

**ARMED FORCES
REPORTABLE MEDICAL EVENTS
GUIDELINES
&
CASE DEFINITIONS**

Functional Proponent:
Armed Forces Health Surveillance Center
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1.0 Overview

A reportable event may represent an inherent, significant threat to public health and military operation. These events have the potential to affect large numbers of people, to be widely transmitted within a population, to have severe/life threatening clinical manifestations, and to disrupt military training and deployment. Timely, accurate reporting of probable, suspected or confirmed cases ensures proper identification, treatment, control, and follow-up of cases.

Reportable events were chosen based by consensus and recommendations from each of the Services about notifiable diseases from the Centers for Disease Control and Prevention (CDC), the Council of State and Territorial Epidemiologists (CSTE), and events that military public health experts have identified as representing significant military threats that deserve additional emphasis for surveillance (References 1 -4). The principal goals of this document are to achieve data consistency and standardization of reportable events tracking across each Service, and to aid local reporting installations by providing programmatic guidance.

As part of the ongoing effort to consolidate Department of Defense (DoD) medical surveillance data, the following sections are included in this *Armed Forces Reportable Medical Events Guidelines and Case Definitions* document:

- Reportable event selection criteria (Section 2)
- Medical events surveillance & the use of ICD-9 codes (Section 3)
- Service point-of-contact (Section 4)
- Compendium of case definitions (Section 5)
- Criteria for standardized data elements (Section 6)
- Reportable disease ICD-9 codes & synonyms (Section 7)
- References (Section 8)

2.0 Selection Criteria for Reportable Medical Events

The list of reportable medical events (Section 5) was compiled based on the selection criteria below. Representatives of each Service's medical department applied the criteria to each medical event/condition that was considered for mandatory reporting:

1. There must be a clear case definition and diagnostic laboratory criteria.
2. An intervention must be available and/or a public health response indicated.
3. A sufficient, timely source of the required information must not already exist.
4. The condition/event must also meet one of the following criteria:
 - It represents an inherent, significant threat to public health by having the potential to affect large numbers of people, to be widely transmitted within a population, or to have severe/life threatening clinical manifestations, or
 - It represents a significant military operational threat by having the potential to disrupt military training, deployment, or operations, or
 - It is commonly reportable by state or federal laws, regulations, or guidelines.
 - Individual services may require reporting of additional conditions; refer to service-specific instructions for details.

3.0 Medical Events Surveillance and the Use of ICD-9 Codes

Medical Events Surveillance:

This list of Reportable Events contains specific diseases and environmental exposures that have clear case definitions and laboratory criteria for diagnosis. Events among all military healthcare system beneficiaries (e.g., service members, family members, retirees, civilian federal government employees) should be reported (unless otherwise noted).

Use of ICD-9 Codes:

The use of ICD-9 codes in medical event surveillance is intended to assist in the search for cases of the reportable disease in healthcare encounter related databases. Other ICD-9 codes may also be needed to find additional reportable medical events in these databases. For example, to identify cases of Invasive Group A Streptococcal disease not coded as ICD-9 038.0, consider looking for cases coded 482.31 or 041.01. As long as cases so coded meet the case definition, all such cases should be reported as “Streptococcus, Group A, Invasive – 038.0”, regardless of ICD-9 code. Commonly used ICD-9 codes and synonyms for each event/condition can be found in Section 7.

4.0 Service Points-of-Contact

In order to address Service-specific needs, each Service will continue to be responsible for implementing its own reporting system, data collection, and quality assurance. The collected data will be integrated into the Defense Medical Surveillance System (DMSS) database, where it will be available to all three Services for further reporting and analysis.

Consult the following individual Service points of contact with suggested changes to this *Armed Forces Reportable Medical Events Guidelines and Case Definitions* document and/or service-specific questions about guideline implementation:

Air Force:	Reportable Disease Project Officer USAF School of Aerospace Medicine DSN 798-3207 (COM 937-938-3207)
Army:	Reportable Disease Project Officer Army Institute of Public Health DSN 584-7605 (COM 410-436-7605)
Navy/MC:	Reportable Disease Project Officer Navy Marine Corps Public Health Center DSN 377-0700 (COM 757-953-0700)
Coast Guard:	Reportable Disease Project Officer Coast Guard Headquarters, CG-1121 DSN: NA (COM 202-475-5172)

The Reportable Medical Events document is available at the Armed Forces Health Surveillance Center (AFHSC) website (URL: <http://www.afhsc.mil>). Personnel with recommendations to change, add to, or delete from the list should complete an inquiry form (also available on the AFHSC website) and forward it through the Service Reportable Disease Project Officer to the Armed Forces Health Surveillance Center.

5.0 Case Definitions

Definition of terms-

- **Clinical Description**

Background information on event/condition.

- **Clinical Case Definition**

- **Laboratory Criteria for Diagnosis**

Supportive/presumptive laboratory results: specified laboratory results that are consistent with the diagnosis, yet do not meet the criteria for laboratory confirmation.

- **Case Classification**

A set of criteria that must be fulfilled in order to identify a person as a case of a particular disease/condition. Case classification can be based on clinical, laboratory, or combined clinical and laboratory criteria.

Clinically compatible case: a clinical syndrome generally compatible with the disease, as described in the clinical case definition. (Note: if “clinical case definition” is not available, a clinical syndrome compatible with “clinical description” is sufficient).

Epidemiologically linked case: a case in which a) the patient has had contact with one or more persons who either have/had the disease or have been exposed to a point source of infection (i.e., a single source of infection, such as an event leading to a foodborne-disease outbreak, to which all confirmed case-patients were exposed) and b) transmission of the agent by the usually modes of transmission is plausible. A case may be considered epidemiologically linked to a laboratory-confirmed case if at least one case in the chain of transmission is laboratory confirmed.

Suspected: A clinically compatible case that is not yet laboratory confirmed and is not epidemiologically linked to a confirmed case.

Probable: A clinically compatible case that is epidemiologically linked to a confirmed case and/or supported by non-laboratory diagnostic procedures (e.g., chest x-ray).

Confirmed: A clinically compatible illness that is laboratory confirmed or meets confirmatory clinical diagnosis definition.

- **Required Comments**

Additional information should be included in the reporting form. If information is unavailable, indicate so in the appropriate section. For events requiring relevant travel/deployment history, please note the incubation period when collecting this information.

Note: Incubation period is the time interval between initial contact with the infectious organism and the first appearance of symptoms associated with the infection.

- **Additional Considerations**

5.1 AMEBIASIS

Clinical Description

Reference 5

Infection of the large intestine by *Entamoeba histolytica* may result in an illness of variable severity ranging from mild, chronic diarrhea to fulminant dysentery (i.e., severe and sudden onset diarrhea containing mucus and/or blood in the stool). Infection also may be asymptomatic. Extraintestinal infection can also occur (e.g., hepatic abscess).

Laboratory Criteria for Diagnosis

1. **Intestinal Amebiasis:** (any of the following):

- Cysts or trophozoites of *E. histolytica* in stool;
- Trophozoites in tissue biopsy or ulcer scrapings by culture or histopathology;
- Immunoassay for parasite antigen in stool.

2. **Extraintestinal Amebiasis:** Demonstration of *E. histolytica* trophozoites in extraintestinal tissue.

Case Classification

1. **Intestinal Amebiasis:**

- **Confirmed:** A clinically compatible case that is laboratory-confirmed.

2. **Extraintestinal Amebiasis:**

- **Confirmed:** A parasitologically-confirmed infection of extraintestinal tissue, or in symptomatic persons (with clinical or radiographic findings consistent with extraintestinal infection), demonstration of specific antibodies against *E. histolytica* as measured by indirect hemagglutination or other reliable immunodiagnostic test (e.g., enzyme-linked immunosorbent assay [ELISA]).

Note: Asymptomatic intestinal carriage of E. histolytica should not be reported. In asymptomatic persons, a positive serologic test does not necessarily indicate extraintestinal amebiasis.

Required Comments

Document the site of infection and relevant travel/deployment history (Note: the incubation period of amebiasis is commonly 2-4 weeks, with a range of a few days to several months or years).

Additional Considerations

None.

5.2 ANTHRAX

Clinical Description

References 1, 6, 7

An illness with acute onset characterized by several distinct clinical forms, including the following:

- **Cutaneous:** A skin lesion evolving during a period of 2-6 days from a papule (i.e., small solid elevation of skin 1mm – 1cm), through a vesicular stage (i.e., elevation of skin containing fluid), to a depressed black eschar (i.e., scab);
- **Inhalation:** A brief prodrome (i.e., early symptoms) resembling a viral respiratory illness, followed by development of hypoxia (i.e., deprivation of adequate oxygen to tissue) and dyspnea (i.e., shortness of breath), with radiographic evidence of mediastinal (i.e., vessels in the heart) widening;
- **Intestinal:** Severe abdominal distress followed by fever and signs of septicemia (i.e., whole-body inflammation and infection); or
- **Oropharyngeal:** Mucosal lesion in the oral cavity or oropharynx (i.e., area of throat behind mouth), cervical adenopathy (i.e., enlargement of lymph nodes in the neck), edema (i.e., swelling), and fever.

Laboratory Criteria for Diagnosis

Any of the following:

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

Case Classification

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

Probable: A clinically compatible illness that does not meet the confirmed case definition, but with one of the following:

- Epidemiological link to a documented anthrax environmental exposure;
- Evidence of *B. anthracis* DNA in clinical specimens collected from a normally sterile site (such as blood or CSF) or lesion of other affected tissue;
- Positive result on testing of clinical serum specimens using the Quick ELISA Anthrax-PA kit;
- Detection of Lethal Factor (LF) in clinical serum specimens by LF mass spectrometry; or
- Positive result on testing of culture from clinical specimens with the RedLine Alert test.

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Specify the clinical form of anthrax and include the patient's anthrax immunization history. Document the site and source of infection.

Additional Considerations

None.

5.3 BOTULISM

Clinical Description

References 1, 6, 7

Clostridium botulinum causes three major forms of illness characterized by the route of infection: food-borne, infantile, wound:

- **Foodborne:** Ingestion of botulinum toxin results in an illness of variable severity.
- **Infant:** An illness of infants, characterized by constipation, poor feeding, and “failure to thrive” that may be followed by progressive weakness, impaired respiration, and death.
- **Wound:** An illness resulting from toxin produced by *Clostridium botulinum* that has infected a wound.

Botulinum toxin exposure results in an illness of variable severity. Common symptoms are diplopia (i.e., double vision), blurred vision, and bulbar weakness (unilateral facial weakness). Symmetric paralysis may progress rapidly. In infants (<1 year of age), constipation, poor feeding, and “failure to thrive” may be followed by progressive weakness, impaired respiration, and death.

Laboratory Criteria for Diagnosis

Any of the following:

- Detection of *C. botulinum* toxin in serum, stool or patient's food, or
- Isolation of *C. botulinum* from stool or a wound.

Case Classification

Foodborne -Case

Probable: A clinically compatible case with an epidemiologic link (e.g., ingestion of a home-canned food within the previous 48 hours).

Confirmed:

- A clinically compatible case that is laboratory-confirmed, or
- A clinically compatible case that occurs among persons who ate the same food as persons who have laboratory-confirmed botulism.

Infant-Case

Confirmed: A clinically compatible case that is laboratory-confirmed, occurring in a child aged less than 1 year.

Wound-Case

Probable:

- A clinically compatible case in a patient who has no suspected exposure to contaminated food, and
- Who has either a history of a fresh, contaminated wound during the 2 weeks before onset of symptoms, or a history of injection drug use within the 2 weeks before onset of symptoms.

Confirmed:

- A clinically compatible case that is laboratory confirmed in a patient who has no suspected exposure to contaminated food, and
- Who has a history of a fresh, contaminated wound during the 2 weeks before onset of symptoms, or a history of injection drug use within the 2 weeks before onset of symptoms.

Other-Case

Confirmed: a clinically compatible case that is laboratory-confirmed in a patient aged greater than or equal to 1 year who has no history of ingestion of suspect food and has no wounds.

Required Comments

Specify the clinical form of botulism. Indicate whether case is probable or confirmed. Document the source of infection if known.

Additional Considerations

None.

5.4 BRUCELLOSIS

Clinical Description

References 1, 6, 7

An illness characterized by acute or insidious onset of fever, night sweats, undue fatigue, anorexia, weight loss, headache, arthralgia (joint pain) and myalgia (muscle aches).

Laboratory Criteria for Diagnosis

Any of the following:

Definitive

- Isolation of *Brucella* spp. from a clinical specimen;
- Fourfold or greater rise in *Brucella* agglutination titer between acute and convalescent serum specimens obtained ≥ 2 weeks apart and studied at the same laboratory; or
- Demonstration by immunofluorescence of *Brucella* sp. in a clinical specimen.

Presumptive

- Brucella total antibody titer of greater than or equal to 160 by standard tube agglutination test (SAT) or Brucella microagglutination test (BMAT) in one or more serum specimens obtained after onset of symptoms, or
- Detection of Brucella DNA in a clinical specimen by polymerase chain reaction (PCR) assay.

Case Classification

Probable: A clinically compatible case that is epidemiologically linked to a confirmed case or that has supportive serology (i.e., *Brucella* agglutination titer of ≥ 160 in one or more serum specimens obtained after onset of symptoms).

Confirmed: A clinically compatible illness with definitive laboratory evidence of Brucella infection.

Required Comments

Indicate whether case is probable or confirmed. Document relevant travel/deployment history (Note: the incubation period of brucellosis is usually 5-60 days, with a range of 1-2 months to several months).

Additional Considerations

Document the source of infection and potential occupational exposure (e.g., veterinarian, lab worker, etc.).

5.5 CAMPYLOBACTER INFECTION

Clinical Description

References 5, 9

Predominant symptoms of *Campylobacter* infections include diarrhea, abdominal pain, malaise (i.e. general discomfort or uneasiness), and fever. Stools may contain visible or occult (i.e. not visible) blood. Mild infection last 1 or 2 days and resembles viral gastroenteritis (e.g., nausea, vomiting, diarrhea, fever, loss of appetite).

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of *Campylobacter jejuni* from any clinical specimen, or
- EIA for antigen in stool.

Case Classification

Probable: A clinically compatible case that is epidemiologically linked to a confirmed case.

Confirmed: A case that is laboratory confirmed.

Required Comments

None.

Additional Considerations

Document the source of infection, if known, and whether case is part of an outbreak.

5.6 CHLAMYDIA TRACHOMATIS, GENITAL INFECTIONS

Clinical Description

Reference 1

Infection with *Chlamydia trachomatis* may result in urethritis (i.e., inflammation of the urethra), epididymitis (i.e., inflammation at the back of testicle), cervicitis (i.e., inflammation of the narrow, lower portion of uterus), acute salpingitis (i.e., inflammation and infection in the fallopian tubes), or other syndromes when sexually transmitted. However, the infection is often asymptomatic in women. Perinatal (i.e., immediately before and after birth) infections may result in inclusion conjunctivitis and pneumonia in newborns. Other syndromes caused by *C. trachomatis* include lymphogranuloma venereum (i.e., bacterial infection of lymph nodes) and trachoma (i.e., infectious eye disease).

Laboratory Criteria for Diagnosis

Any of the following:

- 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.

Required Comments

None.

Additional Considerations

None.

5.7 CHOLERA

Clinical Description

Reference 1

An illness characterized by diarrhea and/or vomiting; severity is variable.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of toxigenic (i.e., cholera toxin-producing) *Vibrio cholerae* O1;
- O139 from stool or vomitus;
- Serologic evidence of recent infection.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Note: Illnesses caused by strains of V. cholerae other than toxigenic V. cholerae O1 or O139 should not be reported as cases of cholera. Only confirmed cases should be reported.

Required Comments

Document relevant travel/deployment history (Note: the incubation period of cholera is usually 2-3 days, with a range of a few hours to 5 days) outside the U.S. Also, document the etiologic agent of the case (either *V. cholerae* O1 or *V. cholerae* O139).

Additional Considerations

Cholera cases may be internationally reportable per International Health Regulations.

5.8 COCCIDIOIDOMYCOSIS

Clinical Description

Reference 1

Infection may be asymptomatic or may produce an acute or chronic disease. Although the disease initially resembles an influenza-like or pneumonia-like febrile illness primarily involving the bronchopulmonary system, dissemination can occur to multiple organ systems.

Clinical Case Definition

One or more of the following:

- Influenza-like signs and symptoms (e.g., fever, chest pain, cough, myalgia [i.e., muscle pain], arthralgia [i.e., joint pain], and headache);
- Pneumonia or other pulmonary lesion, diagnosed by chest radiograph;
- Erythema nodosum (i.e., red bumps) or erythema multiforme rash (i.e., mild to severe self-limited rash);
- Involvement of bones, joints, or skin by dissemination;
- Meningitis; or
- Involvement of viscera (i.e., internal organs) and lymph nodes.

Laboratory Criteria for Diagnosis

Any of the following:

- Cultural, histopathologic, or molecular evidence of presence of *Coccidioides* species;
- Coccidioidal skin-test conversion from negative to positive after onset of clinical signs and symptoms; or
- Positive serologic test for coccidioidal antibodies in serum or cerebrospinal fluid, or other body fluids by any of the following:
 - Detection of coccidioidal immunoglobulin M (IgM) by immunodiffusion, enzyme immunoassay (EIA), latex agglutination, or tube precipitin, or
 - Detection of coccidioidal immunoglobulin G (IgG) by immunodiffusion, EIA, or complement fixation.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Document the source of infection.

Additional Considerations

None.

5.9 COLD WEATHER INJURIES

INCLUDES: Service Member cases only.

Note: Multiple types of cold weather injuries may occur to the same individual. Enter the report for the most severe injury (Hypothermia> Frostbite>Immersion) and specify additional injuries in the comment field.

Clinical Description

Reference 10

- **Hypothermia:** Reduction of body temperature to below 95°F. It can result from either dry-land whole body exposure or immersion in cold water. Freezing temperatures are not required to produce hypothermia.
- **Freezing Peripheral Injuries:** Freezing injuries (e.g. frostbite) only occur due to exposure to temperatures below freezing. They result from the freezing of tissue fluids in the skin and/or subcutaneous tissues.
- **Non-Freezing Peripheral Injuries:** Localized non-freezing injuries, usually of extremities (e.g., trench foot, immersion foot) occur due to prolonged vasoconstriction in response to cold that leads to tissue injury and destruction. These injuries develop over a period of hours to days. They may occur at temperatures below or above freezing and can occur at temperatures as high as 60°F with prolonged exposure. Injury is accelerated by exposure to damp conditions. (Note: The term “trench foot” is also sometimes used to describe a tropical foot injury or “jungle rot.”)

Clinical Case Definition

- **Hypothermia:** Reduction of core body temperature to 95°F or lower. Temperature should have been measured by rectal, esophageal, or other central method.
- **Frostbite:** A localized freezing injury that typically occurs in a relatively rapid fashion and occurred due to exposure to temperatures below freezing. Although it has often been classified as 1-4th degree injury, final classification often takes weeks and is not helpful for immediate treatment. More recently it has been classified as superficial and deep. Do not delay reporting to determine classification.
 - **Superficial:** Partial or full thickness freezing of the epidermis without involvement of the underlying tissue. Mobility is unaffected, and blistering may occur.
 - **Deep:** Full thickness freezing of the epidermis accompanied by freezing of subcutaneous tissue and which may involve muscles, tendons, and bones as severity increases.
- **Immersion / Trench Foot:** Non-freezing injury of a localized area, typically the foot or hand.

Laboratory Criteria for Diagnosis

Cold injuries are diagnosed clinically.

Case Classification

Confirmed: A clinically compatible case with an appropriate history of cold exposure.

Required Comments

Note if injury was duty related.

Additional Considerations

Document the type(s) of injury(s), core body temperature and method measured (for hypothermia), classification of frostbite, anatomic location of injury(s) and environmental and other circumstances that contributed to occurrence.

5.10 CRYPTOSPORIDIOSIS

Clinical Description

Reference 1

An illness caused by the protozoan *Cryptosporidium parvum* and characterized by diarrhea, abdominal cramps, loss of appetite, low-grade fever, nausea, and vomiting. Infected persons may be asymptomatic. The disease can be prolonged and life-threatening in severely immunocompromised persons.

Laboratory Criteria for Diagnosis

Probable: The detection of *Cryptosporidium* antigen by immunodiagnostic methods.

Confirmed: Any of the following

- *Cryptosporidium* oocysts in stool by microscopic examination;
- or *Cryptosporidium* in intestinal fluid or small-bowel biopsy specimens;
- *Cryptosporidium* oocyst or sporozite antigens by immunodiagnostic methods, (e.g., ELISA);
- *Cryptosporidium* by polymerase chain reaction (PCR) techniques; or
- *Cryptosporidium* demonstration of reproductive stages in tissue preparations.

Case Classification

Probable: A case that meets the clinical description and has probable criteria for laboratory diagnosis or that is epidemiologically linked to a confirmed case.

Confirmed: A case that meets the clinical description and the respective criteria for laboratory-confirmation as described above.

Required Comments

None.

Additional Considerations

Test results known to be obtained with commercially-available immunochromatographic card tests are limited to meeting "probable" case criteria due to a recent report of unacceptably high rates of false-positive results (Clin Infect Dis. 2010 Apr 15;50(8):e53-55).

5.11 CYCLOSPORA INFECTION

Clinical Description

Reference 1

An illness of variable severity caused by the protozoan *Cyclospora cayetanensis* and commonly characterized by watery diarrhea, loss of appetite, weight loss, abdominal bloating and cramping, increased flatus, nausea, fatigue, and low-grade fever. Vomiting also may be noted. Relapses and asymptomatic infections can occur.

Note: Direct person-to-person transmission is unlikely because Cyclospora oocysts are not infectious at the time of excretion.

Laboratory Criteria for Diagnosis

Any of the following:

- *Cyclospora* oocysts in stool by microscopic examination;
- *Cyclospora* in intestinal fluid or small bowel biopsy specimens;
- *Cyclospora* demonstration of sporulation; or
- *Cyclospora* DNA (polymerase chain reaction (PCR)) in stool, duodenal/jejunal aspirates or small bowel biopsy specimens.

Case Classification

Probable: A case that meets the clinical description and that is epidemiologically linked to a confirmed case.

Confirmed: A case that meets the clinical description and at least one of the criteria for laboratory confirmation as described above.

Required Comments

None.

Additional Considerations

Document the source of infection and whether the case is part of an outbreak.

5.12 DENGUE FEVER

Clinical Description

References 5, 8, 9

An acute febrile illness of 2-7 days duration with two or more of the following: headache, retro-orbital (i.e., behind the eye) pain, myalgia (i.e., muscle aches), arthralgia (i.e., joint pain) rash, hemorrhagic manifestations, leucopenia (i.e., low white blood cell count). The principal vector is the *Aedes aegypti* mosquito and transmission usually occurs in tropical or subtropical areas. Severe manifestations (e.g., dengue hemorrhagic fever or dengue shock syndrome) are rare, but may be fatal.

Clinical Case Definition

1. Dengue Hemorrhagic Fever (DHF): A probable or confirmed case of dengue with hemorrhagic tendencies evidenced by one or more of the following:
 - Positive tourniquet test;
 - Petechiae (i.e., reddish or purplish spot containing blood as a result of localized hemorrhage), ecchymoses (i.e., escape of blood into the tissues from ruptured blood vessels), or purpura (i.e., patches of purplish discoloration as a result of blood escaping into the skin and mucous);
 - Bleeding from mucosa, gastrointestinal tract, injection sites or other sites;
 - Hematemesis (i.e., vomiting blood), melena (i.e., black, tar-like stool), and thrombocytopenia (100,000 cells per mm³ or less) plus evidence of plasma leakage due to increased vascular permeability manifested by one or more one of the following:
 - A $\geq 20\%$ rise in average hematocrit for age and sex;
 - A $\geq 20\%$ drop in hematocrit following volume replacement treatment compared to baseline; or
 - Signs of plasma leakage [i.e., pleural effusion (e.g. shortness of breath, chest pain, gastric discomfort), ascites (i.e., accumulation of fluid in the abdomen), and hypoproteinemia (i.e., low levels of protein in the blood)].
2. Dengue Shock Syndrome (DSS): All the above criteria for DHF plus evidence of circulatory failure manifested by either:
 - Rapid and weak pulse with narrow pulse pressure (≤ 20 mm Hg), or
 - Hypotension for age, cold, clammy skin and altered mental status.

Laboratory Criteria for Diagnosis

Confirmatory

Any of the following:

- Isolation of dengue virus from or demonstration of specific arboviral antigen or genomic sequences in tissue, blood, cerebrospinal fluid (CSF), or other body fluid by polymerase chain reaction (PCR) test, immunofluorescence or immunohistochemistry;
- Seroconversion from negative for dengue virus-specific serum Immunoglobulin M (IgM) antibody in an acute phase (≤ 5 days after symptom onset) specimen to positive for dengue-specific serum IgM antibodies in a convalescent-phase specimen collected ≥ 5 days after symptom onset;
- Demonstration of a ≥ 4 -fold rise in reciprocal Immunoglobulin G (IgG) antibody titer or Hemagglutination inhibition titer to dengue virus antigens in paired acute and convalescent serum samples;
- Demonstration of a ≥ 4 -fold rise in PRNT (plaque reduction neutralization test) end point titer (as expressed by the reciprocal of the last serum dilution showing a 90% reduction in plaque counts compared to the virus infected control) between dengue viruses and other flaviviruses tested in a convalescent serum sample; or
- Virus-specific immunoglobulin M (IgM) antibodies demonstrated in CSF.

Presumptive/Probable

- Dengue-specific IgM antibodies present in serum with a P/N ratio ≥ 2 .

Case Classification

Suspected: A clinically compatible case of DF, DHF or DSS that is epidemiologically linked to a confirmed case.

Probable: A case compatible with the clinical description with one or more of the following:

- A reciprocal IgG antibody titer ≥ 1280 , or
- A positive IgM antibody test on a single acute (late) serum or convalescent serum to one or more dengue virus antigens.

Confirmed: A clinically compatible case of DF, DHF, or DSS with confirmatory laboratory results.

Required Comments

Indicate whether case is probable or confirmed, whether the case is complicated by DHF or DSS, relevant travel/deployment history, and the dengue serotype (if known). (Note: the incubation period of dengue fever is commonly 4-7 days, with a range of 3-14 days)

Asymptomatic Blood or Tissue Donor: Indicate whether patient has received or donated blood or tissue recently.

Dengue virus: specific viral antigen or genomic sequences demonstrated in donated blood or organs during screening and confirmatory testing in the absence of symptoms in the donor.

Additional Considerations

None.

5.13 DIPHTHERIA

Clinical Description

Reference 1

An upper respiratory tract illness characterized by sore throat, low-grade fever, and an adherent membrane of the tonsil(s), pharynx, and/or nose.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of *Corynebacterium diphtheriae* from a clinical specimen, or
- Histopathologic diagnosis of diphtheria.

Case Classification

Probable:

In the absence of a more likely diagnosis, an upper respiratory tract illness with

- An adherent membrane of the nose, pharynx, tonsils, or larynx;
- Absence of laboratory confirmation; and
- Lack of epidemiologic linkage to a laboratory-confirmed case of diphtheria.

Confirmed:

- A clinically compatible case that is either laboratory-confirmed, or
- A clinically compatible case that is epidemiologically linked to a laboratory-confirmed case.

Note: Respiratory disease caused by nontoxigenic C. diphtheriae should be reported as diphtheria. Cutaneous diphtheria should not be reported.

Required Comments

Include the patient's diphtheria immunization history. Specify the patient's age in months if < 1 year, source of infection, and document relevant travel/deployment history (Note: the incubation period of diphtheria is usually 2-5 days).

Additional Considerations

None.

5.14 *E. COLI, SHIGA TOXIN-PRODUCING (INCLUDES O157:H7)*

Clinical Description

Reference 1

An infection of variable severity characterized by diarrhea (often bloody) and abdominal cramps. The illness may be complicated by hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Asymptomatic infections may also occur.

Hemolytic uremic syndrome (HUS) is characterized by the acute onset of microangiopathic hemolytic anemia, renal (i.e., kidney) injury, and low platelet count. Thrombotic thrombocytopenic purpura (TTP) also is characterized by these features but can include central nervous system (CNS) involvement and fever and may have a more gradual onset. Most cases of HUS (but few cases of TTP) occur after an acute gastrointestinal illness (usually diarrheal).

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of *Escherichia coli* O157:H7 from a clinical specimen (*Escherichia coli* O157:H7 isolates may be assumed to be Shiga toxin-producing), or
- Isolation of other *E. coli* from a clinical specimen with demonstration of toxin production or the presence of Shiga toxin genes.

Note: Strains of E. coli O157:H7 designated "NM" have lost the flagella "H" antigen and become nonmotile.

Case Classification

Suspected: A case of postdiarrheal HUS or TTP (see HUS case definition), or identification of Shiga toxin in a specimen from a clinically compatible case without the isolation of the Shiga toxin-producing *E. coli*.

Probable:

- A case with isolation of *E. coli* O157 from a clinical specimen, without confirmation of H antigen or Shiga toxin production;
- A clinically compatible case that is epidemiologically linked to a confirmed or probable case; or
- Identification of an elevated antibody titer to a known Shiga toxin-producing *E. coli* serotype from a clinically compatible case.

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

When available, O and H antigen serotype characterization should be reported.

Additional Considerations

Document the source of infection and whether the case is part of an outbreak.

Both asymptomatic infections and infections at sites other than the gastrointestinal tract, if laboratory confirmed, are considered confirmed cases that should be reported.

5.15 EHRLICHIOSIS / ANAPLASMOSIS

Clinical Description

Reference 1

A tick-borne illness characterized by acute onset of fever and one or more of the following symptoms or signs: headache, myalgia (i.e., muscle pain), malaise (i.e., general discomfort or uneasiness), anemia, leucopenia (i.e., low white blood cell count), thrombocytopenia (i.e., decrease in the number of blood platelets often associated with hemorrhagic conditions), or elevated hepatic transaminases (i.e., possible indicator of liver damage). Nausea, vomiting, or rash may be present in some cases. Intracytoplasmic bacterial aggregates (morulae) may be visible in the leukocytes (i.e., white blood cells) of some patients.

Laboratory Criteria for Diagnosis

1. *Ehrlichia chaffeensis* infection (formerly included in the category Human Monocytic Ehrlichiosis [HME]):

Supportive: (Any of the following)

- Serological evidence of elevated IgG or IgM antibody reactive with *E. chaffeensis* antigen by IFA, enzyme-linked immunosorbent assay (ELISA), dot-ELISA, or assays in other formats (CDC uses an IFA IgG cutoff of $\geq 1:64$ and does not use IgM test results independently as diagnostic support criteria.), or
- Identification of morulae in the cytoplasm of monocytes or macrophages by microscopic examination.

Confirmed: (Any of the following)

- Serological evidence of a fourfold change in immunoglobulin G (IgG)-specific antibody titer to *E. chaffeensis* antigen by indirect immunofluorescence assay (IFA) between paired serum samples (one taken in first week of illness and a second 2-4 weeks later);
- Detection of *E. chaffeensis* DNA in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay;
- Demonstration of ehrlichial antigen in a biopsy or autopsy sample by immunohistochemical methods; or
- Isolation of *E. chaffeensis* from a clinical specimen in cell culture.

2. *Ehrlichia ewingii* infection (formerly included in the category Ehrlichiosis [unspecified or other agent]):

- Because the organism has never been cultured, antigens are not available. Thus, *Ehrlichia ewingii* infections may only be diagnosed by molecular detection methods: *E. ewingii* DNA detected in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay.

3. *Anaplasma phagocytophilum* infection (formerly included in the category Human Granulocytic Ehrlichiosis [HGE]):

Supportive: Any of the following

- Serological evidence of elevated IgG or IgM antibody reactive with *A. phagocytophilum* antigen by IFA, enzyme-linked immunosorbent Assay (ELISA), dot-ELISA, or assays in other formats (CDC uses an IFA IgG cutoff of $\geq 1:64$ and does not use IgM test results independently as diagnostic support criteria.), or
- Identification of morulae in the cytoplasm of neutrophils or eosinophils by microscopic examination.

Confirmed: Any of the following:

- Serological evidence of a fourfold change in IgG-specific antibody titer to *A. phagocytophilum* antigen by indirect immunofluorescence assay (IFA) in paired serum samples (one taken in first week of illness and a second 2-4 weeks later);
- Detection of *A. phagocytophilum* DNA in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay;
- Demonstration of anaplasma antigen in a biopsy/autopsy sample by immunohistochemical methods; or
- Isolation of *A. phagocytophilum* from a clinical specimen in cell culture.

Case Classification

Suspected: A case with laboratory evidence of past or present infection but no clinical information available (e.g. a laboratory report).

Probable: A clinically compatible case (meets clinical evidence criteria) that has supportive laboratory results. For ehrlichiosis/anaplasmosis – an undetermined case can only be classified as probable. This occurs when a case has compatible clinical criteria with laboratory evidence to support Ehrlichia/Anaplasma infection, but not with sufficient clarity to definitively place it in one of the categories previously described. This may include the identification of morulae in white cells by microscopic examination in the absence of other supportive laboratory results.

Confirmed: A clinically compatible case (meets clinical evidence criteria) that is laboratory confirmed.

Required Comments

Document relevant travel/deployment history, particularly noting the geographic location of the patient when known tick bites occurred and/or of recent field exercises. (Note: the incubation period of ehrlichiosis/anaplasmosis ranges from 7 to 14 days)

Additional Considerations

None.

5.16 ENCEPHALITIS, ARBOVIRAL

INCLUDES: Mosquito-borne encephalitis (Western Equine encephalitis, Eastern Equine encephalitis, St. Louis encephalitis, California virus encephalitis), Tick-borne encephalitis, West Nile Virus, Chikungunya, Japanese encephalitis and others.

EXCLUDES: Bacterial Meningoencephalitis (*Haemophilus influenzae* type b, *Neisseria meningitidis*, and *Streptococcus pneumoniae* bacteria), RMSF, Rift Valley Fever, Rabies, are all reported separately.

Clinical Description

References 5 – 7

Encephalitis is a broad category of central nervous system infections. Symptoms can include headache, confusion or other alteration in sensorium, nausea, and vomiting. Signs may include fever, meningismus (e.g., neck stiffness, intolerance of bright light, headache), cranial nerve palsies (involving the muscles of the face), paresis or paralysis, sensory deficits, altered reflexes, convulsions, abnormal movements, or coma of varying degree.

Arboviral infections may result in a febrile illness of variable severity associated with neurologic symptoms ranging from headache to aseptic meningitis (e.g. inflammation of protective membranes covering the brain and spinal cord not due to bacterial infection) or encephalitis. The seasonality of arboviral transmission is variable and depends on the geographic location of exposure, the specific cycles of viral transmission, and local climatic conditions.

Laboratory Criteria for Diagnosis

Any of the following:

- Fourfold or greater change in virus-specific serum antibody titer;
- Isolation of virus from, or demonstration of viral antigen or genomic sequences in, tissue, blood, cerebrospinal fluid (CSF), or other body fluid;
- Virus-specific immunoglobulin M (IgM) antibodies demonstrated in CSF by antibody-capture enzyme immunoassay (EIA); or
- Virus-specific IgM antibodies demonstrated in serum by antibody-capture EIA and confirmed by demonstration of virus-specific serum immunoglobulin G (IgG) antibodies in the same or a later specimen by another serologic assay (e.g., neutralization or hemagglutination inhibition).

Case Classification

Probable: Viral transmission is likely, with the following supportive serology: a stable (\leq twofold change) elevated antibody titer to an arbovirus (e.g., ≥ 320 by hemagglutination inhibition, ≥ 128 by complement fixation, ≥ 256 by immunofluorescence, ≥ 160 by neutralization, or ≥ 400 by enzyme immunoassay IgM).

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Specify the etiologic agent of encephalitis (e.g., Tick-borne Encephalitis [TBE], Japanese Encephalitis [JE]) and include the patient's encephalitis immunization history. Indicate whether case is probable or confirmed. Document relevant travel/deployment (Note: the incubation period of encephalitis, arboviral is usually 5-15 days) and exposure histories (e.g., field exercises).

Additional Considerations

None.

5.17 FILARIASIS

INCLUDES: Onchocerciasis and Loa-loa.

Clinical Description

Reference 11

Filarial infections are an insect-borne group of diseases, including those caused by the organisms *Wuchereria bancrofti*, *Brugia malayi*, *Loa-loa* and *Onchocerca volvulus*.

- Infections caused by *Wuchereria* and *Brugia*: Classical filariasis; caused by lymphatic-dwelling filariae transmitted by mosquitoes. Acute clinical symptoms may include recurrent fevers, lymphadenitis (i.e., infection of lymph nodes) and retrograde lymphangitis, or tropical pulmonary eosinophilia syndrome [characterized by nocturnal “asthma”, low-grade fever, and eosinophilia (i.e., high amount of eosinophils, type of white blood cells, in blood)].
- *Loa-loa* and *Onchocerciasis*: Transmitted by flies. *Loa-loa* is characterized by transient swellings and pruritis (i.e., generalized itch), often with eosinophilia. *Onchocerciasis* causes fibrous subcutaneous nodules (i.e., small, solid masses beneath the skin that can be felt by touch), pruritis, pigmentation changes, and blindness in severe infections.

Laboratory Criteria for Diagnosis

Microfilaria-positive, antigen-positive or biopsy-positive clinical specimen.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Specify the etiologic agent of filariasis and document relevant travel/deployment history (Note: the incubation period of filariasis ranges from 3-12 months).

Additional Considerations

None.

5.18 GIARDIASIS

Clinical Description

Reference 1

An illness caused by the protozoan *Giardia lamblia* and characterized by diarrhea, abdominal cramps, bloating, weight loss, or malabsorption. Infected persons may be asymptomatic.

Laboratory Criteria for Diagnosis

Any of the following:

- *G. lamblia* cysts in stool;
- *G. lamblia* DNA in stool;
- *G. lamblia* trophozoites in stool, duodenal fluid, or small-bowel biopsy; or
- *G. lamblia* antigen in stool by a specific immunodiagnostic test (e.g., ELISA).

Case Classification

Probable: A case that meets the clinical description and that is epidemiologically linked to a confirmed case.

Confirmed: A case that meets the clinical description and the criteria for laboratory confirmation as described above.

Required Comments

None.

Additional Considerations

Document the source of infection (e.g. the patient's camping/travel history).

When available, molecular characterization (e.g., assemblage designation) should be reported.

5.19 GONORRHEA

Clinical Description

Reference 1

A sexually transmitted infection commonly manifested by urethritis (i.e., inflammation of the urethra), cervicitis (i.e., inflammation of the narrow, lower portion of uterus), or salpingitis (i.e., inflammation and infection in the fallopian tubes). Infection may be asymptomatic, particularly in women.

Laboratory Criteria for Diagnosis

Any of the following:

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

Case Classification

Probable:

- Demonstration of gram-negative intracellular diplococci in an endocervical smear obtained from a female, or
- A written morbidity report of gonorrhea submitted by a physician.

Confirmed:

- A case that is laboratory confirmed Laboratory criteria for diagnosis.

Required Comments

None.

Additional Considerations

None.

5.20 HAEMOPHILUS INFLUENZAE, INVASIVE DISEASE

EXCLUDES: Conjunctivitis

Clinical Description

Reference 1

Invasive disease caused by *Haemophilus influenzae*. It may produce any of several clinical syndromes including meningitis, bacteremia (i.e., presence of bacteria in the blood), epiglottitis (i.e., inflammation of the cartilage that covers the trachea), or pneumonia. Invasive infection does NOT include conjunctivitis.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of *H. influenzae* from a normally sterile site (e.g., blood or cerebrospinal fluid [CSF]; or less commonly, from joint, pleural, or pericardial fluid);
- A positive result on an NHI and API/NH antigen tests (now considered adequately sensitive and specific to be used for diagnosis); or
- A positive result on a FDA-approved polymerase chain reaction (PCR)--based diagnostic test.

Case Classification

Probable: Meningitis with detection of *Haemophilus influenzae* type b antigen in cerebrospinal fluid (CSF).

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

None.

Additional Considerations

Document the clinical form of the infection. For children < 1 year of age, specify age in months. For all children, include the patient's Hib immunization history.

5.21 HANTAVIRUS DISEASE

INCLUDES: Hantavirus Pulmonary Syndrome, Korean Hemorrhagic Fever, and Hemorrhagic Fever with renal syndrome.

Clinical Description

References 1, 5

1. **Hantavirus pulmonary syndrome (HPS):** Commonly referred to as Hantavirus disease, HPS is a febrile illness characterized by bilateral interstitial pulmonary infiltrates and respiratory compromise usually requiring supplemental oxygen and clinically resembling acute respiratory distress syndrome (ARDS). The typical prodrome [early symptom(s)] consists of fever, chills, myalgia (i.e., muscle pain), headache, and gastrointestinal symptoms. Typical clinical laboratory findings include hemoconcentration, left shift in the white blood cell count, neutrophilic leukocytosis, thrombocytopenia (i.e., decrease in the number of blood platelets often associated with hemorrhagic conditions), and circulating immunoblasts.

2. **Hemorrhagic fever with renal syndrome (HFRS), includes Korean hemorrhagic fever):** Characterized by acute onset of fever, lower back pain, hemorrhagic manifestations, and renal (i.e., kidney) involvement. The disease has five clinical phases: febrile, hypotensive, oliguric, diuretic, and convalescent.

Clinical Case Definition

1. **HPS:** One or more of the following:

- A febrile illness (i.e., temperature > 101.0°F) characterized by bilateral diffuse interstitial edema that may radiographically resemble ARDS with respiratory compromise requiring supplemental oxygen, all developing within 72 hours of hospitalization and occurring in a previously healthy person.
- An unexplained respiratory illness resulting in death, with an autopsy examination demonstrating noncardiogenic pulmonary edema without an identifiable cause.

Since the clinical illness is nonspecific and ARDS is common, a useful screening guideline is that in general, a predisposing medical condition (e.g., chronic pulmonary disease, malignancy, trauma, burns, or surgery) is more likely to cause ARDS than HPS. Patients who have such underlying conditions and ARDS need not be tested for hantavirus.

2. **HFRS:**

- A febrile illness characterized by variable hemorrhagic symptoms, shock, proteinuria, leukocytosis, hemoconcentration, thrombocytopenia (i.e., decrease in the number of blood platelets often associated with hemorrhagic conditions) and an elevated blood urea nitrogen (BUN).

Laboratory Criteria for Diagnosis

Any of the following:

- Detection of hantavirus-specific IgM or rising titers of hantavirus-specific IgG;
- Detection of hantavirus-specific RNA sequence by polymerase chain reaction (PCR) in clinical specimens; or
- Detection of hantavirus antigen by immunohistochemistry.

Note: Laboratory testing should be performed or confirmed at a reference laboratory.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Specify the form of hantavirus disease (pulmonary or hemorrhagic/ renal) and document relevant travel/deployment history (Note: the incubation period of hantavirus is usually 2-4 weeks, with a range of a few days to 2 months), including field exercises and outdoor activity.

Additional Considerations

None.

5.22 HEAT ILLNESS

INCLUDES: Service Member cases only

EXCLUDES: Cases of simple parade syncope (heat syncope), heat edema, heat cramps, miliaria rubra, sunburn, transient heat fatigue and isolated rhabdomyolysis (i.e, without evidence for or diagnosis of a reportable heat illness). Cases of heat exhaustion in the absence of medical intervention or change in duty status are also excluded.

Clinical Description

References 12, 13

General. Heat illness represents a continuum in severity, and includes heat exhaustion (HE), heat injury (HI), and heat stroke (HS). HE and HI are difficult to distinguish based on symptoms alone, but lab abnormalities may be present in HI. Heat stroke should be the working diagnosis for any service member with profound altered mental status and exposure history consistent with heat illness.

a. Heat exhaustion (HE) is defined as a syndrome of elevated core body temperature (though temperature may be in the normal range at presentation for care, especially if oral) with physical collapse or debilitation occurring during or immediately following exertion, with no more than minor central nervous system (CNS) symptoms (such as headache, dizziness). HE resolves rapidly with minimal cooling intervention.

b. Heat injury (HI) is defined as HE with clinical evidence of organ (for example, liver, renal, stomach) and/or muscle (for example, rhabdomyolysis) damage but lacking neurological signs or symptoms characteristic of heat stroke.

c. Heat stroke (HS) is defined as a seriously elevated temperature (>104° F or 40° C) that causes CNS injury. Clinically, HS presents as hyperthermia, physical collapse or debilitation, and encephalopathy as evidenced by delirium, stupor, or coma, occurring during or immediately following exertion or significant heat exposure. HS may be complicated by organ and/or tissue damage, systemic inflammatory activation, and disseminated intravascular coagulation.

Laboratory Criteria for Diagnosis

Although laboratory abnormalities may be present in heat injury, heat illness does not require laboratory confirmation.

Case Classification

Confirmed: A clinically compatible case. Report all cases diagnosed as heat exhaustion, heat injury or heat stroke and given a limited duty profile.

Required Comments

Identify if heat illness is heat exhaustion, heat injury or heat stroke.

Also, note the following information:

Duty related? Yes No

Precipitating activity: _____

Weather or Wet Bulb Globe Temperature (WBGT, if known): _____

Max core temperature: _____

Method of core temperature measurement: Rectal Oral Ear

Estimated time between removal from heat exposure and measurement of core temperature: ____ hours.

Worst observed mental status: Alert and Oriented Confused Obtunded Unresponsive

Check all clinical features present with this heat injury (CHECK BOXES, refer to your local CHCS lab reference ranges to determine elevated markers)

Tachycardia Narrowed Pulse Pressure Hemoconcentration

- | | | |
|--|--|--|
| <input type="checkbox"/> Hyponatremia | <input type="checkbox"/> Hypernatremia | <input type="checkbox"/> Impaired Renal Function |
| <input type="checkbox"/> Coagulopathy | <input type="checkbox"/> Myoglobinuria | <input type="checkbox"/> Elevated Muscle CPK |
| <input type="checkbox"/> Elevated Liver Associated Enzymes | | <input type="checkbox"/> Shock |
| <input type="checkbox"/> Pulmonary Edema | | |

Was patient hospitalized? Yes No

Additional Considerations

Note if patient recently used medications and/or supplement use.

5.23 HEMORRHAGIC FEVER

INCLUDES: Arenaviral hemorrhagic fevers of South America (Junin, Machupo, Guanarito, Sabia hemorrhagic fevers), Arthropod-borne viral hemorrhagic fevers (e.g., Crimean Congo fever), Omsk Hemorrhagic Fever (OHF), Kyasanur Forest Disease (KFD), Lassa fever, Luja and Ebola-Marburg viral diseases.

EXCLUDES: Dengue Hemorrhagic Fever (report under Dengue), Korean Hemorrhagic Fever (report under Hantavirus), Hemorrhagic Fever with Renal Syndrome (report under Hantavirus), Chikungunya (report under Encephalitis, Arbovittae), and Yellow Fever.

Clinical Description

References 6, 7, 11

Hemorrhagic fever is a broad category of viral diseases that present with varying degrees of fever, headache, malaise (i.e. general discomfort or uneasiness), and often a hemorrhagic crisis. The diseases are usually zoonotic, with transmission via an arthropod bite or aerosolization of virus from infected rodent excreta.

Laboratory Criteria for Diagnosis

Suspected for Epidemiologic Linkage Criteria: (One or more of the following exposures within the 3 weeks before onset of symptoms)

- Contact with blood or other body fluids of a patient with VHF;
- Residence in—or travel to—a VHF endemic area;
- Work in a laboratory that handles VHF specimens;
- Work in a laboratory that handles bats, rodents, or primates from endemic areas; or
- Exposure to semen from a confirmed acute or convalescent case of VHF within the 10 weeks of that person's onset of symptoms

Laboratory confirmed: (any of the following)

- Detection of VHF viral antigens in blood by enzyme-linked Immunosorbent Assay (ELISA) antigen detection;
- VHF viral isolation in cell culture for blood or tissues ;
- Detection of VHF-specific genetic sequence by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) from blood or tissues; or
- Detection of VHF viral antigens in tissues by immunohistochemistry

Case Classification

Suspected: A clinically compatible case that meets the epidemiologic linkage criteria.

Confirmed: A clinically compatible case that meets the confirmatory laboratory criteria.

Required Comments

Specify the etiologic disease agent, indicate whether case is suspected or confirmed, and document relevant travel/deployment history (Note: the incubation period of hemorrhagic fever ranges from 2-17 days).

Additional Considerations

Document the source of infection. Hemorrhagic fever cases may be internationally reportable per International Health Regulations.

5.24 HEPATITIS A

Clinical Description

Reference 1

A viral disease with abrupt onset of fever, malaise (i.e. general discomfort or uneasiness), anorexia, nausea and abdominal discomfort, followed within a few days by jaundice and/or elevation of serum aminotransferase levels (AST/ALT). Severity ranges from asymptomatic to severe, generally increasing with patient age.

Laboratory Criteria for Diagnosis

Any of the following:

- IgM antibody to hepatitis A virus (anti-HAV) positive, or
- Fourfold or greater rise in antibody titer in paired sera.

Case Classification

Confirmed:

- A clinically compatible case that is laboratory-confirmed;
- A clinically compatible case that occurs in a person who has an epidemiologic link to a person who has laboratory-confirmed hepatitis A (i.e., household or sexual contact with an infected person during the 15-50 days before the onset of symptoms).

Required Comments

Include the patient's hepatitis A immunization history.

Additional Considerations

Document whether patient is food handler, a day care provider, or is an employee at a long term care facility. Also document relevant travel/deployment history (Note: the incubation period of hepatitis A is usually 28-30 days, with a range of 15-50 days).

5.25 HEPATITIS B, ACUTE & CHRONIC

Clinical Description

Reference 1, 15

Hepatitis B is a viral infection of the liver and has two possible phases: acute and chronic. The acute phase, if not resolved, will proceed to chronic illness. After acute HBV infection, the risk of developing chronic infection varies inversely with age. Chronic infection occurs among 90% of infants infected at birth, 20%-50% of children infected from 1-5 years old and 1%-10% of persons infected as older children and adults. Individuals may present in either phase with clinical illness or may be asymptomatic. In those with clinical illness, the onset is usually insidious with anorexia, vague abdominal discomfort, nausea and vomiting, sometimes arthralgias and rash, often progressing to jaundice. Fever may be absent or mild. Severity ranges from unapparent cases detectable only by liver function tests to fulminating, fatal cases of acute hepatic necrosis.

Clinical Case Definition

1. **Acute illness:** This refers to newly acquired infections. Affected individuals may notice symptoms in 1 to 4 months after exposure to the virus. Most people with acute hepatitis will have resolution of illness in a few weeks to months and will then be cured of disease and immune to HBV. However, only a small proportion of acute hepatitis B infections may be clinically recognized. If the infection does not resolve, it will then proceed to chronic hepatitis B.
2. **Chronic illness:** Occurs if acute illness does not resolve. Resolution is marked by the conversion of HBsAg to anti-HBs. The persistence of HBsAg for more than six months implies chronic infection. Persons with chronic HBV infection may have no evidence of liver disease or may have a spectrum of disease ranging from mild cirrhosis to liver failure or hepatocellular carcinoma.

Laboratory Criteria for Diagnosis

1. Acute Hepatitis B: (Any of the following)
 - IgM antibody to hepatitis B core antigen (IgM anti-HBc) positive, or
 - Hepatitis B surface antigen (HBsAg) positive AND chronic illness has been ruled out*
2. Chronic Hepatitis B: (Any of the following)
 - Negative for IgM antibodies to hepatitis B core antigen (IgM anti-HBc) AND a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg), or hepatitis B virus (HBV) DNA, or
 - HBsAg positive or HBV DNA positive or HBeAg positive two times at least 6 months apart (Any combination of these tests performed 6 months apart is acceptable).

**Persons who have chronic hepatitis or who are identified as HbsAg positive should not be reported as having acute viral hepatitis B unless chronic hepatitis B can be ruled out. Chronic hepatitis B can be ruled out by the presence of IgM anti-HBc*

Note: Positive anti-HBe is indicative of a resolving acute infection. Retesting should be completed in 6 months.

Case Classification

1. **Acute Hepatitis B:**
 - **Confirmed:** A clinically compatible case that is laboratory-confirmed and **is not known to have chronic hepatitis B.**
2. **Chronic Hepatitis B:**
 - **Confirmed:** A clinically compatible case that is laboratory-confirmed and **has no prior diagnosis of chronic hepatitis B.** Laboratory confirmation should have a serological pattern consistent with chronic HBV. History of acute HBV may be useful, but not absolutely necessary.

Required Comments

Include the patient's hepatitis B immunization history. Specify whether case is acute or chronic and if patient is showing signs and/or symptoms of hepatic disease.

Additional Considerations

Document potential occupational exposure (e.g., health care worker).

Note: Hepatitis B vaccine will produce a positive anti-HBs result on serology.

5.26 HEPATITIS C

Clinical Description

Reference 1

Hepatitis C is a viral infection of the liver and has two possible stages: acute and chronic. Most acutely affected individuals are asymptomatic, however, approximately 20-30% of individuals will experience non-specific symptoms, including poor appetite, nausea, fatigue, abdominal pain, or jaundice. Symptoms will be present approximately 6 weeks following exposure and illness typically lasts 2 – 12 weeks. Those who clear the infection will do so within 20 weeks. Acute hepatitis C progresses to chronic hepatitis C in approximately 80% of individuals. Most patients with chronic infection are asymptomatic, or have mild non-specific symptoms, including poor appetite, nausea, fatigue, muscle and/or joint pain, weakness, and weight loss. Chronic hepatitis C infection may, over time lead to the development of chronic liver disease, ranging from mild cirrhosis to liver failure or hepatocellular carcinoma.

Laboratory Criteria for Diagnosis

Any of the following:

- Anti-HCV positive by enzyme immunoassay (EIA) verified by at least one additional more specific assay (i.e. recombinant immunoblot assay);
- Anti-HCV screening test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay (e.g. ≥ 3.8 for EIA) and posted by CDC at: <http://www.cdc.gov/hepatitis/HCV/LabTesting.htm>;
- HCV recombinant immunoblot assay (RIBA) positive; or
- Nucleic Acid Test (NAT) positive for HCV RNA

Note: The acute and chronic stages of hepatitis C cannot be distinguished solely based on the results of laboratory studies performed at a single point in time.

Case Classification

Probable: A case that is anti-HCV positive by EIA and has alanine aminotransferase (ALT) values above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the signal to cut-off ratio is unknown.

Confirmed: A case that is laboratory-confirmed.

Required Comments

Document whether the patient is experiencing symptoms of liver disease (nausea, abdominal pain, fatigue, jaundice, etc.).

Additional Considerations

If the patient is suspected to have chronic hepatitis, verify the case has not been reported in the past, to prevent double reporting.

5.27 INFLUENZA-ASSOCIATED HOSPITALIZATION

Clinical Description

Reference 8

An acute viral disease of the respiratory tract characterized by fever, headache, myalgia (i.e., muscle pain), prostration (e.g., extreme exhaustion or lack of energy), rhinitis (e.g., inflammation of the lining the nose), sore throat, and cough requiring hospitalization.

Clinical Case Definition

An illness compatible with influenza virus infection (fever $\geq 100.5^{\circ}\text{F}$ accompanied by cough or sore throat in the absence of other diagnoses) in individuals < **65 years of age** that results in hospitalization.

AND

Laboratory test confirmation or positive rapid test result supporting influenza diagnosis obtained less than 4 days after hospital admission (to minimize the reporting of nosocomial [hospital acquired] rather than community acquired infections).

Comment

Hospitalization is defined as an admission to an inpatient ward of a hospital, or a medical transfer or evacuation to a facility with a higher level of care. Patients admitted for observation and discharged the same day are considered hospitalized for this case definition. An overnight stay is not required. Emergency room or outpatient clinic visits that do not result in hospital admission are not considered hospitalizations.

Laboratory Criteria for Diagnosis

Any of the following:

Probable:

- Commercial influenza diagnostic rapid antigen test (RAT) of respiratory specimens.

Confirmed:

- Detection of influenza-specific RNA by RT-PCR testing of respiratory specimens;
- Influenza virus isolation in tissue cell culture from respiratory specimens;
- Direct antigen detection by immunofluorescent antibody (IFA) staining (direct or indirect) of respiratory specimens;
- Antigen detection by immunohistochemical (IHC) staining for influenza viral antigens in respiratory tract or other tissue from biopsy or autopsy specimens; or
- Four-fold rise in influenza hemagglutination inhibition (HI) antibody titer in paired acute and convalescent sera.

Case Classification

Probable: A hospitalization for acute illness associated with a diagnosis of influenza with a positive result from a rapid antigen test (RAT). A confirmatory test should be ordered following a positive RAT.

Confirmed: A hospitalization for acute illness associated with a diagnosis of influenza and confirmed by an appropriate laboratory test as defined above.

Note: For all confirmed cases a nasal wash specimen should be submitted to an appropriate laboratory for further influenza laboratory testing (i.e., gene sequencing).

Required Comments

- Include the patient's influenza immunization for the current or most recent influenza season. Include date received and type of vaccine TIV (shot) or LAIV (nasal mist).
- Include virus type (A or B) and subtype (e.g., H1N1) if available.
- Include the type of lab test that was positive (PCR, culture, IFA, IHC tissue, HI titer, or RAT).

Additional Considerations

As resources are available, consider broadening testing to include other viral respiratory pathogens by ordering a complete respiratory panel.

5.28 LEGIONELLOSIS

Clinical Description

Reference 1

Legionellosis is associated with two clinically and epidemiologically distinct illnesses:

- *Legionnaires Disease*: Characterized by fever, myalgia, cough, and clinical or radiographic pneumonia.
- *Pontiac Fever*: A milder illness without pneumonia.

Laboratory Criteria for Diagnosis

Any of the following:

Suspected:

- By seroconversion: fourfold or greater rise in antibody titer to specific species or serogroups of *Legionella* other than *L. pneumophila* serogroup 1 (e.g., *L. micdadei*, *L. pneumophila* serogroup 6);
- By seroconversion: fourfold or greater rise in antibody titer to multiple species of *Legionella* using pooled antigen and validated reagents;
- By the detection of specific *Legionella* antigen or staining of the organism in respiratory secretions, lung tissue, or pleural fluid by direct fluorescent antibody (DFA) staining, Immunohistochemistry (IHC), or other similar method, using validated reagents; or
- By detection of *Legionella* species by a validated nucleic acid assay.

Confirmed:

- By culture: isolation of any *Legionella* organism from respiratory secretions, lung tissue, pleural fluid, or other normally sterile fluid;
- By detection of *Legionella pneumophila* serogroup 1 antigen in urine using validated reagents; or
- By seroconversion: fourfold or greater rise in specific serum antibody titer to *Legionella pneumophila* serogroup 1 using validated reagents.

Case Classification

Suspected: A clinically compatible case that meets at least one of the presumptive (suspected) laboratory criteria.

Confirmed: A clinically compatible case that meets at least one of the confirmatory laboratory criteria.

Required Comments

Specify the form of illness (Pontiac fever or Legionnaires).

Document relevant travel/deployment history: A Travel-associated is a case that has a history of spending at least one night away from home, either in the same country of residence or abroad, in the ten days before onset of illness.

(Note: the incubation period of Legionnaire disease is usually 5-6 days, with a range of 2-10 days; Pontiac fever is usually 24-48 hours, with a range of 5-66 hours).

Additional Considerations

None.

5.29 LEISHMANIASIS

Clinical Description

References 8, 9, 14

Leishmaniasis typically is a zoonosis with a variety of mammalian reservoir hosts, including canines and rodents. The vectors are female phlebotomine sand flies. Leishmaniasis is endemic from northern Argentina to southern Texas, in southern Europe, Asia, the Middle East, and Africa but not in Australia or Oceania.

Organisms of the genus *Leishmania* cause two major forms of disease:

1. **Cutaneous and Mucosal/Mucocutaneous:** Appearance of one or more lesions on uncovered parts of the body. The face, neck, arms and legs are the most common sites. A nodule appears at the site of inoculation, enlarges, and becomes an indolent ulcer. The sore remains in this stage for a variable time before healing, and leaves a depressed scar. Certain strains can disseminate and cause mucosal lesions in some individuals; these sequelae involve nasopharyngeal tissues and can be disfiguring.
2. **Visceral:** A chronic systemic illness with persistent irregular fever, hepatosplenomegaly, lymphadenopathy, pancytopenia and weight loss as its main symptoms.

Laboratory Criteria for Diagnosis

1. **Cutaneous and Mucosal/Mucocutaneous:** (any of the following)
 - Positive parasitology (stained smear or culture from the lesion), or
 - PCR-positive.
2. **Visceral:** (any of the following)
 - Positive parasitology (stained smears from bone marrow, spleen, liver, lymph node, blood or culture of the organism from a biopsy or aspirated material), or
 - Positive serology (rK39 assay).

Case Classification

1. Cutaneous and Mucosal/Mucocutaneous:

Confirmed: A case that has a clinically compatible lesion with parasitological confirmation of the diagnosis (positive smear or culture).

2. Visceral:

Confirmed: A case exhibiting clinical signs with serological and/or parasitological confirmation of leishmaniasis.

Required Comments

Document relevant travel/deployment history (Note: the incubation period of cutaneous/mucosal leishmaniasis is usually a week to many months; visceral leishmaniasis is generally 2-6 months, with a range of 10 days to years).

Additional Considerations

None.

5.30 LEPROSY

Clinical Description

Reference 1

A chronic bacterial disease characterized by the involvement primarily of skin as well as peripheral nerves and the mucosa of the upper airway. Clinical forms of leprosy (or Hansen's disease) represent a spectrum reflecting the cellular immune response to *Mycobacterium leprae*. The following characteristics are typical of the major forms of the disease:

- *Tuberculoid*: One or a few well-demarcated, hypopigmented, and anesthetic skin lesions, frequently with active, spreading edges and a clearing center. Peripheral nerve swelling or thickening also may occur.
- *Lepromatous*: A number of erythematous papules and nodules or an infiltration of the face, hands, and feet with lesions in a bilateral and symmetrical distribution that progress to thickening of the skin.
- *Borderline (Dimorphous)*: Skin lesions characteristic of both the tuberculoid and lepromatous forms.
- *Indeterminate*: Early lesions, usually hypopigmented macules, without developed tuberculoid or lepromatous features.

Laboratory Criteria for Diagnosis

Demonstration of acid-fast bacilli in skin or dermal nerve, obtained from the full-thickness skin biopsy of a lepromatous lesion.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Document the source and clinical form of the infection.

Additional Considerations

None.

5.31 LEPTOSPIROSIS

Clinical Description

References 5, 8

An illness characterized by fever, headache, chills, myalgia, conjunctival suffusion, and less frequently by meningitis, rash, jaundice, or renal insufficiency.

Laboratory Criteria for Diagnosis

Any of the following:

- Fourfold or greater increase in *Leptospira* agglutination titer between acute and convalescent serum specimens obtained ≥ 2 weeks apart and studied at the same laboratory;
- Demonstration of *Leptospira* in a clinical specimen by immunofluorescence;
- Isolation and typing from blood or other clinical materials by culture of pathogenic leptospires;
- Positive serology, preferably by the Microscopic Agglutination Test (MAT). Ideally, the panel of *Leptospira* strains used for antigens should be representative of the locally occurring strains; or
- Detection of leptospiral DNA by PCR.

Case Classification

Probable: A clinically compatible case with supportive serologic findings (i.e., a *Leptospira* agglutination titer of ≥ 200 in one or more serum specimens)

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Document relevant travel/deployment history (Note: the incubation period of leptospirosis is usually 10 days, with a range of 2-30 days) and fresh water exposure.

Additional Considerations

None.

5.32 LISTERIOSIS

Clinical Description

Reference 1

In adults, invasive disease caused by *Listeria monocytogenes* manifests most commonly as meningitis or bacteremia; infection during pregnancy may result in fetal loss through miscarriage or stillbirth, or neonatal meningitis or bacteremia. Other manifestations can also be observed.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of *L. monocytogenes* from a normally sterile site (e.g., blood or cerebrospinal fluid [CSF] or, less commonly, joint, pleural, or pericardial fluid) or in the case of miscarriage from placental or fetal tissue, or
- FDA-cleared Nucleic Acid Test (NAT).

Note: The usefulness of other laboratory methods such as fluorescent antibody testing or PCR to diagnose invasive listeriosis has not been established.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

None.

Additional Considerations

For children <1 year, specify age in months.

5.33 LYME DISEASE

Clinical Description

Reference 1

A systemic tick-borne disease with protean manifestations, including dermatologic, rheumatologic, neurologic, and cardiac abnormalities. The best clinical marker for the disease is erythema migrans (EM), the initial skin lesion that occurs in 60%-80% of patients.

Clinical Case Definition

Erythema Migrans: For purposes of surveillance, EM is defined as a skin lesion that typically begins as a red macule or papule and expands (over a period of days to weeks) to form a large round lesion, often with partial central clearing. A single primary lesion must reach ≥ 5 centimeters in size. Secondary lesions may also occur. Annular erythematous lesions occurring within several hours of a tick bite represent hypersensitivity reactions and do not qualify as EM.

For most patients, the expanding EM lesion is accompanied by other acute symptoms, particularly fatigue, fever, headache, mildly stiff neck, arthralgia, or myalgia. These symptoms are typically intermittent. The diagnosis of EM must be made by an experienced clinician. Laboratory confirmation is recommended for persons with no known exposure.

Late Manifestations: These include any of the following when an alternate explanation is not found:

- *Musculoskeletal System:* Recurrent brief attacks (weeks or months) of objective joint swelling in one or a few joints, sometimes followed by chronic arthritis in one or a few joints. Manifestations not considered as criteria for diagnosis include chronic progressive arthritis not preceded by brief attacks and chronic symmetrical polyarthritis. Additionally, arthralgia, myalgia, or fibromyalgia syndromes alone are not criteria for musculoskeletal involvement.
- *Nervous System:* Any of the following, alone or in combination: lymphocytic meningitis; cranial neuritis, particularly facial palsy (may be bilateral); radiculoneuropathy; or, rarely, encephalomyelitis. Encephalomyelitis must be confirmed by demonstration of antibody production against *B. burgdorferi* in the CSF, evidenced by a higher titer of antibody in CSF than in serum. Headache, fatigue, paresthesia, or mildly stiff neck alone is not a criterion for neurologic involvement.
- *Cardiovascular System:* Acute onset of high grade (2nd degree or 3rd degree) atrioventricular conduction defects that resolve in days to weeks and are sometimes associated with myocarditis. Palpitations, bradycardia, bundle branch block, or myocarditis alone is not a criterion for cardiovascular involvement.

Laboratory Criteria for Diagnosis

Any of the following:

For the purposes of surveillance, the definition of a qualified laboratory assay is

- Positive Culture for *B. burgdorferi*;
- Two-tier testing interpreted using established criteria [1], where:
 - Positive IgM is sufficient only when ≤ 30 days from symptom onset
 - Positive IgG is sufficient at any point during illness
- Single-tier IgG immunoblot seropositivity using established criteria [1-4]; or
- CSF antibody positive for *B. burgdorferi* by Enzyme Immunoassay (EIA) or Immunofluorescence Assay (IFA), when the titer is higher than it was in serum.

Case Classification

Suspected:

- A case of EM where there is no known exposure (as defined above) and no laboratory evidence of infection (as defined above), or
- A case with laboratory evidence of infection but no clinical information available (e.g. a laboratory report).

Probable: Any other case of physician-diagnosed Lyme disease that has laboratory evidence of infection (as defined above).

Confirmed:

- A case that meets the clinical criteria for diagnosis of EM with a known exposure;
- A case of EM with laboratory evidence of infection and without a known exposure; or
- A case with at least one late manifestation that has laboratory evidence of infection.

Exposure is defined as having been (≤ 30 days before onset of EM) in wooded, brushy, or grassy areas (i.e., potential tick habitats) in a county in which Lyme disease is endemic. A history of tick bite is not required.

Required Comments

Document the patient's geographic location and likelihood of exposure to ticks in the preceding 1 year (e.g., during field exercises or other outdoor activities).

Additional Considerations

None.

5.34 MALARIA (ALL)

Clinical Description

Reference 1

Infections with the 4 human types of malaria can present symptoms sufficiently similar to make species differentiation impossible without laboratory studies.

Signs and symptoms are variable; however, most patients experience fever. In addition to fever, common associated symptoms include headache, back pain, chills, sweats, myalgia, nausea, vomiting, diarrhea and cough. Untreated *Plasmodium falciparum* infection can lead to coma, renal failure, pulmonary edema, and death. The diagnosis of malaria should be considered for any person who has these symptoms and who has traveled to an area in which malaria is endemic. Asymptomatic parasitemia can occur in long-term residents of areas in which malaria is endemic.

Laboratory Criteria for Diagnosis

Any of the following:

- Detection of circulating malaria-specific antigens using rapid diagnostic test (e.g. Binax Now);
- Detection of species specific parasite DNA in a sample of peripheral blood using a Polymerase Chain Reaction test; or
- Detection of malaria parasites in thick or thin peripheral blood films.

Note: Multiple smears/specimens taken over several days may be necessary for diagnosis.

Case Classification

Suspected:

- Detection of Plasmodium species by rapid diagnostic antigen testing without confirmation by microscopy or nucleic acid testing in any person (symptomatic or asymptomatic) diagnosed in the United States, regardless of whether the person experienced previous episodes of malaria while outside the country.

Confirmed:

- Detection and specific identification of malaria parasites by microscopy on blood films in a laboratory with appropriate expertise in any person (symptomatic or asymptomatic) diagnosed in the United States, regardless of whether the person experienced previous episodes of malaria while outside the country, or
- Detection of Plasmodium species by nucleic acid test in any in any person (symptomatic or asymptomatic) diagnosed in the United States, regardless of whether the person experienced previous episodes of malaria while outside the country.

Note: Mixed-type infections should be reported separately (i.e., two reports for the same patient).

Required Comments

Document relevant travel/deployment history (Note: the incubation period of *P. falciparum* is usually 9-14 days; *P. vivax* and *P. ovale* 12-18 days; *P. malariae* 18-40 days; and all incubation periods may be prolonged up to 2 months with suboptimal drug suppression). Also document prophylaxis regimen (if none, so state).

Additional Considerations

Specify species if known.

5.35 MEASLES (*Rubeola*)

Clinical Description

Reference 1

An acute, highly contagious viral rash illness with prodromal fever, conjunctivitis (i.e, inflammation of the membrane lining the eyelids), coryza (e.g., a head cold), and cough. Koplik spots on the buccal mucosa are also frequent. The rash typically appears on the 3rd to 5th day, beginning on the face and becoming generalized. Complications and secondary infections (otitis media, pneumonia, and encephalitis) are common.

Clinical Case Definition

All of the following:

- A generalized rash lasting ≥ 3 days;
- A temperature ≥ 101.0 F (≥ 38.3 C); and
- Cough, coryza, or conjunctivitis.

Laboratory Criteria for Diagnosis

Any of the following:

- Positive serologic test for measles IgM antibody;
- Significant rise (fourfold) in measles antibody level by any standard serologic assay;
- Detection of measles-virus specific nucleic acid by polymerase chain reaction; or
- Isolation of measles virus from a clinical specimen.

Case Classification

Suspected: Any febrile illness that is accompanied by rash and that does not meet the criteria for probable or confirmed measles or any other illness.

Probable:

- In the absence of a more likely diagnosis, an illness characterized by the above clinical case definition; and
- No epidemiologic linkage to a confirmed case of measles; and
- Noncontributory or no serologic or virologic testing.

Confirmed:

- Case that is laboratory-confirmed,
- or
- An illness characterized by the above clinical case definition; and
 - Epidemiologic linkage to a confirmed case of measles.

Note: A laboratory-confirmed case does not need to meet the clinical case definition.

Required Comments

Include the patient's measles immunization history and document relevant travel/deployment history (Note: the incubation period of measles is usually 10 days, with a range of 7-18 days).

Additional Considerations

Specify the patient's age in months if < 1 year and any known measles contacts.

5.36 MENINGOCOCCAL DISEASE

Clinical Description

Reference 1

Meningococcal disease typically presents in one of two forms: meningitis or septicemia. However, other manifestations might be observed.

- **Meningococcal Meningitis:** May follow an upper respiratory infection with the onset of fever, headache, vomiting, altered consciousness or other meningeal signs.
- **Meningococcal Septicemia:** May present gradually after a prodrome of cough, headache and sore throat progressing to spiking fever with chills, arthralgias, myalgias and acute prostration. A petechial rash may be present at the axillae, wrists and ankles, and may progress to a purpuric rash. Shock is not uncommon, and may lead to death. Fulminant meningococemia may present abruptly with a petechial rash that progresses rapidly to purpura fulminans, shock, and death – often within hours.

Laboratory Criteria for Diagnosis

See below.

Case Classification

Suspected: (any of the following)

- Clinical purpura fulminans in the absence of a positive blood culture, or
- A clinically compatible case with gram negative diplococci from a normally sterile site (e.g., blood or CSF).

Probable: A clinically compatible case that has either:

- Evidence of *N. meningitidis* DNA using a validated polymerase chain reaction (PCR), obtained from a normally sterile site (e.g., blood or CSF), or
- Evidence of *N. meningitidis* antigen by immunohistochemistry (IHC) on formalin-fixed tissue or latex agglutination of CSF.

Confirmed:

- A clinically compatible case AND isolation of *Neisseria meningitidis* from a normally sterile site (e.g., blood or cerebrospinal fluid or, less commonly, synovial, pleural, or pericardial fluid) or skin scrapings of purpuric lesions.

Required Comments

Include the serogroup (A, B, C, Y, Z, W135) and include the patient's meningococcal immunization history. Indicate whether case is suspected, probable or confirmed.

Additional Considerations

Document relevant travel/deployment history (Note: the incubation period of meningococcal disease is commonly 3-4 days, with a range of 2-10 days) and any known exposures to other cases.

5.37 MUMPS

Clinical Description

Reference 1

An acute viral disease characterized by fever, swelling and tenderness of one or more salivary glands. It can be complicated by orchitis, oophoritis, aseptic meningitis, encephalitis (rarely), mastitis, pancreatitis (usually mild) and in rare instances can lead to permanent nerve deafness.

Clinical Case Definition

An illness with acute onset of unilateral or bilateral tender, self-limited swelling of the parotid and or other salivary gland(s), lasting at least 2 days, and without other apparent cause.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of mumps virus from a clinical specimen;
- Detection of mumps nucleic acid (e.g., standard or real time RT-PCR assays);
- Positive serological test for mumps IgM antibody; or
- Demonstration of specific mumps antibody response in absence of recent vaccination, either a four-fold increase in IgG titer as measured by quantitative assays, or a seroconversion from negative to positive using a standard serologic assay of paired acute and convalescent serum specimens.

Case Classification

Suspected:

- A person with a clinically compatible illness without laboratory testing;
- Acute onset of unilateral or bilateral tender, self-limited swelling of the parotid and or other salivary gland(s), lasting at least 2 days without laboratory testing; or
- A person without clinical information but that is laboratory-confirmed.

Probable:

- Acute onset of unilateral or bilateral tender, self-limited swelling of the parotid and or other salivary gland(s), lasting at least 2 days without laboratory confirmation, and
- Epidemiologically linked to a clinically compatible case.

Confirmed:

- Acute onset of unilateral or bilateral tender, self-limited swelling of the parotid and or other salivary gland(s), lasting at least 2 days, or
- A person with a clinically compatible illness,
and
- A clinically compatible case that is epidemiologically linked to a confirmed case, or
- A case that is laboratory-confirmed.

Required Comments

Document the patient's MMR vaccination history and relevant travel/deployment history (note: the incubation period of mumps is about 16-18 days, with a range of 14-25 days).

Specify the patient's age in months if < 1 year and any known exposures to mumps.

Additional Considerations

None.

5.38 NOROVIRUS

INCLUDES: Only single cases of disease should be reported under this category/event. Cases associated with an outbreak should be reported under the “Outbreak” category/event.

Clinical Description

References 9, 16

An acute, highly contagious viral gastroenteritis characterized by vomiting, watery non-bloody diarrhea with abdominal cramps, and nausea. Vomiting is the most commonly reported symptom and occurs in more than 50% of cases. Low-grade fever also occasionally occurs. Dehydration is the most common complication, especially among the young and elderly, and may require medical attention. Symptoms usually last 24 to 60 hours. Recovery is usually complete and there is no evidence of any serious long-term sequelae. The incubation period for norovirus-associated gastroenteritis in humans is usually between 24 and 48 hours (median in outbreaks 33 to 36 hours), but cases can occur within 12 hours of exposure.

Laboratory Criteria for Diagnosis

Any of the following:

- Detection of virus in stool or vomitus by reverse transcriptase polymerase chain reaction (RT-PCR);
- Fourfold or greater rise in antibody titer in paired sera; or
- Identification of virus in stool by electron microscopy (EM).

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

None.

Additional Considerations

Document the source of infection (foodborne, person-to-person contact), general living/working conditions (e.g. training, deployed setting, in-garrison, dormitory residence, ship-board), day care attendance/employment, healthcare employment, and/or food handler employment. Also report associated outbreak under “outbreak” report.

5.39 OUTBREAK or DISEASE CLUSTER

Description

An "outbreak" is defined as the occurrence of a medical condition that exceeds the baseline/expected rate within a specific place or group of people over a given period of time. Outbreaks can be caused by a variety of biological agents, transmitted person-to-person or via a common source, resulting in mild or serious illness. There is no minimum number of cases that constitutes an outbreak. The rate increase that should trigger reporting will vary according to the circumstances surrounding the event and requires exercise of professional judgment.

Laboratory Criteria for Diagnosis

Laboratory testing, of human and environmental samples, is an important part of outbreak investigations. Laboratory confirmation can serve to guide effective control measures as well as preventive policies. It is important to know that laboratory testing is specific to the etiologic agent in question including the type of specimen collected as well as the specimen collection tools used (i.e. Cary-Blair transport media, unpreserved stool, nasopharyngeal swab, etc). If you have questions or need assistance contact your respective Service Public Health Center.

Laboratory confirmation of the etiologic agent causing the outbreak is not required for reporting. Report outbreaks regardless of specimen collection activities.

Case Classification

While the decision to report an outbreak requires professional judgment, outbreaks should be reported when an increase in illness leads local public health personnel to: (a) identify cases, (b) seek causes, and/or (c) institute control measures. When in doubt report, but know that Service public health authorities are most interested in the following:

- Illnesses causing a rapid rise in numbers of affected persons
- Severe illnesses, e.g, hospitalized cases
- Illnesses which appear to be limited to a specific group (demographic, occupational, etc).
- Illnesses indicative of highly infectious or virulent organisms requiring rapid implementation of control measures
- Illnesses which affect or have the potential to affect mission readiness
- Illnesses leading to control measure recommendations which are invasive, involve mass prophylaxis, or are potentially resource intensive
- Illnesses with the potential to attract media attention or generate public concern
- Illnesses which may prompt an installation commander to exercise his public health emergency powers (i.e. illnesses indicative of a public health emergency or act of bioterrorism)
- Vaccine-preventable illnesses occurring in a highly vaccinated population

Required Comments

List location, source of outbreak if known or suspected, case symptoms and likely etiological agent if known, number affected, group affiliation (e.g., military unit, boy scouts), time course, and actions taken to mitigate outbreak.

Additional Considerations

Not all outbreaks will require a separate Reportable Medical Event for each individual case. Please check with your respective Service Public Health Center for guidance on entering individual Medical Event Reports for outbreaks.

Outbreaks are reportable regardless of whether the etiologic agent itself is known or on the reportable disease list.

5.40 PERTUSSIS (*Whooping Cough*)

Clinical Description

Reference 1

An acute bacterial disease that typically begins as a “cold” with gradually worsening cough. The cough becomes paroxysmal, frequently with a characteristic “whooping” sound heard on inspiration, and may be followed by vomiting. Untreated, the illness lasts 1-2 months and may be complicated by pneumonia or neurologic sequelae.

Clinical Case Definition

A cough illness lasting ≥ 2 weeks with one of the following: paroxysms of coughing, inspiratory “whoop”, or post-tussive vomiting, without other apparent cause (as reported by a health professional).

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of *Bordetella pertussis* from a clinical specimen;
- Positive DFA; or
- Positive polymerase chain reaction (PCR) for *B. pertussis*.

Case Classification

Probable: In the absence of a more likely diagnosis, a cough illness lasting ≥ 2 weeks, with at least one of the following symptoms:

- Paroxysms of coughing;
 - Inspiratory “whoop”; or
 - Post-tussive vomiting;
- AND
- Absence of laboratory confirmation, and
 - No epidemiologic linkage to a laboratory-confirmed case of pertussis.

Confirmed:

- A case that is laboratory confirmed, or
- A clinically compatible case that is epidemiologically linked to a laboratory-confirmed case.

Required Comments

Include the patient’s pertussis immunization history.

Additional Considerations

Specify the patient’s age in months if < 1 year and any pertussis contacts.

5.41 PLAGUE

Clinical Description

References 1, 6, 7

Plague is transmitted to humans by fleas or by direct exposure to infected tissues or respiratory droplets. The disease is characterized by fever, chills, headache, malaise, prostration, and leukocytosis, and has four major clinical forms:

- *Bubonic*: Lymphadenitis in the lymph nodes that drain the region of the infected flea bite. Most often (> 90%) inguinal; alternatively cervical or axillary.
- *Pneumonic*: May be primary or secondary. Primary pneumonic plague is acquired from person to person transmission by droplet spread. Secondary pneumonic plague arises as a complication of bubonic plague.
- *Septicemic*: May be a complication of any of the other forms of plague, or may be the presenting syndrome.
- *Pharyngeal*: Results from exposure to infectious droplets, usually from a patient with pneumonic plague.

Laboratory Criteria for Diagnosis

Laboratory presumptive: (any of the following)

- Elevated serum antibody titer(s) to *Yersinia pestis* fraction 1 (F1) antigen (without documented fourfold or greater change) in a patient with no history of plague vaccination, or
- Detection of F1 antigen in a clinical specimen by fluorescent assay.

Laboratory confirmed: (any of the following):

- Isolation of *Y. pestis* from a clinical specimen (buboes, blood, CSF or Sputum);
- Passive hemagglutination test (PHA test) demonstrating fourfold or greater change in serum antibody titer specific for *Y. pestis* F1 antigen (HI test) in paired sera; or
- Positive FDA approved PCR test.

Case Classification

Suspected: A clinically compatible case without presumptive or confirmatory laboratory results.

Probable: A clinically compatible case with presumptive laboratory results.

Confirmed: A clinically compatible case with confirmatory laboratory results.

Required Comments

Indicate whether case is suspected, probable or confirmed. Document relevant travel/deployment history (Note: the incubation period of plague is usually 1-7 days but may be longer in those immunized who develop illness) including recent field exercises or outdoor activity where infected fleas might have been encountered.

Additional Considerations

Document the clinical form of the infection. Plague cases may be internationally reportable per International Health Regulations.

5.42 POLIOMYELITIS

Clinical Description

Reference 1

A viral infection spread through fecal material, oral secretions, some aerosols and fomites that typically is asymptomatic or causes mild febrile disease. Poliovirus infections occasionally cause aseptic meningitis and one out of 200 infections from poliovirus type 1 results in paralytic poliomyelitis, characterized by acute onset of flaccid paralysis that is typically asymmetric and associated with a prodromal fever. The maximum extent of paralysis typically occurs within 3-4 days and any paralysis present after 60 days is likely to be permanent.

Clinical Case Definition

Acute onset of flaccid paralysis of one or more limbs with decreased or absent tendon reflexes in the affected limbs, without other apparent cause, and without sensory or cognitive loss.

Laboratory Criteria for Diagnosis

Poliovirus isolate identified in an appropriate clinical specimen (e.g., stool, cerebrospinal fluid, oropharyngeal secretions), with confirmatory typing and sequencing performed by the CDC Poliovirus Laboratory, as needed.

Case Classification

Paralytic

Probable: A clinically compatible case without lab confirmation.

Confirmed:

- A clinically compatible case that is laboratory-confirmed, and
- In which the patient has a neurologic deficit 60 days after onset of initial symptoms;
- Has died; or
- Has unknown follow-up status.

Non-Paralytic

Confirmed: Any person without symptoms of paralytic poliomyelitis in whom a poliovirus isolate was identified in an appropriate clinical specimen, with confirmatory typing and sequencing performed by the CDC Poliovirus Laboratory, as needed.

Required Comments

Include the patient's poliomyelitis immunization history (OPV or IPV). Indicate whether case is probable or confirmed and whether patient has acute flaccid paralysis or not. Document relevant travel/deployment history (Note: the incubation period of poliomyelitis is commonly 7-14 days, with a range of 3-35 days).

Additional Considerations

Document the recent vaccination history (OPV or IPV) and relevant travel/deployment history of close contacts. Although inactivated poliovirus vaccine (IPV) replaced oral poliovirus vaccine (OPV) in the U.S., OPV is still widely used in most countries. Vaccine-derived poliovirus (VDPV) may revert to a wild phenotype and has caused polio infections and outbreaks of paralytic poliomyelitis in several countries that no longer use OPV.

Wild type polio cases are always internationally reportable per International Health Regulations.

5.43 Q FEVER

Clinical Description

References 1, 6, 7

An acute febrile rickettsial disease; exposure is usually via aerosol and may be unknown (especially for chronic infection). Often includes the presence of goats, sheep, or other livestock, especially during periods of parturition. Direct contact with animals is not required, and variable incubation periods may be dose dependent.

1. **Acute Q Fever:** Acute fever usually accompanied by rigors, myalgia, malaise, and a severe retrobulbar headache. Fatigue, night-sweats, dyspnea, confusion, nausea, diarrhea, abdominal pain, vomiting, non-productive cough, and chest pain have also been reported. Severe disease can include acute hepatitis, atypical pneumonia with abnormal radiograph, and meningoencephalitis. Pregnant women are at risk for fetal death and abortion. Clinical laboratory findings may include elevated liver enzyme levels, leukocytosis, and thrombocytopenia. Asymptomatic infections may also occur.
2. **Chronic Q Fever:** Infection that persists for more than 6 months. Potentially fatal endocarditis may evolve months to years after acute infection, particularly in persons with underlying valvular disease. Infections of aneurysms and vascular prostheses have been reported. Immunocompromised individuals are particularly susceptible. Rare cases of chronic hepatitis without endocarditis, osteomyelitis, osteoarthritis, and pneumonitis have been described.

Clinical Case Definition

1. **Acute Q Fever:** Acute fever and one or more of the following: rigors, severe retrobulbar headache, acute hepatitis, pneumonia, or elevated liver enzyme levels.
2. **Chronic Q Fever:** Newly recognized, culture-negative endocarditis, particularly in a patient with previous valvulopathy or compromised immune system, suspected infection of a vascular aneurysm or vascular prosthesis, or chronic hepatitis, osteomyelitis, osteoarthritis, or pneumonitis in the absence of other known etiology.

Laboratory Criteria for Diagnosis

1. Acute Q Fever:

Laboratory confirmed: (any of the following)

- Serological evidence of a fourfold change in immunoglobulin G (IgG)-specific antibody titer to *C. burnetii* phase II antigen by indirect immunofluorescence assay (IFA) between paired serum samples, (CDC suggests one taken during the first week of illness and a second 3-6 weeks later, antibody titers to phase I antigen may be elevated or rise as well);
- Detection of *C. burnetii* DNA in a clinical specimen via amplification of a specific target by polymerase chain reaction (PCR) assay (only in cases of recent infection);
- Demonstration of *C. burnetii* in a clinical specimen by immunohistochemical methods (IHC); or
- Isolation of *C. burnetii* from a clinical specimen by culture.

Laboratory supportive: (any of the following)

- Has a single supportive IFA IgG titer of $\geq 1:128$ to phase II antigen (phase I titers may be elevated as well), or
- Has serologic evidence of elevated IgG or IgM antibody reactive with *C. burnetii* antigen by ELISA, dot-ELISA, or latex agglutination.

Note: For acute testing, CDC uses in-house IFA IgG testing (cutoff of $\geq 1:128$), preferring simultaneous testing of paired specimens, and does not use IgM results for routine diagnostic testing.

2. Chronic Q Fever:

Laboratory confirmed: (any of the following)

- Serological evidence of IgG antibody to *C. burnetii* phase I antigen $\geq 1:800$ by IFA (while phase II IgG titer will be elevated as well; phase I titer is higher than the phase II titer);
- Detection of *C. burnetii* DNA in a clinical specimen via amplification of a specific target by PCR assay;
- Demonstration of *C. burnetii* antigen in a clinical specimen by IHC; or

- Isolation of *C. burnetii* from a clinical specimen by culture.

Laboratory supportive: (any of the following)

- Has an antibody titer to *C. burnetii* phase I IgG antigen $\geq 1:128$ and $< 1:800$ by IFA.

Note: Samples from suspected chronic patients should be evaluated for IgG titers to both phase I and phase II antigens. Current commercially available ELISA tests (which test only for phase 2) are not quantitative, cannot be used to evaluate changes in antibody titer, and hence are not useful for serological confirmation. IgM tests are not strongly supported for use in serodiagnosis of acute disease, as the response may not be specific for the agent and the IgM response may be persistent. Complement fixation tests and other older test methods are neither readily available nor commonly used.

Serologic test results must be interpreted with caution, because baseline antibodies acquired as a result of historical exposure to Q fever may exist, especially in rural and farming areas.

Case Classification

1. Acute Q Fever:

- **Probable:** A clinically compatible case of acute illness (meets clinical evidence for acute Q fever) that has laboratory supportive results for past or present acute disease (antibody to Phase II antigen) but is not laboratory-confirmed.
- **Confirmed:**
 - A clinically compatible case that is laboratory-confirmed case, or
 - A clinically compatible case that is epidemiologically linked to a laboratory-confirmed case.

2. Chronic Q Fever:

- **Probable:** A clinically compatible case of chronic illness (meets clinical evidence for chronic Q fever) that has laboratory supportive results for past or present chronic infection (antibody to Phase I antigen).
- **Confirmed:** A clinically compatible case of chronic illness that is laboratory confirmed for chronic infection.

Required Comments

Indicate whether case is acute or chronic and probable or confirmed.

Additional Considerations

Document the source of infection, potential exposure to infected animals, and potential occupational exposure (e.g., veterinarian).

5.44 RABIES, HUMAN

EXCLUDES: Animal bites requiring prophylaxis

Clinical Description

Reference 1

Rabies is an acute encephalomyelitis that almost always progresses to coma or death within 10 days after the first symptom.

Laboratory Criteria for Diagnosis

Any of the following:

- Detection by direct fluorescent antibody of viral antigens in a clinical specimen (preferably from the brain or the nerves surrounding hair follicles in the nape of the neck);
- Isolation (in cell culture or in a laboratory animal) of rabies virus from saliva, cerebrospinal fluid (CSF), or central nervous system tissue; or
- Identification of a rabies-neutralizing antibody titer ≥ 5 (complete neutralization) in the serum or CSF of an unvaccinated person.

Note: Laboratory confirmation by all of the above methods is strongly recommended.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Document history of animal bites or presence at probable locations of exposure (e.g., bat cave), and potential occupational exposure (e.g., veterinarian, animal control officer). Include the patient's relevant immunization history and type of rabies identified (implicated species).

Additional Considerations

None.

5.45 RELAPSING FEVER

Clinical Description

Reference 15

An arthropod-borne spirochetal disease characterized by a fever lasting 2-9 days that alternates with afebrile periods of 2-4 days. The total number of relapses varies from a single incident to over ten. Louse-borne disease lasts 13-16 days and the tick-borne usually lasts longer. Transitory petechial rashes are common during the initial febrile period.

Laboratory Criteria for Diagnosis

Any of the following:

- Demonstration of the infectious agent in darkfield preparations of fresh blood or stained thick or thin films;
- Intraperitoneal inoculation of laboratory rats or mice with blood taken during the febrile period; or
- Isolation of organism through blood culture.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Document relevant travel/deployment history (Note: the incubation period of relapsing fever is usually 8 days, with a range of 2-15 days), with particular attention to the geographic locations of field exercises and outdoor activities.

Additional Considerations

Document exposure to lice or ticks.

5.46 RHEUMATIC FEVER (ACUTE)

Clinical Description

Reference 12

Rheumatic fever is a delayed sequel to pharyngeal infection with Group A beta hemolytic streptococci. Usual acute manifestations are migratory polyarthritides, fever and carditis. Other typical manifestations are Sydenham's chorea, subcutaneous nodules and erythema marginatum.

Clinical Case Definition

Rheumatic fever is generally defined by the Jones criteria. These stipulate that the presence of either two major manifestations or one major and two minor manifestations, with evidence of a preceding streptococcal infection, is considered diagnostic of rheumatic fever.

- Major manifestations: Carditis, polyarthritides, chorea, erythema marginatum, subcutaneous nodules.
- Minor manifestations: Fever, arthralgia, previous rheumatic disease, elevated ESR or CRP, prolonged EKG P-R interval.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of Group A streptococcus from a throat culture;
- Nucleic Acid Test-positive (Gen-Probe);
- Positive antihyaluronidase (AH), anti-DNAse B, anti-NADase or anti-streptokinase (ASK); or
- Positive anti-streptolysin O test (ASO).

Case Classification

Confirmed: An illness characterized by a) two major manifestations or one major manifestation and two minor manifestations and b) supporting evidence of preceding group A streptococcal infection.

Note: Confirmation is clinical, based upon the presence of the Jones criteria as defined above with a history of preceding scarlet fever or other streptococcal infection, untreated pharyngitis, or an increased ASO titer. Laboratory testing alone is insufficient to make a diagnosis.

Required Comments

None.

Additional Considerations

Document relevant training/travel/deployment history (Note: the incubation period of acute rheumatic fever is usually 19 days).

5.47 RIFT VALLEY FEVER

Clinical Description

Reference 15

A primarily mosquito-borne viral disease characterized by fever, chills, headache, myalgia, and arthralgia. May include retinitis, encephalitis and hemorrhage. May have biphasic fever.

Laboratory Criteria for Diagnosis

Any of the following:

- Viral isolation;
- Plaque reduction neutralization assay;
- Virus detection by antigen detection tests or RT-PCR); or
- Presence of specific IgM antibodies or fourfold or greater rise in specific IgG antibody titer.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Document relevant travel/deployment history (Note: the incubation period of rift valley fever is usually 3-12 days) outside the U.S.

Additional Considerations

Document relevant occupational exposure (lab/abattoir worker).

5.48 ROCKY MOUNTAIN SPOTTED FEVER (*Rickettsia rickettsii*)

Clinical Description

Reference 1

A tick-borne febrile illness characterized by an acute onset of myalgia, headache, and a petechial rash that is present on the palms and soles in two-thirds of cases.

Clinical Case Definition

Any reported fever and one or more of the following: rash, headache, myalgia, anemia, thrombocytopenia, or any hepatic transaminase elevation.

Laboratory Criteria for Diagnosis

Laboratory confirmed: (any of the following)

- Serological evidence of a fourfold change in immunoglobulin G (IgG)-specific antibody titer reactive with *Rickettsia rickettsii* antigen by indirect IFA between paired serum specimens (one taken in the first week of illness and a second 2-4 weeks later);
- Detection of *R. rickettsii* DNA in a clinical specimen via amplification of a specific target by PCR assay;
- Demonstration of spotted fever group antigen in a biopsy or autopsy specimen by IHC; or
- Isolation of *R. rickettsii* from a clinical specimen in cell culture.

Laboratory supportive:

- Has serologic evidence of elevated IgG or IgM antibody reactive with *R. rickettsii* antigen by IFA, enzyme-linked immunosorbent assay (ELISA), dot-ELISA, or latex agglutination.

Note: Acute illness is best detected by polymerase chain reaction (PCR) and immunohistochemical methods (IHC) in skin biopsy specimens, and occasionally by PCR in appropriate whole blood specimens taken during the first week of illness, prior to antibiotic treatment. Serology can also be employed for detection, however an antibody response may not be detectable in initial samples, and paired acute and convalescent samples are essential for confirmation. Current commercially available ELISA tests are not quantitative, cannot be used to evaluate changes in antibody titer, and hence are not useful for serological confirmation. IgM tests are not strongly supported for use in serodiagnosis of acute disease, as the response may not be specific for the agent and the IgM response may be persistent. CDC uses in-house IFA IgG testing (cutoff $\geq 1:64$), preferring simultaneous testing of paired specimens, and does not use IgM results for routine diagnostic testing.

Case Classification

Probable: A clinically compatible case that has supportive laboratory results.

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Document the patient's geographic location and likelihood of exposure to ticks in the preceding 2 weeks (e.g., during field exercises or other outdoor activities). Exposure is defined as having been in potential tick habitats within the past 14 days before onset of symptoms. A history of a tick bite is not required.

Additional Considerations

None.

5.49 RUBELLA (*German measles*)

Clinical Description

Reference 1

A mild febrile viral rash illness. Clinically, this is usually indistinguishable from febrile rash illness due to measles, dengue, parvovirus B19, human herpes virus 6, Coxsackie virus, Echovirus, adenovirus or scarlet fever. Children usually present few or no constitutional symptoms, but adults may experience a 1-5 day prodrome of low grade fever, headache, malaise, mild coryza and conjunctivitis. Rash is often absent in adults. Post-auricular, occipital, and posterior cervical lymphadenopathy is characteristic and precedes the rash by up to 10 days. Complications include arthritis, encephalitis, and thrombocytopenia and commonly occur primarily in adults. Congenital rubella syndrome occurs in up to 90% of infants born to pregnant women who acquire rubella during the first trimester of pregnancy.

Clinical Case Definition

All of the following:

- Acute onset of generalized maculopapular rash;
- Temperature > 99.0° F; and
- Arthralgia, arthritis, lymphadenopathy, or conjunctivitis.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of rubella virus;
- Significant rise between acute- and convalescent-phase titers in serum rubella immunoglobulin G antibody level by any standard serologic assay; or
- Positive serologic test for rubella immunoglobulin M (IgM) antibody.

Note: Serum rubella IgM test results that are false positives have been reported in persons with other viral infections (e.g., acute infection with Epstein-Barr virus, recent cytomegalovirus infection, and parvovirus infection) or in the presence of rheumatoid factor.

Case Classification

Suspected: Any generalized rash illness of acute onset that does not meet the criteria for probable or confirmed rubella or any other illness

Probable:

In the absence of a more likely diagnosis, an illness that is:

- A clinically compatible case; and a
- Lack of epidemiologic linkage to a laboratory-confirmed case of rubella with
- Noncontributory or no serologic or virologic testing.

Confirmed:

- A case with or without symptoms that is laboratory-confirmed, or
- A clinically compatible case that is epidemiologically linked to a laboratory-confirmed case.

Required Comments

Include the patient's rubella immunization history and whether the case is congenital rubella syndrome. Document relevant travel/deployment history (Note: the incubation period of rubella is usually 14-17 days, with a range of 14-21 days).

Additional Considerations

Specify the patient's age in months if < 1 year, whether patient is pregnant, and location/nature of exposure.

5.50 SALMONELLOSIS (*Salmonella* spp.)

EXCLUDES: *Salmonella typhi* and *Salmonella paratyphi*.

Clinical Description

Reference 1

An illness of variable severity commonly manifested by diarrhea, abdominal pain, nausea, and sometimes vomiting. Asymptomatic infections may occur, and the organism may cause extraintestinal infections.

Laboratory Criteria for Diagnosis

Isolation of *Salmonella* sp. from a clinical specimen

Case Classification

Probable: A clinically compatible case that is epidemiologically linked to a confirmed case.

Confirmed: A case that is laboratory-confirmed.

Required Comments

When available, O and H antigen serotype characterization should be reported.

Additional Considerations

Document the source of exposure (Note: the incubation period of salmonellosis is usually 12-36 hours, with a range of 6-72 hours).

Both asymptomatic infections and infections at sites other than the gastrointestinal tract, if laboratory confirmed, are considered confirmed cases that should be reported.

5.51 SCHISTOSOMIASIS

Clinical Description

Reference 8

Schistosomiasis is a trematode disease caused by *Schistosoma sp.* It is the second most prevalent tropical disease (following malaria) and a leading cause of severe morbidity in large parts of Africa, Asia and South America. There are three primary varieties that cause disease in humans: *S. mansoni*, *S. haematobium* and *S. japonicum*. These organisms produce two clinical forms of the disease:

- **Urinary Schistosomiasis** gives rise to dysuria, frequency, and hematuria at the end of urination, and is usually caused by *S. haematobium*.
- **Intestinal Schistosomiasis** is normally accompanied by diarrhea, abdominal pain, and hepatosplenomegaly, and is caused by *S. mansoni* and *S. japonicum*.

Laboratory Criteria for Diagnosis

Demonstration of eggs in stool, urine, or biopsy specimens.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Specify the form of schistosomiasis and document relevant travel/deployment history (Note: the incubation period of schistosomiasis is usually 2-6 weeks).

Additional Considerations

Document relevant exposure to fresh water (i.e., wading, swimming, etc.) in an endemic area.

5.52 SEVERE ACUTE RESPIRATORY SYNDROME (SARS)

Clinical Description

References 1, 15

A severe respiratory infection often with associated gastrointestinal symptoms caused by a coronavirus. SARS typically presents with malaise, myalgia, and fever, quickly followed followed by respiratory symptoms including shortness of breath and cough.

Clinical Case Definition

- Early illness: Presence of two or more of the following features: fever (might be subjective), chills, rigors, myalgia, headache, diarrhea, sore throat, rhinorrhea.
- Mild-to-moderate respiratory illness:
 - Temperature of >100.4° F (>38° C), and
 - One or more clinical findings of lower respiratory illness (e.g., cough, shortness of breath, difficulty breathing)
- Severe respiratory illness:
 - Temperature of >100.4° F (>38° C), and
 - One or more clinical findings of lower respiratory illness (e.g., cough, shortness of breath, difficulty breathing), and
 - One or more of the following findings:
 - Radiographic evidence of pneumonia;
 - Acute respiratory distress syndrome; or
 - Autopsy findings consistent with pneumonia or acute respiratory distress syndrome without an identifiable cause

Epidemiologic Criteria

Possible exposure: One or more of the following exposures in the 10 days before onset of symptoms:

- Travel to a foreign or domestic location with documented or suspected recent transmission of SARS-CoV2, or
- Close contact with a person with mild-to-moderate or severe respiratory illness and with history of travel in the 10 days before onset of symptoms to a foreign or domestic location with documented or suspected recent transmission of SARS-CoV2

Likely exposure: One or more of the following exposures in the 10 days before onset of symptoms:

- Close contact with a confirmed case of SARS-CoV disease, or
- Close contact with a person with mild-moderate or severe respiratory illness for whom a chain of transmission can be linked to a confirmed case of SARS-CoV disease in the 10 days before onset of symptoms

Laboratory Criteria for Diagnosis

Any of the following:

- Detection by a validated test, with confirmation in a reference laboratory: (any of the following)
 - Serum antibodies to SARS-CoV in a single serum specimen;
 - A four-fold or greater increase in SARS-CoV antibody titer between acute- and convalescent-phase serum specimens tested in parallel; or
 - Negative SARS-CoV antibody test result on acute-phase serum and positive SARS-CoV antibody test result on convalescent-phase serum tested in parallel
- Isolation in cell culture of SARS-CoV from a clinical specimen, with confirmation using a test validated by CDC; or

- Detection of SARS-CoV RNA by RT-PCR (reverse transcription polymerase chain reaction) validated by CDC, with confirmation in a reference laboratory: (any of the following)
 - Two clinical specimens from different sources, or
 - Two clinical specimens collected from the same source on two different days.

Information about the current criteria for laboratory diagnosis of SARS-CoV is available at:
<http://www.cdc.gov/ncidod/sars/labdiagnosis.htm>

Case Classification

Suspected: (SARS report under investigation)

- Patients from a high risk group for SARS infection with severe illness compatible with SARS without a clear epidemiological link;
- Patients with mild to moderate or severe illness and that meet the epidemiologic criteria for possible exposure; or
- Patients who meet the clinical criteria for early or mild-moderate illness and the epidemiologic criteria for likely exposure to SARS-CoV.

Probable: A case that meets the clinical criteria for severe respiratory illness and the epidemiologic criteria for likely exposure to SARS-CoV

Confirmed: A clinically compatible case (i.e., early, mild-to-moderate, or severe) that is laboratory-confirmed

Exclusion Criteria: A case may be excluded as a SARS report under investigation (SARS RUI), including as a CDC-defined probable SARS-CoV case, if any of the following apply:

- An alternative diagnosis can explain the illness fully;
- Antibody to SARS-CoV is undetectable in a serum specimen obtained >28 days after onset of illness; or
- The case was reported on the basis of contact with a person who was excluded subsequently as a case of SARS-CoV disease; then the reported case also is excluded, provided other epidemiologic or laboratory criteria are not present.

Required Comments

Indicate whether case is suspected, probable, or confirmed. Document relevant travel/deployment history (Note: the incubation period of SARS-CoV is usually 3-10 days).

Additional Considerations

Immediate isolation and notification of public health authorities must occur. SARS-CoV cases are always internationally reportable per International Health Regulations.

5.53 SHIGELLOSIS (*Shigella spp.*)

Clinical Description

Reference 1

An illness of variable severity characterized by diarrhea, fever, nausea, cramps, and tenesmus. Asymptomatic infections may occur.

Laboratory Criteria for Diagnosis

Isolation of *Shigella sp.* from a clinical specimen.

Case Classification

Probable: A clinically compatible case that is epidemiologically linked to a confirmed case.

Confirmed: A case is laboratory-confirmed.

Both asymptomatic infections and infections at sites other than the gastrointestinal tract, if laboratory confirmed, are considered confirmed cases that should be reported.

Required Comments

When available, O antigen serotype characterization should be reported.

Additional Considerations

Document relevant travel/deployment history (Note: the incubation period of shigellosis is usually 1-3 days, with a range of 12-96 hours and up to 1 week), the source of infection (if known) and day care attendance/employment.

Both asymptomatic infections and infections at sites other than the gastrointestinal tract, if laboratory confirmed, are considered confirmed cases that should be reported.

5.54 SMALLPOX

EXCLUDES: Vaccinations and Vaccine adverse events (report under “Vaccine Adverse Event” category)

Clinical Description

References 1, 6, 7

Smallpox is a severe contagious viral rash illness that was eradicated in 1977. High fever, headache, myalgia, abdominal pain and vomiting, and occasionally a transient blotchy erythematous rash herald the onset. After 3-4 days, the patient defervesces and appears to improve. At this time, painful mouth lesions occur on the buccal mucosa, followed by macules on the face and forearms that progress to papules. The rash spreads from the distal extremities to the trunk, and includes the palms and soles. After 3-4 days, the papules become vesicular and then pustular. The rash typically leaves scarring after healing.

Clinical Case Definition

An illness with acute onset of fever $\geq 101^{\circ}\text{F}$ followed by a rash characterized by firm, deep seated vesicles or pustules in the same stage of development without other apparent cause. Clinically consistent cases are those presentations of smallpox that do not meet this classical clinical case definition: hemorrhagic type, flat type, and *variola sine eruptione*.

Laboratory Criteria for Diagnosis

Any of the following:

- PCR identification of *variola* DNA in a clinical specimen, or
- Isolation of smallpox (*variola*) virus from a clinical specimen (Level D laboratory only; confirmed by *variola* PCR).

Note: Indications for laboratory testing of patients with suspected smallpox should be followed as described in detail in Guide A of the CDC Smallpox Response Plan

(URL: <http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp>). Laboratory diagnostic testing for *variola* virus should be conducted in Level C or D labs only. PCR diagnosis can be performed by USAMRIID or CDC.

Case Classification

Suspected: A case with a generalized, acute vesicular or pustular rash illness with fever preceding development of rash by 1-4 days.

Probable:

- A clinically compatible case, or
- a clinically consistent case that does not meet the clinical case definition and is epidemiologically linked to a confirmed case of smallpox.

Confirmed:

- A case that is laboratory confirmed, or
- a clinically compatible case that is epidemiologically linked to a laboratory-confirmed case.

Note: A case may be excluded as a suspect or probable smallpox case if an alternative diagnosis fully explains the illness or appropriate clinical specimens are negative for laboratory criteria for smallpox.

Required Comments

Detailed history of possible exposures is required. Indicate whether case is suspected, probable or confirmed.

Additional Considerations

Smallpox cases are always internationally reportable per International Health Regulations.

5.55 *STREPTOCOCCUS, GROUP A, INVASIVE*

EXCLUDES: Group A Streptococcal Pharyngitis (**Strep Throat**), Rheumatic Fever, Streptococcal Toxic Shock Syndrome

Clinical Description

Reference 1

Invasive Group A streptococcal infections may manifest as any of various clinical syndromes, including pneumonia, bacteremia in association with cutaneous infection (e.g., cellulitis, erysipelas, or infection of a surgical or nonsurgical wound), deep soft-tissue infection (e.g., myositis or necrotizing fasciitis), meningitis, peritonitis, osteomyelitis, septic arthritis, postpartum sepsis (i.e., puerperal fever, endometritis), neonatal sepsis, and nonfocal bacteremia.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of Group A streptococcus (*Streptococcus pyogenes*) by culture from a normally sterile site (e.g., blood or cerebrospinal fluid, or, less commonly, joint, pleural, or pericardial fluid), or
- Nucleic acid test-positive on a sample from a normally sterile site.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

None.

Additional Considerations

Specify the type of clinical presentation and note if nosocomial.

A complex disease caused by the bacteria *Treponema pallidum* that has a highly variable clinical course. The stage of syphilis is determined by the clinical signs and generally by the time elapsed since primary infection. Syphilis can be divided into the following classifications:

- **Primary:** A stage of infection characterized by one or more chancres (ulcers); chancres might differ considerably in clinical appearance.
- **Secondary:** A stage characterized by localized or diffuse mucocutaneous lesions, often with generalized lymphadenopathy. The primary chancre may still be present.
- **Latent (early or late):** A stage 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.
- **Tertiary:** Latent syphilis of long duration, usually past one year, that subsequently becomes clinical. Clinical signs depend upon the degree and organ system affected, but may be cardiac, neurologic, ophthalmic, auditory and gummatous in nature.
- **Congenital:** A condition caused by infection in utero. A wide spectrum of severity exists; only severe cases are clinically apparent at birth. An infant or child < 2 years may have signs such as hepatosplenomegaly, rash, condyloma lata, snuffles, jaundice, pseudoparalysis, anemia, or edema (from nephrotic syndrome and/or malnutrition). An older child may have syphilitic stigmata such as interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson teeth, saddle nose, rhagades, or Clutton joints.

Laboratory Criteria for Diagnosis

Any of the following:

- Demonstration of *T. pallidum* in clinical specimens by dark-field microscopy, direct fluorescent antibody (DFA-TP), or equivalent methods, or
- A positive non-treponemal test (RPR or VDRL) AND a positive treponemal test (FTA-ABS or MHA-TP).

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 *T. pallidum* [MHA-TP])

Confirmed: A clinically compatible case that is laboratory-confirmed.

Note: Neurosyphilis should be reported by the stage of syphilis in which it presents (usually tertiary).

Required Comments

None.

Additional Considerations

Note if neurosyphilis (evidence of central nervous system infection with *T. pallidum*) is present.

5.57 TETANUS

Clinical Description

Reference 1

Acute onset of hypertonia and/or painful muscular contractions (usually of the muscles of the jaw and neck) and generalized muscle spasms without other apparent medical cause.

Laboratory Criteria for Diagnosis

Diagnosis is made clinically from history and clinical signs. There is no detectable antibody response and the organism is rarely recovered from the site of infection.

Case Classification

Probable:

- In the absence of a more likely diagnosis, an acute illness with
 - muscle spasms or hypertonia; and
 - diagnosis of tetanus by a health care provider;

or

- Death, with tetanus listed on the death certificate as the cause of death or a significant condition contributing to death

Confirmed: There is no definition for “confirmed” tetanus.

Required Comments

Include the patient’s tetanus immunization history.

Additional Considerations

Include the patient's age in months if <1 year.

5.58 TOXIC SHOCK SYNDROME

INCLUDES: Cases caused by both *Staphylococcus aureus* and *Streptococcus pyogenes*.

Clinical Description

Reference 1

1. **Staphylococcal Toxic Shock Syndrome (TSS):** A severe illness characterized by high fever, vomiting, profuse watery diarrhea and myalgia, followed by hypotension and shock. Often accompanied by a “sunburn-like” rash. Frequently, desquamation of the palms and soles occurs 1-2 weeks after the onset. The causative agent is *S. aureus*, although the organism is frequently not recovered.
2. **Streptococcal Toxic Shock Syndrome (STSS):** A severe illness with signs and symptoms as above for TSS. Associated with invasive or noninvasive Group A streptococcal (*Streptococcus pyogenes*) infection. STSS may occur with infection at any site but most often occurs in association with infection of a cutaneous lesion. Signs of toxicity and a rapidly progressive clinical course are characteristic, and the case-fatality rate may exceed 50%.

Clinical Case Definition

1. **Staphylococcal Toxic Shock Syndrome:** An illness with all 5 of the following clinical manifestations:

- Fever: Temperature $\geq 102.0^{\circ}$ F;
- Rash: Diffuse macular erythroderma;
- Desquamation: 1-2 weeks after onset of illness, particularly on the palms and soles;
- Hypotension: Systolic blood pressure ≤ 90 mm Hg for adults or less than fifth percentile by age for children aged less than 16 years; orthostatic drop in diastolic blood pressure ≥ 15 mm Hg from lying to sitting, orthostatic syncope, or orthostatic dizziness; and
- Multisystem involvement: (≥ 3 of the following)
 - Gastrointestinal: vomiting or diarrhea at onset of illness
 - Muscular: severe myalgia or creatine phosphokinase level at least twice the upper limit of normal
 - Mucous membrane: vaginal, oropharyngeal, or conjunctival hyperemia
 - Renal: blood urea nitrogen or creatinine at least twice the upper limit of normal for laboratory or urinary sediment with pyuria (≥ 5 leukocytes per high-power field) in the absence of urinary tract infection
 - Hepatic: total bilirubin, alanine aminotransferase enzyme, or aspartate aminotransferase enzyme levels at least twice the upper limit of normal for laboratory
 - Hematologic: platelets less than 100,000/mm³
 - Central nervous system: disorientation or alterations in consciousness without focal neurologic signs when fever and hypotension are absent

2. **Streptococcal Toxic Shock Syndrome (STSS):** An illness with the following clinical manifestations occurring within the first 48 hours of hospitalization or, for a nosocomial case, within the first 48 hours of illness:

- **Hypotension:** defined by a systolic blood pressure < 90 mm Hg for adults or less than the fifth percentile by age for children aged < 16 years.
- **Multi-organ involvement:** (≥ 2 of the following)
 - Renal impairment: Creatinine ≥ 2 mg/dL for adults or \geq twice the upper limit of normal for age. In patient with preexisting renal disease, a greater than twofold elevation over the baseline level.
 - Coagulopathy: Platelets $\leq 100,000$ /mm³ or disseminated intravascular coagulation, defined by prolonged clotting times, low fibrinogen level, and the presence of fibrin degradation products.
 - Liver involvement: Alanine aminotransferase, aspartate aminotransferase, or total bilirubin levels \geq twice the upper limit of normal for the patient’s age. In patients with preexisting liver disease, a greater than twofold increase over the baseline level.

- Acute respiratory distress syndrome: defined by acute onset of diffuse pulmonary infiltrates and hypoxemia in the absence of cardiac failure or by evidence of diffuse capillary leak manifested by acute onset of generalized edema, or pleural or peritoneal effusions with hypoalbuminemia.
- Erythematous macular rash: a generalized rash that may desquamate.
- Soft-tissue necrosis: includes necrotizing fasciitis or myositis, or gangrene.

Laboratory Criteria for Diagnosis

For Staphylococcal Toxic Shock Syndrome (TSS): Negative results on the following tests, if obtained:

- Blood or cerebrospinal fluid cultures blood culture may be positive for *Staphylococcus aureus*
- Negative serologies for Rocky Mountain spotted fever, leptospirosis, or measles

For Streptococcal Toxic Shock Syndrome (STSS) only: Isolation of group A *Streptococcus* from a normally sterile site (e.g., blood or cerebrospinal fluid or less commonly, joint, pleural, or pericardial fluid)

Case Classification

1. Staphylococcal Toxic Shock Syndrome (TSS):

- **Probable:** A case which meets the laboratory criteria and in which four of the five clinical findings described above are present.
- **Confirmed:** Confirmation is clinical and is defined as a case in which the required clinical findings described above are present (including desquamation, unless the patient dies before desquamation occurs) in the absence of Group A *Streptococcus*.

2. Streptococcal Toxic Shock Syndrome (STSS):

- **Probable:** A case that meets the clinical case definition in the absence of another identified etiology for the illness and with isolation of group A *Streptococcus* from a nonsterile site.
- **Confirmed:** A clinically compatible case that is laboratory-confirmed.

Required Comments

Specify the form of toxic shock syndrome (staphylococcal or streptococcal).

Additional Considerations

None.

5.59 TRICHINOSIS

Clinical Description

Reference 1

A disease caused by ingestion of *Trichinella* sp. larvae. The disease has variable clinical manifestations. Common signs and symptoms among symptomatic persons include eosinophilia, fever, myalgia, and periorbital edema.

Laboratory Criteria for Diagnosis

Any of the following:

- Demonstration of *Trichinella* larvae in tissue obtained by muscle biopsy, or
- Positive serologic test for *Trichinella*.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Note: In an outbreak setting, at least one case must be laboratory confirmed. Associated cases should be reported as confirmed if the patient shared an epidemiologically implicated meal or ate an epidemiologically implicated meat product and has either a positive serologic test for trichinosis or a clinically compatible illness.

Required Comments

None.

Additional Considerations

Document the source of infection (e.g., poorly cooked meat).

5.60 TRYPANOSOMIASIS

Clinical Description

Reference 8

An arthropod-borne protozoal disease with two distinct forms:

1. **African Trypanosomiasis (Sleeping sickness):** In the early stages, a painful chancre, which originates as a papule and evolves into a nodule may be found at the primary tsetse fly bite site. There may be fever, intense headache, insomnia, painless lymphadenopathy, anemia, local edema and rash. In the later stages, there are cachexia, somnolence and CNS signs. The disease may run a protracted course of several years in the case of *Trypanosoma brucei gambiense* (B56-0). In cases of *T. b. rhodesiense* (B56-1), the disease has a rapid and acute evolution. Both diseases are always fatal without treatment.
2. **American Trypanosomiasis (Chagas' disease):** The main clinical signs are fever, malaise, hepatosplenomegaly and lymphadenopathy in the acute phase. Many patients present without clinical signs. An inflammatory response at the site of infection (chagoma) may last up to 8 weeks. Chronic infection can lead to myocarditis and meningoencephalitis.

Laboratory Criteria for Diagnosis

1. African Trypanosomiasis:

- **Presumptive:** serological: card agglutination trypanosomiasis test (CATT) for *T. b. gambiense* only or immunofluorescent assay (IFA) for *T. b. rhodesiense* mainly and possibly for *T. b. gambiense*.
- **Confirmative:** parasitological: detection (microscopy) of trypanosomes in blood, lymph node aspirates or CSF.

2. American Trypanosomiasis: (any of the following)

- Positive parasitology (direct, xenodiagnosis, blood culture), or
- Positive serology for *Trypanosoma cruzi* antibodies (IgM) by indirect haemagglutination test (IHA), indirect immunofluorescent antibody test (IFAT), direct agglutination test (DA), or ELISA.

Case Classification

1. African Trypanosomiasis:

- **Suspected:** A clinically compatible case and/or a history of exposure.
- **Probable:** A case with a positive serology with or without clinical symptoms in persons without previous history of trypanosomiasis diagnosis or treatment.
- **Confirmed:** A case with positive parasitology, with or without clinical symptoms.

Note: In the early stage or even early in the late stage of the disease there are often no clinical signs or symptoms which can be associated with the disease. Suspicion is then based on local risk of contracting the disease and local disease historical background

2. American Trypanosomiasis:

- **Probable:** (Endemic areas) a case with unexplained fever, hepatosplenomegaly and a *chagoma* (inflammation at site of infection).
- **Confirmed:** A clinically compatible case that is laboratory-confirmed.
- **Congenital:** A newborn with positive parasitology (direct, xenodiagnosis, culture).

Required Comments

Specify the form of trypanosomiasis, indicate whether case is suspected, probable, confirmed or congenital and document relevant travel/deployment history to endemic areas (Note: the incubation period of African trypanosomiasis is usually 3 days to a few weeks and longer for *T.b. rhodesiense*; American trypanosomiasis 5-14 days).

Additional Considerations

None.

5.61 TUBERCULOSIS, PULMONARY

EXCLUDES: Latent Tuberculosis Infection which includes personnel that are screening test positive (TST/PPD+ or FDA-approved blood assay+) without evidence of active disease.

Clinical Description

Reference 1

A chronic bacterial infection caused by *Mycobacterium tuberculosis*, characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs may be involved. Specific symptoms of pulmonary tuberculosis include cough, chest pain and hemoptysis. Systemic symptoms also include fever, chills, night sweats, fatigue and weight loss.

Clinical Case Definition

All of the following:

- A positive tuberculin skin test or an FDA-approved blood assay for *M. Tuberculosis* (unless immunocompromised);
- Other signs and symptoms compatible with tuberculosis (e.g., an abnormal and unstable [worsening or improving] chest radiograph, or clinical evidence of current disease); and
- Completed diagnostic evaluation, including: history, physical exam, smear and culture, Mantoux skin test and CXR.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of *M. tuberculosis* from a clinical specimen, or
- Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test.

Case Classification

Probable: Clinical signs and symptoms of pulmonary tuberculosis with demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained.

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments:

Indicate whether case is probable or confirmed.

Additional Considerations

Document the patient's history of exposure to a known or suspected case, travel to or origin from highly endemic countries, potential occupational exposure (e.g., health care worker), evidence of multi-drug resistance, and history of tuberculosis vaccine (i.e., BCG).

A case should not be counted twice within any consecutive 12-month period. However, a case occurring in a patient who had previously had verified TB disease should be reported and counted again if more than 12 months have elapsed since the patient completed therapy. A case should also be reported and counted again if the patient was lost to supervision for greater than 12 months and TB disease can be verified again.

5.62 TULAREMIA

Clinical Description

References 1, 6, 7

A zoonotic bacterial disease with a variety of clinical manifestations related to the route of introduction and the virulence of the disease agent:

- **Percutaneous:** From the bite of an arthropod. Normally presents as an indolent ulcer at the site of introduction along with swelling of the regional lymph nodes.
- **Ingestion:** Normally produces a painful pharyngitis, abdominal pain, diarrhea, and vomiting.
- **Inhalation:** May be followed by pneumonic involvement or a primary septicemia. Blood-borne organisms may localize in the lung and pleural spaces.

Laboratory Criteria for Diagnosis

Presumptive:

- Elevated serum antibody titer(s) to *F. tularensis* antigen (without documented fourfold or greater change) in a patient with no history of tularemia vaccination, or
- Detection of *F. tularensis* in ulcerative exudate, lymph node aspirate, or other clinical specimen by fluorescent assay.

Confirmatory:

- Fourfold or greater rise in specific serum antibodies *F. tularensis* antigen;
- Isolation of *F. tularensis* in a clinical specimen; or
- PCR-positive (by FDA-cleared test).

Case Classification

Probable: A clinically compatible case with laboratory results indicative of presumptive infection.

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Document the clinical manifestation and the patient's history of possible exposure (hunting, known arthropod bites, etc.).

Additional Considerations

None.

5.63 TYPHOID FEVER

INCLUDES: Salmonella typhi and Salmonella paratyphi

Clinical Description

Reference 1

An illness caused by *Salmonella typhi* (may be reported as *S. enterica serovar Typhi*, abbreviated *S. Typhi*) or *S. Paratyphi* characterized by insidious onset of sustained fever, headache, malaise, anorexia, relative bradycardia, constipation or diarrhea, and nonproductive cough. However, many mild and atypical infections occur. Carriage of *S. typhi* (*S. Typhi*) or *S. Paratyphi* may be prolonged.

Laboratory Criteria for Diagnosis

Isolation of *S. Typhi* or *S. Paratyphi* from blood, stool, or other clinical specimen.

Note: Serologic evidence alone is insufficient for diagnosis. Isolation of the organism is required for confirmation.

Case Classification

Probable: A clinically compatible case that is epidemiologically linked to a confirmed case in an outbreak.

Confirmed: A clinically compatible case that is laboratory-confirmed.

Note: Asymptomatic carriage of S. Typhi or S. Paratyphi should not be reported as typhoid fever.

Required Comments

Indicate species and include the patient's typhoid immunization history. Also document relevant travel/deployment history (Note: the incubation period of typhoid fever is usually 8-14 days, with a range of 3-60 days; paratyphoid fever 1-10 days).

Additional Considerations

Document the source of infection and potential occupational exposure.

5.64 TYPHUS FEVER

Clinical Description

References 8, 9

A group of arthropod-borne rickettsial diseases with four clinically distinct presentations, each with its own specific infectious agent and vector:

1. **Epidemic (Louse-borne) Typhus:** (*Rickettsia prowazekii*.) Characterized by headache, chills, prostration, fever and general pain. A macular eruption appears on the fifth to sixth day, initially on the upper trunk followed by spread to the entire body, but usually sparing the face, palm, and soles. The infectious agent is transmitted by body lice.
2. **Murine Typhus Fever:** (*R. typhi*.) Similar to louse-borne typhus, but often milder. The infectious agent is transmitted by fleas.
3. **Scrub Typhus:** (*Orientia tsutsugamushi*) Often produces a primary “punched out” skin ulcer (eschar) corresponding to the primary attachment of an infected mite. The acute onset of symptoms follows within several days, characterized by fever, headache, profuse sweating, conjunctival injection and lymphadenopathy. A dull red maculopapular eruption appears on the trunk late in the first week, gradually extending to the extremities.
4. **Tick-borne Typhus:** (*R. conorii*, *sibirica* and *australis*.) Tick-borne typhus has a clinical presentation similar to that seen in scrub typhus, frequently with an ulcer at the site of the tick bite.

Laboratory Criteria for Diagnosis

For *R. prowazekii*, *R. typhi*, *R. conorii*, *R. sibirica*, or *R. australis* ONLY:

- Fourfold or greater rise in antibody titer to *R. prowazekii*, *R. typhi*, *R. conorii*, *R. sibirica*, or *R. australis* antigen by IFA, complement fixation (CF), latex agglutination (LA), microagglutination (MA), or indirect hemagglutination antibody (IHA) test in acute- or convalescent-phase specimens ideally taken at least 3 weeks apart;
- Positive PCR assay to *R. prowazekii*, *R. typhi*, *R. conorii*, *R. sibirica*, or *R. australis*;
- Demonstration of positive IF of skin lesion (biopsy) or organ tissue (autopsy); or
- Isolation of *R. prowazekii*, *R. typhi*, *R. conorii*, *R. sibirica*, or *R. australis* from clinical specimen.

For *O. tsutsugamushi* ONLY:

- Isolation of *O. tsutsugamushi* by inoculation of patient blood in white mice (preferably treated with cyclophosphamide at 0.2 mg/g intraperitoneally or intramuscularly on days 1, 2 and 4 after inoculation, or
- Serologic detection of specific IgM.
Note: Serological tests are complicated by the antigenic differences between various strains of the causal agent.

Case Classification

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Specify the form of typhus and document relevant foreign travel/deployment history (Note: the incubation period of typhus fever is usually 10-12 days, with a range of 6-21 days).

Additional Considerations

Document history of arthropod exposure.

5.65 VARICELLA (*Chickenpox*)

INCLUDES: Service Member cases only.

Clinical Description

Reference 1

An illness with acute onset of mild constitutional symptoms, slight fever and generalized papulovesicular rash.

Clinical Case Definition

An illness with acute onset of diffuse (generalized) papulovesicular rash without other apparent cause.

Laboratory Criteria for Diagnosis

Any of the following:

- Isolation of varicella virus from a clinical specimen;
- Varicella antigen detected by direct fluorescent antibody (DFA);
- Varicella-specific nucleic acid detected by polymerase chain reaction (PCR);
- Positive IgM Serology; or
- Significant rise in serum varicella immunoglobulin G (IgG) antibody level by any standard serologic assay.

Case Classification

Probable:

- An acute illness with
 - Diffuse (generalized) maculopapulovesicular rash;
 - Lack of laboratory confirmation; and
 - Lack of epidemiologic linkage to another probable or confirmed case.

Confirmed:

- A clinically compatible case that is laboratory-confirmed, or
- A clinically compatible case that is epidemiologically linked to a confirmed or probable case.

Note: Two probable cases that are epidemiologically linked would be considered confirmed, even in the absence of laboratory confirmation.

Required Comments

Include the patient's varicella immunization history.

Additional Considerations

Document the patient's exposure history. Laboratory confirmation of varicella cases is not routinely recommended; laboratory confirmation is recommended for fatal cases and in other special circumstances

5.66 YELLOW FEVER

Clinical Description

Reference 1

A mosquito-borne viral illness characterized by acute onset and constitutional symptoms followed by a brief remission, then a recurrence of fever with hepatitis and albuminuria. Renal failure, shock, and generalized hemorrhaging are possible.

Laboratory Criteria for Diagnosis

Any of the following:

- Fourfold or greater rise in yellow fever antibody titer in a patient who has no history of recent yellow fever vaccination and cross-reactions to other flaviviruses have been excluded;
- Presence of yellow fever specific IgM; or
- Demonstration of yellow fever virus, antigen, or genome in tissue, blood, or other body fluid.

Case Classification

Probable: A clinically compatible case with supportive serology (stable elevated antibody titer to yellow fever virus [e.g., ≥ 32 by complement fixation, ≥ 256 by immunofluorescence assay, ≥ 320 by hemagglutination inhibition, ≥ 160 by neutralization, or a positive serologic result by immunoglobulin M-capture enzyme immunoassay]. Cross-reactive serologic reactions to other flaviviruses must be excluded, and the patient must not have a history of yellow fever vaccination.)

Confirmed: A clinically compatible case that is laboratory-confirmed.

Required Comments

Include the patient's yellow fever immunization history. Document relevant travel/deployment history (Note: the incubation period of yellow fever is 3-6 days).

Additional Considerations

Yellow fever cases may be internationally reportable per International Health Regulations.

6.0 Required Data Elements

To assure consistency of the Armed Forces data, this section lists the minimum required data elements for each report, along with recommended reporting guidelines for each element. Each service may add its own additional data fields for internal analysis without compromising eventual data integration.

6.1 DEMOGRAPHIC DATA

- 1 **Case Number**
Unique case identifier.
- 2 **Patient's First and Last Name**
- 3 **FMP/SSN**
Family member prefix code and sponsor social security number.
- 4 **Patient Beneficiary Category**
From beneficiary category list (e.g., A11, N15).
- 5 **Race/Ethnicity**
White, black, Hispanic, Asian, American Indian, other.
- 6 **Patient's Sex/Gender**
- 7 **Date of Birth**
Four-digit year, month, day.

6.2 MEDICAL DATA

1. **Diagnosis**
Name of event.
2. **Date of Onset**
If unsure of date of onset, date of presentation is an adequate substitute.
3. **Confirmation**
Yes, no or pending. Do not delay transmitting a report pending laboratory confirmation. Unconfirmed cases are not included for analysis or further reporting; reports must therefore be updated when confirmation becomes available.
Indicate case status (i.e., suspected, probable, confirmed) in the Required Comments section.
4. **Method of Confirmation**
Biopsy, slide, serology, culture, clinical, other. For example, heat injuries do not have laboratory criteria for diagnosis so indicate "clinical" in the method of confirmation field.
5. **Travel History**
Specify country where disease was probably acquired, when applicable. See individual case definitions to determine the time period for which reporting of travel destinations is required, generally 1-2 incubation periods.

6.3 COMMENTS

Text comments. Content will vary by condition; see case definitions for minimum suggested content.

Comments are important for data interpretation and should be provided whenever possible.

7.0 ICD-9 Codes & Synonyms

(Also refer to Section 3 on the use of ICD-9 codes)

Condition	Synonyms	ICD-9 Codes
Amebiasis		006, 006.0, 006.1, 006.2, 006.3, 006.4, 006.5, 006.6, 006.8, 006.9
Anthrax		022, 022.0, 022.1, 022.2, 022.3, 022.8, 022.9
Botulism	Infant botulism	005.1
Brucellosis	Malta fever; Mediterranean fever; Undulant fever	023, 023.0, 023.1, 023.2, 023.3, 023.8, 023.9
Campylobacter infection	Vibronic enteritis	008.43
Chlamydia trachomatis, genital infections		099.41
Cholera		001, 001.0, 001.1
Coccidioidomycosis	Desert fever / rheumatism; San Joaquin valley fever; Valley fever	114, 114.0, 114.1, 114.2, 114.3, 114.4, 114.5, 114.9
Cold weather injuries	Immersion foot; Trench foot	991.0, 991.1, 991.2, 991.3, 991.4, 991.6
Cryptosporidiosis		007.4
Cyclospora infection		007.5
Dengue fever	Breakbone fever; Dengue hemorrhagic fever	061, 065.4
Diphtheria		032, 032.0, 032.1, 032.2, 032.3
E. coli, Shiga toxin-producing		008.04
Ehrlichiosis / anaplasmosis	Senetsu fever	082.4, 082.40, 082.41, 082.49
Encephalitis, arboviral	Japanese B encephalitis; Tick-borne encephalitis (TBE); West Nile encephalitis	062, 062.0, 062.1, 062.2, 062.3, 062.4, 062.5, 062.8, 062.9, 063, 063.0, 063.1, 063.2, 063.8, 063.9, 066.41
Filariasis	Loa loa; Onchocerciasis	125, 125.0, 125.1, 125.2, 125.3, 125.9
Giardiasis		007.1
Gonorrhea		098, 098.0, 098.1, 098.4, 098.5, 098.6, 098.7, 098.8
Haemophilus influenzae, invasive disease	Hemophilis meningitis	038.41, 041.5, 320.0, 464.0, 482.2, 711.0
Hantavirus disease	Hemorrhagic fever with renal syndrome; Korean hemorrhagic fever	079.81

Condition	Synonyms	ICD-9 Codes
Heat injuries	Heat exhaustion	992.0, 992.3, 992.4, 992.5
Hemorrhagic fever	Crimean Congo fever; Ebola-Marburg disease; Guanarito virus; Junin virus; Kyasanur forest disease; Lassa fever; Machupo virus; Omsk hemorrhagic fever; Sabia virus	065, 065.0, 065.1, 065.2, 065.3, 065.4, 065.8, 065.9
Hepatitis A	Catarrhal jaundice; Epidemic hepatitis / jaundice; Infectious hepatitis	070.0, 070.1
Hepatitis B, acute & chronic	Serum hepatitis	070.2, 070.3
Hepatitis C,	Parenterally transmitted non-A non-B hepatitis; Post transfusion non-A non-B hepatitis	070.41, 070.51
Influenza		487, 487.0, 487.1, 487.8
Legionellosis	Legionnaires disease; Pontiac fever	482.84
Leishmaniasis	Kala-azar	085.0, 085.1, 085.2, 085.3, 085.4, 085.5, 085.9
Leprosy	Hansen disease	030, 030.0, 030.1, 030.2, 030.3, 030.8, 030.9
Leptospirosis	Hemorrhagic jaundice; Mud fever; Weil disease	100, 100.0, 100.8, 100.81, 100.89, 100.9
Listeriosis		027.0
Lyme disease	Tick-borne meningopolyneuritis	088.81
Malaria (all)		084.0, 084.1, 084.2, 084.3, 084.6
Measles	Hard measles; Morbilla; Red measles; Rubeola	055, 055.0, 055.1, 055.2, 055.7, 055.8, 055.9
Meningococcal disease	Cerebrospinal fever; Meningococcal meningitis	036.0, 036.1, 036.2
Mumps	Infectious parotitis	072, 072.0, 072.1, 072.2, 072.3, 072.7, 072.8, 072.9
Norovirus	Norwalk-like virus; Norwalk-like agent	008.63
Outbreak		136.9
Pertussis	Whooping cough	033, 033.0
Plague	Pestis	020, 020.0, 020.1, 020.2, 020.3, 020.4, 020.5, 020.8, 020.9
Poliomyelitis	Infant paralysis	045, 045.0, 045.1, 045.2, 045.9
Q fever	Query fever	083.0
Rabies, human	Hydrophobia; Lyssa	071
Relapsing fever		087, 087.0, 087.1, 087.9

Condition	Synonyms	ICD-9 Codes
Rheumatic fever, acute		390, 391.0, 391.1, 391.2, 391.8, 391.9, 392.0, 392.9
Rift valley fever		066.3
Rocky mountain spotted fever	Sao Paulo fever	082.0
Rubella	Congenital rubella syndrome; German measles	056, 056.0, 056.7, 056.8, 056.9, 771.0
Salmonellosis		003, 003.0
Schistosomiasis	Bilharziasis	120, 120.0, 120.1, 120.2, 120.3, 120.8, 120.9
Severe acute respiratory syndrome	SARS; SARS-CoV	079.82
Shigellosis	Bacillary dysentery	004, 004.0, 004.1, 004.2, 004.3, 004.8, 004.9
Smallpox		050, 050.0, 050.9
Streptococcus, group A, invasive		038.0, 041.01, 482.31
Syphilis	Lues	090, 091, 092, 093, 094, 095, 096, 097
Tetanus	Lockjaw	037
Toxic shock syndrome	Streptococcal toxic shock syndrome	040.82
Trichinosis	Trichinellosis; Trichiniasis	124
Trypanosomiasis	Chagas's disease; Sleeping sickness	086, 086.0, 086.1, 086.2, 086.3, 086.4, 086.5, 086.9
Tuberculosis, pulmonary		011, 011.0, 011.1, 011.2, 011.3, 011.4, 011.5, 011.6, 011.7, 011.8, 011.9
Tularemia	Deer fly fever; Rabbit fever	021, 021.0, 021.1, 021.2, 021.3, 021.8, 021.9
Typhoid	Enteric fever; Typhus abdominalis	002.0, 002.1, 002.2, 002.3, 002.9
Typhus fever	Boutonneuse fever; South African tick typhus; Tsutsugamushi; Typhus exanthematicus	080, 081.0, 081.1, 081.2, 081.9
Varicella	Chickenpox	052, 052.0, 052.1, 052.7, 052.8, 052.9
Yellow fever		060, 060.0, 060.1, 060.9

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