C. STD Surveillance Case Definitions

C1. CASE DEFINITIONS[1] FOR NATIONALLY NOTIFIABLE INFECTIOUS DISEASES

C1.1 Chancroid (Revised 9/96)

Clinical description

A sexually transmitted disease characterized by painful genital ulceration and inflammatory inguinal adenopathy. The disease is caused by infection with *Haemophilus ducreyi*.

Laboratory criteria for diagnosis

- Isolation of *H. ducreyi* from a clinical specimen

Case classification

Probable: a clinically compatible case with both a) no evidence of *Treponema pallidum* infection by darkfield microscopic examination of ulcer exudate or by a serologic test for syphilis performed ≥7 days after onset of ulcers and b) either a clinical presentation of the ulcer(s) not typical of disease caused by herpes simplex virus (HSV) or a culture negative for HSV.

Confirmed: a clinically compatible case that is laboratory confirmed.

C1.2 *Chlamydia trachomatis* Infection (Revised 6/09)

Clinical description

Infection with *Chlamydia trachomatis* may result in urethritis, epididymitis, cervicitis, acute salpingitis, or other syndromes when sexually transmitted; however, the infection is often asymptomatic in women. Perinatal infections may result in inclusion conjunctivitis and pneumonia in newborns. Other syndromes caused by *C. trachomatis* include lymphogranuloma venereum (see Lymphogranuloma Venereum) and trachoma.

Laboratory criteria for diagnosis

- Isolation of *C. trachomatis* by culture or
- Demonstration of *C. trachomatis* in a clinical specimen by detection of antigen or nucleic acid

Case classification

Confirmed: a case that is laboratory confirmed

C1.3 Gonorrhea (Effective 1/14)

Clinical description

A sexually transmitted infection commonly manifested by urethritis, cervicitis, proctitis, salpingitis, or pharyngitis. Infection may be asymptomatic.

[1] Centers for Disease Control and Prevention. Case definitions for infectious conditions under public health surveillance, 1997. MMWR Morb Mortal Wkly Rep. 1997;46(No. RR-10).

Laboratory criteria for diagnosis

- Observation of gram-negative intracellular diplococci in a urethral smear obtained from a male or an endocervical smear obtained from a female, or
- Isolation of typical gram-negative, oxidase-positive diplococci by culture (presumptive *Neisseria gonorrhoeae*) from a clinical specimen, or
- Demonstration of *N. gonorrhoeae* in a clinical specimen by detection of antigen or nucleic acid

Case classification

Probable: demonstration of gram-negative intracellular diplococci in a urethral smear obtained from a male or an endocervical smear obtained from a female.

Confirmed: a person with laboratory isolation of typical gram-negative, oxidase-positive diplococci by culture (presumptive *Neisseria gonorrhoeae)* from a clinical specimen, or demonstration of *N. gonorrhoeae* in a clinical specimen by detection of antigen or detection of nucleic acid via nucleic acid amplification (e.g., PCR) or hybridization with a nucleic acid probe.

C1.4 Syphilis (Effective 1/14)

Syphilis is a complex sexually transmitted disease that has a highly variable clinical course. Adherence to the following surveillance case definitions will facilitate understanding the epidemiology of this disease across the U.S.

Syphilis, primary (Effective 1/14)

Clinical description

A stage of infection with *Treponema pallidum* characterized by one or more ulcerative lesions (e.g. chancre), which might differ considerably in clinical appearance.

Laboratory criteria for diagnosis

- Demonstration of *T. pallidum* in clinical specimens by darkfield microscopy, or by polymerase chain reaction (PCR) or equivalent direct molecular methods.

Case classification

Probable: a case that meets the clinical description of primary syphilis with a reactive serologic test (nontreponemal: Venereal Disease Research Laboratory [VDRL], rapid plasma reagin [RPR], or equivalent serologic methods; treponemal: fluorescent treponemal antibody absorbed [FTA-ABS], *T. pallidum* particle agglutination [TP-PA], enzyme immunoassay [EIA], chemiluminescence immunoassay [CIA], or equivalent serologic methods). These treponemal tests supersede older testing technologies, including microhemagglutination assay for antibody to *T. pallidum* [MHA-TP].

Confirmed: a case that meets the clinical description of primary syphilis that is laboratory confirmed.

Syphilis, secondary (Effective 1/14)

Clinical description

A stage of infection caused by *T. pallidum* characterized by localized or diffuse mucocutaneous lesions (e.g., rash – such as non-pruritic macular, maculopapular, popular, or pustular lesions), often with generalized lymphadenopathy. Other symptoms can include mucous patches, condyloma lata, and alopecia. The primary ulcerative lesion may still be present. Because of the wide array of symptoms possibly indicating secondary syphilis, serologic tests for syphilis and a thorough sexual history and physical examination are crucial to determining if a case should be classified as secondary syphilis.

Laboratory criteria for diagnosis

- Demonstration of *T. pallidum* in clinical specimens by darkfield microscopy, or by polymerase chain reaction (PCR) or equivalent direct molecular methods.

Case classification

Probable: a case that meets the clinical description of secondary syphilis with a nontreponemal (VDRL, RPR, or equivalent serologic methods) titer ≥4 and a reactive treponemal test (FTA-ABS, TP-PA, EIA, CIA, or equivalent serologic methods).

Confirmed: a case that meets the clinical description of secondary syphilis (with at least one sign or symptom) that is laboratory confirmed.

Syphilis, early latent (Effective 1/14)

Clinical description

A subcategory of latent syphilis (a stage of infection caused by *T. pallidum* in which organisms persist in the body of the infected person without causing symptoms or signs) when initial infection has occurred within the previous 12 months.

Case classification

Probable: A person with no clinical signs or symptoms of syphilis who has one of the following:

- No past diagnosis of syphilis, and a reactive nontreponemal test (e.g., VDRL, RPR, or equivalent serologic methods), and a reactive treponemal test (e.g., FTA-ABS, TP-PA, EIA, CIA, or equivalent serologic methods), or
- A current nontreponemal test titer demonstrating fourfold or greater increase from the last nontreponemal test titer

AND 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
- Documented seroconversion of a treponemal 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 within the previous 12 months who had primary, secondary, or early latent syphilis (documented independently as duration <12 months)
- Only sexual contact was within the last 12 months (sexual debut)

There is no confirmed case classification for early latent syphilis.

Syphilis, late latent (Effective 1/14)

Clinical description

A subcategory of latent syphilis (a stage of infection caused by *T. pallidum* in which organisms persist in the body of the infected person without causing symptoms or signs)when initial infection has occurred >12 months previously.

Case classification

Probable: a person with no clinical signs or symptoms of syphilis who has one of the following:

- No past diagnosis of syphilis, and a reactive nontreponemal test (e.g., VDRL, RPR, or equivalent serologic methods), and a reactive treponemal test (e.g., FTA-ABS, TP-PA, EIA, CIA, or equivalent serologic methods). or
- A past history of syphilis therapy and a current nontreponemal test titer demonstrating fourfold or greater increase from the last nontreponemal test titer.

AND who has no evidence of having acquired the disease within the preceding 12 months (see Syphilis, early latent).

There is no confirmed case classification for late latent syphilis.

Neurosyphilis (Effective 1/14)

Neurosyphilis can occur at any stage of syphilis. If the patient has neurologic manifestations of syphilis, the case should be reported with the appropriate stage of infection (as if neurologic manifestations were not present) and neurologic manifestations should be noted in the case report data. If no other stage is appropriate, the case should be staged as "late, with clinical manifestations".

Neurosyphilis can apply to all stages of infection of syphilis listed, including: primary syphilis, secondary syphilis, early latent syphilis, late latent syphilis, and late syphilis with clinical manifestations.

Clinical description

Infection of the central nervous system with *T. pallidum*, as evidenced by manifestations including syphilitic meningitis, meningovascular syphilis, optical involvement including interstitial keratitis and uveitis, general paresis, including dementia, and tabes dorsalis.

Laboratory criteria for diagnosis

A reactive VDRL in cerebrospinal fluid (CSF) and either (1) a reactive treponemal serologic test for syphilis (e.g., FTA-ABS, TP-PA, EIA, CIA, or equivalent serologic methods) or (2) a reactive nontreponemal serologic test for syphilis (VDRL, RPR, or equivalent serologic method).

Case classification

Probable: syphilis of any stage with a negative VDRL test in CSF specimen and either (1) a reactive treponemal serologic test for syphilis (e.g., FTA-ABS, TP-PA, EIA, CIA, or equivalent serologic methods) or (2) a reactive non-treponemal serologic test for syphilis (VDRL, RPR, or equivalent serologic method), and both of the following:

- Elevated CSF protein (>50 mg/dL2) or leukocyte count (>5 white blood cells/cubic millimeter CSF) in the absence of other known causes of these abnormalities, and
- 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 (including late benign syphilis and cardiovascular syphilis) (Effective 1/14)

Clinical description

Clinical manifestations of late syphilis may include inflammatory lesions of the cardiovascular system (e.g., aortitis, coronary vessel disease), skin (e.g., gummatous lesions) bone (e.g., osteitis) or other tissue. 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. If only neurologic manifestations of syphilis (e.g., tabes dorsalis, dementia) are present and infection occurred more than 12 months ago, the case should be reported as "late syphilis".

Laboratory criteria for diagnosis

- Demonstration of *T. pallidum* in late lesions by special stains (although organisms are rarely visualized in late lesions), or equivalent methods, or by polymerase chain reaction (PCR) or equivalent direct molecular methods.

Case classification

Probable: characteristic abnormalities or lesions of the cardiovascular system (e.g., aortitis, coronary vessel disease), skin (e.g., gummatous lesions), bone (e.g., osteitis), or other tissue and a reactive treponemal test (e.g., FTA-ABS, TP-PA, EIA, CIA, or equivalent serologic methods), in the absence of other known causes of these abnormalities. CSF abnormalities and clinical symptoms or signs consistent with neurologic manifestations of syphilis might be present.

Confirmed: a case that meets the clinical description of late syphilis that is laboratory confirmed.

Syphilitic Stillbirth

Clinical description

A fetal death that occurs after a 20-week gestation or in which the fetus weighs >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.

Syphilis, Congenital (Revised 9/96)

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 <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 *T. 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 nonpenicillin therapy or penicillin administered < 30 days before delivery.

C2. CASE DEFINITIONS[1] FOR NON-NOTIFIABLE INFECTIOUS DISEASES

C2.1 Genital Herpes (Herpes Simplex Virus) (Revised 9/96)

Clinical description

A condition characterized by visible, painful genital or anal lesions

Laboratory criteria for diagnosis

- Isolation of herpes simplex virus from cervix, urethra, or anogenital lesion, or
- Demonstration of virus by antigen detection technique in clinical specimens from cervix, urethra, or anogenital lesion, or
- Demonstration of multinucleated giant cells on a Tzanck smear of scrapings from an anogenital lesion

Case classification

Probable: a clinically compatible case (in which primary and secondary syphilis have been excluded by appropriate serologic tests and darkfield microscopy, when available) with either a diagnosis of genital herpes based on clinical presentation (without laboratory confirmation) or a history of one or more previous episodes of similar genital lesions

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

Genital herpes should be reported only once per patient. The first diagnosis for a patient with no previous diagnosis should be reported.

C2.2 Genital Warts (Revised 9/96)

Clinical description

An infection characterized by the presence of visible, exophytic (raised) growths on the internal or external genitalia, perineum, or perianal region

Laboratory criteria for diagnosis

- Histopathologic changes characteristic of human papillomavirus infection in specimens obtained by biopsy or exfoliative cytology or
- Demonstration of virus by antigen or nucleic acid detection in a lesion biopsy

Case classification

Probable: a clinically compatible case without histopathologic diagnosis and without microscopic or serologic evidence that the growth is the result of secondary syphilis

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

Genital warts should be reported only once per patient. The first diagnosis for a patient with no previous diagnosis should be reported.

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[1] Centers for Disease Control and Prevention. Case definitions for infectious conditions under public health surveillance, 1997. MMWR Morb Mortal Wkly Rep. 1997;46(No. RR-10).

C2.3 Granuloma Inguinale

Clinical description

A slowly progressive ulcerative disease of the skin and lymphatics of the genital and perianal area caused by infection with *Calymmatobacterium granulomatis*. A clinically compatible case would have one or more painless or minimally painful granulomatous lesions in the anogenital area.

Laboratory criteria for diagnosis

- Demonstration of intracytoplasmic Donovan bodies in Wright or Giemsa-stained smears or biopsies of granulation tissue

Case classification

Confirmed: a clinically compatible case that is laboratory confirmed

C2.4 Lymphogranuloma Venereum

Clinical description

Infection with L1, L2, or, L3 serovars of *Chlamydia trachomatis* may result in a disease characterized by genital lesions, suppurative regional lymphadenopathy, or hemorrhagic proctitis. The infection is usually sexually transmitted.

Laboratory criteria for diagnosis

- Isolation of *C. trachomatis*, serotype L1, L2, or L3 from clinical specimen, or
- Demonstration by immunofluorescence of inclusion bodies in leukocytes of an inguinal lymph node (bubo) aspirate, or
- Positive microimmunofluorescent serologic test for a lymphogranuloma venereum strain of *C. trachomatis*

Case classification

Probable: a clinically compatible case with one or more tender fluctuant inguinal lymph nodes or characteristic proctogenital lesions with supportive laboratory findings of a single *C. trachomatis* complement fixation titer of >64

Confirmed: a clinically compatible case that is laboratory confirmed

C2.5 Mucopurulent Cervicitis (Revised 9/96)

Clinical description

Cervical inflammation that is not the result of infection with *Neisseria gonorrhoeae* or *Trichomonas vaginalis*. Cervical inflammation is defined by the presence of one of the following criteria:

- Mucopurulent secretion (from the endocervix) that is yellow or green when viewed on a white, cotton-tipped swab (positive swab test)
- Induced endocervical bleeding (bleeding when the first swab is placed in the endocervix)

Laboratory criteria for diagnosis

No evidence of *N. gonorrhoeae* by culture, Gram stain, or antigen or nucleic acid detection, and no evidence of *T. vaginalis* on wet mount

Case classification

Confirmed: a clinically compatible case in a female who does not have either gonorrhea or trichomoniasis

Comment

Mucopurulent cervicitis (MPC) is a clinical diagnosis of exclusion. The syndrome may result from infection with any of several agents (see *Chlamydia trachomatis*). If gonorrhea, trichomoniasis, and chlamydia are excluded, a clinically compatible illness should be classified as MPC. An illness in a female that meets the case definition of MPC and *C. trachomatis* infection should be classified as chlamydia.

C2.6 Nongonococcal Urethritis (Revised 9/96)

Clinical description

Urethral inflammation that is not the result of infection with *Neisseria gonorrhoeae*. Urethral inflammation may be diagnosed by the presence of one of the following criteria:

- A visible abnormal urethral discharge, or
- A positive leukocyte esterase test from a male aged <60 years who does not have a history of kidney disease or bladder infection, prostate enlargement, urogenital anatomic anomaly, or recent urinary tract instrumentation, or
- Microscopic evidence of urethritis (≥5 white blood cells per high-power field) on a Gram stain of a urethral smear

Laboratory criteria for diagnosis

- No evidence of *N. gonorrhoeae* infection by culture, Gram stain, or antigen or nucleic acid detection

Case classification

Confirmed: a clinically compatible case in a male in whom gonorrhea is not found, either by culture, Gram stain, or antigen or nucleic acid detection

Comment

Nongonococcal urethritis (NGU) is a clinical diagnosis of exclusion. The syndrome may result from infection with any of several agents (see *Chlamydia trachomatis*). If gonorrhea and chlamydia are excluded, a clinically compatible illness should be classified as NGU. An illness in a male that meets the case definition of NGU and *C. trachomatis* infection should be classified as chlamydia.

C2.7 Pelvic Inflammatory Disease (Revised 9/96)

Clinical case definition

A clinical syndrome resulting from the ascending spread of microorganisms from the vagina and endocervix to the endometrium, fallopian tubes, and/or contiguous structures. In a female who has lower abdominal pain and who has not been diagnosed as having an established cause other than pelvic inflammatory disease (PID) (e.g., ectopic pregnancy, acute appendicitis, and functional pain), all the following clinical criteria must be present:

- Lower abdominal tenderness, and
- Tenderness with motion of the cervix, and
- Adnexal tenderness

In addition to the preceding criteria, at least one of the following findings must also be present:

- Meets the surveillance case definition of *C. trachomatis* infection or gonorrhea
- Temperature >100.4 F (>38.0 C)
- Leukocytosis >10,000 white blood cells/mm^3
- Purulent material in the peritoneal cavity obtained by culdocentesis or laparoscopy
- Pelvic abscess or inflammatory complex detected by bimanual examination or by sonography
- Patient is a sexual contact of a person known to have gonorrhea, chlamydia, or nongonococcal urethritis

Case classification

Confirmed: a case that meets the clinical case definition

Comment

For reporting purposes, a clinician's report of PID should be counted as a case.