exposure event (e.g., adventure race, triathlon, flooding, occupational exposure) with associated laboratory-confirmed cases of leptospirosis.

**** Epidemiologic linkage criteria for reporting must be paired with clinical criteria for reporting to trigger a report to public health.*

A4. Vital Records Criteria for Reporting

- A person whose death certificate lists leptospirosis as an underlying cause of death or a significant condition contributing to death.

A5. Healthcare Record Criteria for Reporting

- A person whose healthcare record contains a diagnosis[^] of leptospirosis.

[^] Rule-out testing should not be considered a reportable diagnosis.

B. Disease-Specific Data Elements to be Included in the Initial Report

Disease-specific data elements should be included in addition to the common data elements that are to be reported for all initial individual case reports (see CSTE Position Statement 09-SI-01 “Common Core Data Elements for Case Reporting and Laboratory Result Reporting” <https://cdn.ymaws.com/www.cste.org/resource/resmgr/PS/09-SI-01.pdf>). Public health authorities do not expect that an initial report will contain all the information necessary for case investigation and case classification.

Clinical Information

- Clinical symptoms (mortality, severe manifestations [e.g., hemorrhage, jaundice, renal insufficiency, organ failure, meningitis])
- Date of diagnosis
- Hospitalization
- Treatment and outcome

Laboratory Information

- Microbiological and serological data (serovar or serogroup, if known)

Epidemiological Information

- Animal Exposures: Specify animal, contact type, and location
 - Wild or domestic animals (including zoo, abattoir, research, vet)
 - Animal products (e.g., excreta, bodily fluids)
- Exposure to wet soil or mud
- Exposure to fresh water (e.g., flooding, puddles, runoff, river, stream, lake, pond)
- Exposure to sewage
- Occupation
- Residence in low-income or congested housing
- Recreational exposure (e.g., swimming, rafting, boating, fishing, farm, other)
- Recent travel (destination, dates of travel)

VII. Case Definition for Case Classification

This case definition for case classification is intended solely for public health surveillance purposes and does not recommend criteria for clinical diagnosis purposes. Once a public health agency has ascertained data on potential cases of a disease or condition from reporting entities, the public health agency assigns case statuses based on the case classifications included within this position statement.

A. Narrative: A description of criteria to determine how public health should classify a case of Leptospirosis.**A1. Clinical Criteria**

- An illness characterized by one or more of the following: fever, headache, chills, myalgia, vomiting, nausea, diarrhea, abdominal pain, conjunctival suffusion, renal insufficiency, jaundice, respiratory insufficiency, meningitis, or rash. Symptoms may be biphasic.

A2. Laboratory Criteria****Confirmatory Laboratory Evidence:***

- Isolation of *Leptospira* from a clinical specimen,
OR
- Fourfold or greater increase in *Leptospira* agglutination titer between acute and convalescent phase serum specimens studied at the same laboratory,
OR
- Demonstration of *Leptospira* in tissue by direct immunofluorescence,
OR
- *Leptospira* agglutination titer of ≥ 800 by Microscopic Agglutination Test (MAT) in one or more serum specimens,
OR
- Detection of pathogenic (P1 clade) or intermediate (P2 clade) *Leptospira* DNA (e.g., by PCR) from a clinical specimen

Presumptive Laboratory Evidence:

- *Leptospira* agglutination titer of ≥ 200 but < 800 by Microscopic Agglutination Test (MAT) in one or more serum specimens,
OR
- Demonstration of anti-*Leptospira* antibodies in a clinical specimen by indirect immunofluorescence,
OR
- Demonstration of *Leptospira* in a clinical specimen by darkfield microscopy,
OR
- Detection of IgM antibodies against *Leptospira* in an acute phase serum specimen.

Supportive Laboratory Evidence:
N/A

** Note: The categorical labels used here to stratify laboratory evidence are intended to support the standardization of case classifications for public health surveillance. The categorical labels should not be used to interpret the utility or validity of any laboratory test methodology.*

A3. Epidemiologic Linkage Criteria

- Involvement in an exposure event (e.g., adventure race, triathlon, flooding, occupational exposure) with associated laboratory-confirmed cases of leptospirosis.

A4. Case Classifications

Confirmed:

- Meets confirmatory laboratory evidence.

Probable:

- Meets clinical criteria AND meets presumptive laboratory evidence, OR
- Meets clinical criteria AND meets epidemiologic linkage criteria.

B. Criteria to Distinguish a New Case of Leptospirosis from Reports or Notifications which Should Not be Enumerated as a New Case for Surveillance

- A person previously enumerated as a probable or confirmed case with new onset of symptoms that meets the criteria for a confirmed or probable case, after consultation with CDC leptospirosis SMEs.

VIII. Period of Surveillance

Surveillance should be ongoing.

IX. Data Sharing/Release and Print Criteria

CSTE recommends the following case statuses* be included in the 'case' count released outside of the public health agency:

- ☒ Confirmed
- ☒ Probable
- ☐ Suspect
- ☐ Unknown

**Which case statuses are included in case counts constitute the "print criteria."*

Jurisdictions (e.g., States and Territories) conducting surveillance under this case definition can voluntarily submit de-identified case information to CDC, if requested and in a mutually agreed upon format.

Production of national data summaries and national data re-release for non-NNCs:

- Prior to release of national data summaries CDC should follow the CDC/ATSDR Policy on Releasing & Sharing Data, issued on April 16, 2003 and referenced in 11-SI-01 and custodians of such data should consult the CDC-CSTE Intergovernmental Data Release Guidelines Working Group report (www.cste2.org/webpdfs/drgwgreport.pdf) which contains data release guidelines and procedures for CDC programs re-releasing state, local, or territorial-provided data.
- CDC programs have a responsibility, in collaboration with states, localities, and territories, to ensure that CDC program-specific data re-release procedures meet the needs of those responsible for protecting data in the states and territories.

X. Revision History

Position Statement ID	Section of Document	Revision Description
24-ID-07	Section V. Data Sources and Recommended Methods for Surveillance	Added “death certificates” to and removed “reporting by other entities (e.g., hospitals veterinarians, pharmacies” from sources of data for case identification
24-ID-07	Section VI.A. Case Ascertainment	<ul style="list-style-type: none"> Simplified Clinical Criteria for Reporting to only one sign or symptom paired with Epidemiologic Linkage Criteria for Reporting to trigger a report to public health. Updated Laboratory Criteria for Reporting: <ul style="list-style-type: none"> Removed minimum threshold (≥ 800) for <i>Leptospira</i> total agglutination titer by MAT Clarified detection of pathogenic OR intermediate <i>Leptospira</i> DNA from a clinical specimen Changed type of specimen needed for demonstration of <i>Leptospira</i> by direct immunofluorescence from “clinical specimen” to “tissue” Removed “Fourfold or greater increase in <i>Leptospira</i> agglutination titer between acute- and convalescent phase serum specimens studied at the same laboratory” Updated Epidemiologic Linkage Criteria for Reporting to add “occupational exposure” to list of example exposure events
24-ID-07	Section VII.B. Disease-Specific Data Elements	<ul style="list-style-type: none"> Added “Treatment and outcome” and “Exposure to sewage” Updated exposure to “standing water” to “fresh water” Removed animal exposure related to “Animal bedding, stall material, food contact” Removed exposure to “vegetation” and added exposure to “mud” Removed “Residence in rural area” Removed “Walk barefoot or in sandals”
24-ID-07	Section VII.A. Case Classification	<ul style="list-style-type: none"> Simplified Clinical Criteria to only one sign or symptom needed to characterize an illness associated with leptospirosis. Updated Laboratory Criteria to clarify detection of pathogenic OR intermediate <i>Leptospira</i> DNA from a clinical specimen Updated Epidemiologic Linkage Criteria to add “occupational exposure” to list of example exposure events
12-ID-02	N/A	Established a standardized surveillance case definition for leptospirosis and added leptospirosis to the NNC list as routinely notifiable.

XI. References

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Technical Supplement

Table VI. Table of criteria to determine whether a case should be reported to public health authorities.

Criterion	Leptospirosis	
<i>Clinical Criteria for Reporting</i>		
Fever		O
Headache		O
Chills		O
Myalgia		O
Vomiting		O
Nausea		O
Diarrhea		O
Abdominal pain		O
Conjunctival suffusion		O
Renal insufficiency		O
Jaundice		O
Respiratory insufficiency		O
Meningitis		O
Rash		O
<i>Laboratory Criteria for Reporting</i>		
Isolation of <i>Leptospira</i> from a clinical specimen	S	
Demonstration of <i>Leptospira</i> in tissue by direct immunofluorescence	S	
Positive <i>Leptospira</i> total agglutination titer by Microscopic Agglutination Test (MAT) in one or more serum specimens	S	
Detection of pathogenic (P1 clade) or intermediate (P2 clade) <i>Leptospira</i> DNA (e.g., by PCR) from a clinical specimen.	S	
Demonstration of anti- <i>Leptospira</i> antibodies in a clinical specimen by indirect immunofluorescence	S	
Demonstration of <i>Leptospira</i> in a clinical specimen by darkfield microscopy	S	
Detection of IgM antibodies against <i>Leptospira</i> in an acute phase serum specimen	S	
<i>Epidemiologic Linkage Criteria for Reporting</i>		
Involvement in an exposure event (e.g., adventure race, triathlon, flooding, occupational exposure) with associated laboratory-confirmed cases of leptospirosis		N
<i>Vital Record Criteria for Reporting</i>		
A person whose death certificate lists leptospirosis as an underlying cause of death or a significant condition contributing to death	S	
<i>Healthcare Record Criteria for Reporting</i>		
A person whose healthcare record contains a diagnosis* of leptospirosis	S	

Notes:

S = This criterion alone is SUFFICIENT to report a case.

N = All "N" criteria in the same column are NECESSARY to report a case.

O = At least one of these "O" (ONE OR MORE) criteria in each category (categories=clinical, laboratory, epidemiologic linkage, vital records, etc.) in the same column—in conjunction with all "N" criteria in the same column—is required to report a case.

* Rule-out testing should not be considered a reportable diagnosis.

[continued]

Table VII.A. Classification Table: Criteria for defining a case of Leptospirosis.

Criterion	Confirmed	Probable
Clinical Evidence		
Fever		O O
Headache		O O
Chills		O O
Myalgia		O O
Vomiting		O O
Nausea		O O
Diarrhea		O O
Abdominal pain		O O
Conjunctival suffusion		O O
Renal insufficiency		O O
Jaundice		O O
Respiratory insufficiency		O O
Meningitis		O O
Rash		O O
Laboratory Evidence		
Isolation of <i>Leptospira</i> from a clinical specimen	S	
Fourfold or greater increase in <i>Leptospira</i> agglutination titer between acute- and convalescent-phase serum specimens studied at the same laboratory	S	
Demonstration of <i>Leptospira</i> in tissue by direct immunofluorescence	S	
<i>Leptospira</i> agglutination titer of ≥ 800 by Microscopic Agglutination Test (MAT) in one or more serum specimens	S	
Detection of pathogenic (P1 clade) or intermediate (P2 clade) <i>Leptospira</i> DNA (e.g., by PCR) from a clinical specimen	S	
<i>Leptospira</i> agglutination titer of ≥ 200 but < 800 by Microscopic Agglutination Test (MAT) in one or more serum specimens		O
Demonstration of anti- <i>Leptospira</i> antibodies in a clinical specimen by indirect immunofluorescence		O
Demonstration of <i>Leptospira</i> in a clinical specimen by darkfield microscopy		O
Detection of IgM antibodies against <i>Leptospira</i> in an acute phase serum specimen		O
Epidemiologic Linkage Evidence		
Involvement in an exposure event (e.g., adventure race, triathlon, flooding, occupational exposure) with associated laboratory-confirmed cases of leptospirosis		N

Notes: S = This criterion alone is SUFFICIENT to classify a case.

N = All "N" criteria in the same column are NECESSARY to classify a case.

O = At least one of these "O" (ONE OR MORE) criteria in each category (categories=clinical evidence, laboratory evidence, and epidemiologic evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to classify a case.

Table VII.B. Classification Table: Criteria to distinguish a new case of leptospirosis from reports or notifications which should not be enumerated as a new case for surveillance*.

Criterion	Confirmed	Probable
Criteria to distinguish a new case		
A person previously enumerated as a probable or confirmed case with new onset of symptoms that meets the criteria for a confirmed case, after consultation with CDC leptospirosis SMEs	S	
A person previously enumerated as a probable or confirmed case with new onset of symptoms that meets the criteria for a probable case, after consultation with CDC leptospirosis SMEs		S

Notes: S = This criterion alone is SUFFICIENT to enumerate as a new case.

*In individuals with clinically compatible illness, consultation with leptospirosis SMEs at CDC is recommended for interpretation of laboratory testing and case classification.

Appendix 1

Fig. 1. Frequency of signs & symptoms among confirmed, probable and suspect cases that reported at least 1 sign or symptom, supplemental case report data submitted to CDC between 2013-2023

