09-ID-62

Committee: Infectious

Title: Public Health Reporting and National Notification for Syphilis

I. Statement of the Problem

CSTE position statement 07-EC-02 recognized the need to develop an official list of nationally notifiable conditions and a standardized reporting definition for each condition on the official list. The position statement also specified that each definition had to comply with American Health Information Community recommended standards to support "automated case reporting from electronic health records or other clinical care information systems." In July 2008, CSTE identified sixty-eight conditions warranting inclusion on the official list, each of which now requires a standardized reporting definition.

II. Background and Justification

Background[1]

Syphilis is a sexually transmitted disease (STD) caused by the bacterium *Treponema pallidum*. Syphilis is passed from person to person through direct contact with a syphilitic chancre. Chancres occur mainly on the external genitals, vagina, anus, or in the rectum but can also occur on the lips and in the mouth. Transmission of the organism occurs during vaginal, anal, or oral sex. Pregnant women with the disease can transmit it through the placenta to the fetus or at birth to the neonate. Many people infected with syphilis do not have any symptoms for years, yet remain at risk for late complications if they are not treated. Although transmission occurs from persons with chancres who are in the primary or secondary stage, many of these chancres are unrecognized. Thus, transmission may occur from persons who are unaware of their infection.

In the United States, testing for syphilis traditionally has consisted of initial screening with an inexpensive nontreponemal test, followed by retesting reactive specimens with a more specific treponemal test. Nontreponemal tests, such as the RPR test and venereal disease research laboratory (VDRL) test, detect antibodies to cardiolipin and are not specific for treponemal infection. Nontreponemal tests are more likely than treponemal tests to produce nonreactive results after treatment; therefore, reactive results from nontreponemal tests are more reliable indicators of untreated infection. Quantitative nontreponemal tests also are used to monitor responses to treatment or to indicate new infections. False-positive nontreponemal tests occur in 1%–2% of the U.S. population, and have been associated with multiple conditions, including pregnancy, human immunodeficiency virus (HIV) infection, intravenous drug use, tuberculosis,

[1] Much of the material in the background is quoted directly from either the CDC Syphilis Website, the March 2003 CDC and CSTE recommendations on conducting surveillance for syphilis, or the 15 August 2008 CDC MMWR article on using treponemal tests for initial screening. See the References for further information on these source documents.

rickettsial infection, spirochetal infection other than syphilis, bacterial endocarditis, and disorders of immunoglobulin production. Nontreponemal test results might be falsely negative in longstanding latent infection.

Treponemal tests detect antibodies specific to *Treponema pallidum*. In addition to *Treponema pallidum*, which causes syphilis, other treponemal subspecies (e.g., *pertenue*, which causes yaws, and *carateum*, which causes pinta) also can produce reactive results to treponemal tests, but these subspecies are rare in the United States. A reactive treponemal test result indicates that treponemal infection has occurred at some point in the past but cannot distinguish between treated and untreated infections. As such, treponemal tests can produce reactive results for life, even after adequate treatment for syphilis. Both treponemal and nontreponemal tests can produce nonreactive results when the infection has been acquired recently; approximately 20% of test results are negative when patients have primary syphilis.

Justification

Syphilis meets the following criteria for a nationally and routinely notifiable condition, as specified in CSTE position statement 08-EC-02:

- A majority of state and territorial jurisdictions—or jurisdictions comprising a majority of the US population—have laws or regulations requiring routine reporting of syphilis to public health authorities
- CDC requests routine notification of syphilis to federal authorities.
- CDC has condition-specific policies and practices concerning the agency's response to, and use of, notifications.

III. Statement of the desired action(s) to be taken

CSTE requests that CDC adopt this standardized reporting definition for syphilis to facilitate more timely, complete, and standardized local and national reporting of this condition.

IV. Goals of Surveillance

To provide information on the temporal, geographic, and demographic occurrence of syphilis to facilitate its prevention and control.

V. Methods for Surveillance

Surveillance for syphilis should use the sources of data and the extent of coverage listed in table V.

Table V. Recommended sources of data and extent of coverage for ascertaining cases of syphilis.

	Coverage	
Source of data for case ascertainment	Population-wide	Sentinel sites
clinician reporting	x	
laboratory reporting	x	
reporting by other entities (e.g., hospitals, veterinarians, pharmacies)	x	x (e.g., STD clinics)
death certificates	x	
hospital discharge or outpatient records	x	
extracts from electronic medical records	x	
telephone survey		
school-based survey		
other _____		

VI. Criteria for Reporting

Reporting refers to the process of healthcare providers or institutions (e.g., clinicians, clinical laboratories, hospitals) submitting basic information to governmental public health agencies about cases of illness that meet certain reporting requirements or criteria. Cases of illness may also be ascertained by the secondary analysis of administrative health data or clinical data. The purpose of this section is to provide those criteria that should be used by humans and machines to determine whether a specific illness should be reported.[2]

[2] "Human-based" criteria (described below under "A. Narrative") can be applied by medical care providers and laboratory staff based on clinical judgment and clinical diagnosis. Machine-based criteria (described below under "B. Table") can be applied using computerized algorithms that operate in electronic health record systems, including computerized records of laboratory test orders and laboratory test results; other clinical data systems (e.g., hospital discharge data systems serving multiple hospitals); or administrative data (e.g., healthcare provider billing data, vital records, and EMS data).

A. Narrative description of criteria to determine whether a case should be reported to public health authorities

Report any illness to public health authorities that meets any of the following laboratory criteria:

- demonstration of *Treponema pallidum* in clinical specimens by darkfield microscopy
- demonstration of *Treponema pallidum* in clinical specimens by direct fluorescent antibody (DFA-TP)
- reactive Venereal Disease Research Laboratory [VDRL] serologic test.
- reactive rapid plasma reagin [RPR] serologic test.
- reactive treponemal serological test.
- reactive Venereal Disease Research Laboratory [VDRL] in a specimen of cerebrospinal fluid.

Report any person whose healthcare record contains a diagnosis of syphilis.

Report any death certificate that lists syphilis as a cause of death or a significant condition contributing to death.

Other recommended reporting procedures[3]

- All cases of syphilis should be reported. Public and private providers and laboratories should report the following cases to the local health department *within one working day*:
  - all probable or confirmed cases of early (primary, secondary or early-latent infection) syphilis (regardless of treatment status)
  - all reactive, nontreponemal laboratory tests
  - reactive syphilis tests in pregnant women
- Frequency of reporting of other stages of syphilis should follow state disease reporting statutes and regulations.
- Syphilis cases should be categorized and reported by stage at the time of initial examination (which is often the time of initial specimen collection), not at the time of treatment or interview.
- All cases of probable or confirmed syphilis should be reported regardless of treatment or interview status. Stage determination should be based on available clinical and serological information.
- In the absence of symptoms or serological history, sex partners for the last year should be evaluated to determine whether the case should be classified as early latent, late latent, or latent of unknown duration.
- All confirmatory treponemal test results should be reported when available, but their availability should not delay reporting a reactive nontreponemal test result.

[3] For further information on reporting procedures, see CDC, Division of STD Prevention. Recommendations for Public Health Surveillance of Syphilis in the United States. Atlanta: CDC; March 2003.

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

Table VI-B. Proposed Table of criteria to determine whether a case should be reported to public health authorities. Note: The following criteria are proposed for evaluation before general implementation. For purposes of currently implementing reporting the narrative description in VI-A, should be used.

Criterion	Reporting
Clinical Presentation	
chancre (firm, non-painful ulcer)	C
localized or diffuse mucocutaneous lesions (nonpruritic macular, maculopapular, papular, or pustular lesions)	C
generalized lymphadenopathy	C
evidence of congenital syphilis on physical examination	C
evidence of congenital syphilis on radiographs of long bones	C
syphilitic lesions of the cardiovascular system, skin, bone, or other tissue	C
healthcare record contains a current diagnosis of syphilis	C
death certificate that lists syphilis as a cause of death or a significant condition contributing to death	C
Laboratory findings	
demonstration of *Treponema pallidum* in clinical specimens by darkfield microscopy	S
demonstration of *Treponema pallidum* in clinical specimens by direct fluorescent antibody (DFA-TP)	S
reactive Venereal Disease Research Laboratory [VDRL] serologic test	S
reactive rapid plasma reagin [RPR] serologic test	S
reactive treponemal serological test	S
reactive Venereal Disease Research Laboratory [VDRL] test in a specimen of cerebrospinal fluid	S
elevated CSF protein in absence of other known cause	C
elevated CSF leukocyte count in absence of other known cause	C
Epidemiological Risk Factors	
an infant whose mother had untreated or inadequately treated syphilis at delivery, regardless of signs in the infant. (Inadequate treatment consists of any non-penicillin therapy or penicillin given less than 30 days before delivery.)	S

Notes:
S = This criterion alone is sufficient to report a case
C = This finding corroborates (i.e., supports) the diagnosis of—or is associated with—syphilis, but is not required for reporting.

C. Disease Specific Data Elements:

Disease-specific data elements to be included in the initial report are listed below.

Stage of syphilis
Pregnancy status

VII. Case Definition for Case Classification

A. Narrative description of criteria to determine whether a case should be classified as confirmed, probable (presumptive), or suspected (possible).

Syphilis is a complex sexually transmitted disease that has a highly variable clinical course. Classification by a clinician with expertise in syphilis may take precedence over the following case definitions developed for surveillance purposes.

- Syphilis, primary
- Syphilis, secondary
- Syphilis, latent
- Syphilis, early latent
- Syphilis, late latent
- Syphilis, latent unknown duration
- Neurosyphilis
- Syphilis, late, non-neuro
- Syphilitic stillbirth
- Syphilis, congenital

Syphilis, primary

Clinical description

A stage of infection with *Treponema pallidum* characterized by one or more chancres (ulcers); chancres might differ considerably in clinical appearance.

Laboratory criteria for diagnosis

Demonstration of *Treponema pallidum* in clinical specimens by darkfield microscopy, direct fluorescent antibody (DFA-TP), or equivalent methods.

Case classification

Probable: a clinically compatible case with one or more ulcers (chancres) consistent with primary syphilis and a reactive serologic test (nontreponemal: Venereal Disease Research Laboratory [VDRL] or rapid plasma reagin [RPR]; treponemal: fluorescent treponemal antibody absorbed [FTA-ABS] or microhemagglutination assay for antibody to *Treponema pallidum* [MHA-TP])
Confirmed: a clinically compatible case that is laboratory confirmed

Syphilis, secondary

Clinical description

A stage of infection caused by *Treponema pallidum* and characterized by localized or diffuse mucocutaneous lesions, often with generalized lymphadenopathy. The primary chancre may still be present.

Laboratory criteria for diagnosis

Demonstration of *Treponema pallidum* in clinical specimens by darkfield microscopy, DFA-TP, or equivalent methods

Case classification

Probable: a clinically compatible case with a nontreponemal (VDRL or RPR) titer greater than or equal to 4

Confirmed: a clinically compatible case that is laboratory confirmed

Syphilis, latent

Clinical description

A stage of infection caused by *Treponema pallidum* in which organisms persist in the body of the infected person without causing symptoms or signs. Latent syphilis is subdivided into early, late, and unknown categories based on the duration of infection.

Case classification

Probable: no clinical signs or symptoms of syphilis and the presence of one of the following:

- No past diagnosis of syphilis, a reactive nontreponemal test (i.e., VDRL or RPR), and a reactive treponemal test (i.e., FTA-ABS or MHA-TP)
- A past history of syphilis therapy and a current nontreponemal test titer demonstrating fourfold or greater increase from the last nontreponemal test titer

Syphilis, early latent

Clinical description

A subcategory of latent syphilis. When initial infection has occurred within the previous 12 months, latent syphilis is classified as early latent.

Case classification

Probable: latent syphilis (see Syphilis, latent) in a person who has evidence of having acquired the infection within the previous 12 months based on one or more of the following criteria:

- Documented seroconversion or fourfold or greater increase in titer of a nontreponemal test during the previous 12 months
- A history of symptoms consistent with primary or secondary syphilis during the previous 12 months
- A history of sexual exposure to a partner who had confirmed or probable primary or secondary syphilis or probable early latent syphilis (documented independently as duration less than 1 year)
- Reactive nontreponemal and treponemal tests from a person whose only possible exposure occurred within the preceding 12 months

Syphilis, late latent

Clinical description

A subcategory of latent syphilis. When initial infection has occurred greater than 1 year previously, latent syphilis is classified as late latent.

Case classification

Probable: latent syphilis (see Syphilis, latent) in a patient who has no evidence of having acquired the disease within the preceding 12 months (see Syphilis, early latent) and whose age and titer do not meet the criteria specified for latent syphilis of unknown duration.

Syphilis, latent, of unknown duration

Clinical description

A subcategory of latent syphilis. When the date of initial infection cannot be established as having occurred within the previous year and the patient's age and titer meet criteria described below, latent syphilis is classified as latent syphilis of unknown duration.

Case classification

Probable: latent syphilis (see Syphilis, latent) that does not meet the criteria for early latent syphilis, and the patient is aged 13-35 years and has a nontreponemal titer greater than or equal to 32

Neurosyphilis

Clinical description

Evidence of central nervous system infection with *Treponema pallidum*

Laboratory criteria for diagnosis

A reactive serologic test for syphilis and reactive VDRL in cerebrospinal fluid (CSF)

Case classification

Probable: syphilis of any stage, a negative VDRL in CSF, and both the following:

- Elevated CSF protein or leukocyte count in the absence of other known causes of these abnormalities
- Clinical symptoms or signs consistent with neurosyphilis without other known causes for these clinical abnormalities

Confirmed: syphilis of any stage that meets the laboratory criteria for neurosyphilis

Syphilis, late, with clinical manifestations other than neurosyphilis (late benign syphilis and cardiovascular syphilis)

Clinical description

Clinical manifestations of late syphilis other than neurosyphilis may include inflammatory lesions of the cardiovascular system, skin, and bone. Rarely, other structures (e.g., the upper and lower respiratory tracts, mouth, eye, abdominal organs, reproductive organs, lymph nodes, and skeletal muscle) may be involved. Late syphilis usually becomes clinically manifest only after a period of 15-30 years of untreated infection.

Laboratory criteria for diagnosis

Demonstration of *Treponema pallidum* in late lesions by fluorescent antibody or special stains (although organisms are rarely visualized in late lesions)

Case classification

Probable: characteristic abnormalities or lesions of the cardiovascular system, skin, bone, or other structures with a reactive treponemal test, in the absence of other known causes of these abnormalities, and without CSF abnormalities and clinical symptoms or signs consistent with neurosyphilis
Confirmed: a clinically compatible case that is laboratory confirmed
Comment: Analysis of CSF for evidence of neurosyphilis is necessary in the evaluation of late syphilis with clinical manifestations.

Syphilitic Stillbirth

Clinical case definition

A fetal death that occurs after a 20-week gestation or in which the fetus weighs greater than 500 g and the mother had untreated or inadequately treated* syphilis at delivery

Comment

For reporting purposes, syphilitic stillbirths should be reported as cases of congenital syphilis.

*Inadequate treatment consists of any non-penicillin therapy or penicillin given less than 30 days before delivery.

Syphilis, Congenital

Clinical description

A condition caused by infection in utero with *Treponema pallidum*. A wide spectrum of severity exists, and only severe cases are clinically apparent at birth. An infant or child (aged less than 2 years) may have signs such as hepatosplenomegaly, rash, condyloma lata, snuffles, jaundice (nonviral hepatitis), pseudoparalysis, anemia, or edema (nephrotic syndrome and/or malnutrition). An older child may have stigmata (e.g., interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson teeth, saddle nose, rhagades, or Clutton joints).

Laboratory criteria for diagnosis

Demonstration of *Treponema pallidum* by darkfield microscopy, fluorescent antibody, or other specific stains in specimens from lesions, placenta, umbilical cord, or autopsy material

Case classification

Probable: a condition affecting an infant whose mother had untreated or inadequately treated* syphilis at delivery, regardless of signs in the infant, or an infant or child who has a reactive treponemal test for syphilis and any one of the following:

- Any evidence of congenital syphilis on physical examination
- Any evidence of congenital syphilis on radiographs of long bones
- A reactive cerebrospinal fluid (CSF) venereal disease research laboratory (VDRL)
- An elevated CSF cell count or protein (without other cause)
- A reactive fluorescent treponemal antibody absorbed--19S-IgM antibody test or IgM enzyme-linked immunosorbent assay

Confirmed: a case that is laboratory confirmed

Comment

Congenital and acquired syphilis may be difficult to distinguish when a child is seropositive after infancy. Signs of congenital syphilis may not be obvious, and stigmata may not yet have developed. Abnormal values for CSF VDRL, cell count, and protein, as well as IgM antibodies, may be found in either congenital or acquired syphilis. Findings on radiographs of long bones may help because radiographic changes in the metaphysis and epiphysis are considered classic signs of congenitally acquired syphilis. The decision may ultimately be based on maternal history and clinical judgment. In a young child, the possibility of sexual abuse should be considered as a cause of acquired rather than congenital syphilis, depending on the clinical picture. For reporting purposes, congenital syphilis includes cases of congenitally acquired syphilis among infants and children as well as syphilitic stillbirths.

*Inadequate treatment consists of any non-penicillin therapy or penicillin given less than 30 days before delivery.

B. Classification Tables

Table VII-B lists the criteria that must be met for a case to be classified as confirmed or probable (presumptive).

Table VII-B. Proposed table of criteria to determine whether a case is classified. Note: The following criteria are proposed for evaluation before general implementation. For purposes of current notification, the narrative description in VII-A, should be used.

	Case Definition													
	Confirmed					Probable								
	1º	2º	Neuro	Late (non neuro)	Cong.	1º	2º	Latent			Neuro	Late (non neuro)	Cong.	
Criterion								E	L	L U				
Clinical Presentation														
chancre (firm, non-painful ulcer)	N	C				N	C	A	A	A				
localized or diffuse mucocutaneous lesions (nonpruritic macular, maculopapular, papular, or pustular lesions)		N					N	A	A	A				
generalized lymphadenopathy		C					C							
no past diagnosis of syphilis									O	O				

Criterion	Case Definition													
	Confirmed					Probable								
	1º	2º	Neuro	Late (non neuro)	Cong.	1º	2º	Latent			Neuro	Late (non neuro)	Cong.	
								E	L	LU				
evidence of congenital syphilis on physical examination														O
evidence of congenital syphilis on radiographs of long bones														O
syphilitic lesions of the cardiovascular system, skin, bone, or other tissue				N								N		
clinical symptoms or signs consistent with neurosyphilis without other known causes for these clinical abnormalities											N	A		
Laboratory findings														
demonstration of *Treponema pallidum* in clinical specimens by darkfield microscopy	O	O			O									
demonstration of *Treponema pallidum* in clinical specimens by direct fluorescent antibody (DFA-TP)	O	O		N	O									
reactive Venereal Disease Research Laboratory [VDRL] serological test			N*			N*		N*	N*	N*	N*			
reactive rapid plasma reagin [RPR] serological test			N*			N*		N*	N*	N*	N*			
reactive Venereal							N							

Criterion	Case Definition													
	Confirmed					Probable								
	1º	2º	Neuro	Late (non neuro)	Cong.	1º	2º	Latent			Neuro	Late (non neuro)	Cong.	
								E	L	LU				
Disease Research Laboratory [VDRL] serological test with a titer ≥4							*							
reactive rapid plasma reagin [RPR] serological test with a titer ≥4							N*							
reactive Venereal Disease Research Laboratory [VDRL] test in a specimen of cerebrospinal fluid			N								A	A		O
reactive treponemal serologic test			N			N	N	N	N	N	N	N		N
reactive fluorescent treponemal antibody absorbed –19S-IgM antibody test or IgM enzyme-linked immunosorbent assay														O
elevated CSF protein in absence of other known cause											O	A		O
elevated CSF leukocyte count in absence of other known cause											O	A		O
Epidemiological Risk Factors														
age < 2 years					N								N	N
age is 13–35 years									^	N				
an infant whose mother had untreated or inadequately treated syphilis at delivery,													N	

Criterion	Case Definition												
	Confirmed					Probable							
	1º	2º	Neuro	Late (non neuro)	Cong.	1º	2º	Latent			Neuro	Late (non neuro)	Cong.
								E	L	L U			
regardless of signs in the infant. (Inadequate treatment consists of any non-penicillin therapy or penicillin given less than 30 days before delivery.)													
Criteria for assessing the stage of latent syphilis													
history of symptoms consistent with primary or secondary syphilis within the previous 12 months								O	A	A			
history of sexual exposure to a partner who had confirmed or probable primary or secondary syphilis or probable early latent syphilis (documented independently as duration less than 1 year)								O	A	A			
only possible exposure to a partner with syphilis occurred within the preceding 12 months								O	A	A			
seroconversion or fourfold or greater increase in titer of a nontreponemal test during the previous 12 months								O	A	A			
seroconversion or									O	O			

Criterion	Case Definition													
	Confirmed					Probable								
	1º	2º	Neuro	Late (non neuro)	Cong.	1º	2º	Latent			Neuro	Late (non neuro)	Cong.	
								E	L	LU				
fourfold or greater increase in titer of a nontreponemal test														
reactive Venereal Disease Research Laboratory [VDRL] serologic test with a titer ≥ 32									^	N *				
reactive rapid plasma reagin [RPR] serologic test with a titer ≥ 32									^	N *				

Notes:
N = This criterion in conjunction with all other "N" and any "O" criteria in the same column is required to classify a case.
O = At least one of these "O" criteria in each category in the same column (e.g., clinical presentation and laboratory findings)—in conjunction with all other "N" criteria in the same column—is required to classify a case.
A = This criterion must be absent (i.e., NOT present) for the case to meet the case definition.
C = This finding corroborates (i.e., supports) the diagnosis of—or is associated with—syphilis, but is not included in the case definition.
* At least one of the non-treponemal test criteria must be met (i.e., VDRL or RPR)
^ = patients cannot be BOTH 13-35 AND have a VDRL or RPR titer ≥32 BUT can have one or the other criteria to be classified as a case of late latent syphilis.

VIII. Period of Surveillance

Surveillance should be on-going.

IX. Data sharing/release and print criteria

Notification to CDC of confirmed and probable cases of syphilis is recommended.

De-identified data are provided bv jurisdictions to CDC. Jurisdiction-specific case counts are reported weekly in the MMWR. Data are also analyzed and published in the CDC's annual *Sexually Transmitted Disease Surveillance,* in STD surveillance updates within the MMWR, and in peer-reviewed publications. Reports and publications are provided to jurisdictions, to other interested parties, and made available on the internet.

X. References

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