Commission Decision of 28 April 2008 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C(2008) 1589) (Text with EEA relevance) (2008/426/EC)

COMMISSION DECISION

of 28 April 2008

amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council

(notified under document number C(2008) 1589)

(Text with EEA relevance)

(2008/426/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community[(1)], and in particular Article 3(c) thereof,

Whereas:

(1) According to Article 2 of Commission Decision 2002/253/EC[(2)] the case definitions laid down in Annex to that Decision should be updated to the extent necessary on the basis of the latest scientific data.

(2) In accordance with Article 9 of the Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control[(3)] (ECDC), the ECDC provided, at the request of the Commission and in agreement with its Advisory Forum, a technical document on case definitions aiding the Commission in the development of intervention strategies in the field of surveillance and response. The technical document has been further published on the web site of the ECDC. The case definitions listed in the Annex to Decision 2002/253/EC should be updated on the basis of this contribution.

(3) Those case definitions have the purpose of facilitating the reporting on the diseases and special health issues listed in Annex I to Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council[(4)]. Decision 2002/253/EC however does not entail any reporting obligation.

(4) The measures provided for in this Decision are in accordance with the opinion of the Committee set up by Decision No 2119/98/EC,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2002/253/EC is replaced by the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 28 April 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX

EXPLANATION OF THE SECTIONS USED FOR THE DEFINITION AND CLASSIFICATION OF CASES

Clinical criteria

These should include common and relevant signs and symptoms of the disease which either individually or in combination constitutes a clear or indicative clinical picture of the disease. The clinical criteria give the general outline of the disease and do not necessarily indicate all the features needed for individual clinical diagnosis.

Laboratory criteria

Laboratory criteria should be a list of laboratory methods that are used to confirm a case. Usually only one of the listed tests will be enough to confirm the case. If a combination of methods is needed to meet the laboratory confirmation, this is specified. The type of specimen to be collected for the laboratory tests is only specified when only certain specimen types are considered relevant for the confirmation of a diagnosis. For some agreed exceptions, laboratory criteria for a probable case are included. This is a list of laboratory methods which can be used to support the diagnosis of a case but which are not confirmatory.

Epidemiological criteria and epidemiological link

Epidemiological criteria are deemed to have been met when an epidemiological link can be established.

Epidemiological link, during the incubation period, is defined as one of the six following:

— human to human transmission: Any person who has had contact with a laboratory confirmed human case in such a way as to have had the opportunity to acquire the infection,

— animal to human transmission: Any person who has had contact with an animal with a laboratory confirmed infection/colonisation in such a way as to have had the opportunity to acquire the infection,

— exposure to a common source: Any person who has been exposed to the same common source or vehicle of infection, as a confirmed human case,

— exposure to contaminated food/drinking water: Any person who has consumed food or drinking water with a laboratory confirmed contamination or a person who has consumed potentially contaminated products from an animal with a laboratory confirmed infection/colonisation,

— environmental exposure: Any person who has bathed in water or has had contact with a contaminated environmental source that has been laboratory confirmed,

— laboratory exposure: Any person working in a laboratory where there is a potential for exposure.

A person may be considered epidemiologically linked to a confirmed case if at least one case in the chain of transmission is laboratory confirmed. In case of an outbreak of faeco-oral or airborne transmitted infections, the chain of transmission does not necessarily need to be established to consider a case epidemiologically linked.

Transmission may occur by one or more of the following routes:

— airborne, by projection of aerosol from an infected person onto the mucous membranes while coughing, spitting, singing or talking, or when microbial aerosols dispersed into the atmosphere are inhaled by others,

— contact, direct contact with an infected person (faecal-oral, respiratory droplets, skin or sexual exposure) or animal (e.g. biting, touching) or indirect contact to infected materials or objects (infected fomites, body fluids, blood),

— vertical, from mother to child, often in utero, or as a result of the incidental exchange of body fluids usually during the perinatal period,

— vector transmission, indirect transmission by infected mosquitoes, mites, flies and other insects which transmit disease to humans through their bites,

— food or water, consumption of potentially contaminated food or drinking water.

Case classification

Cases will be classified as ‘possible’, ‘probable’ and ‘confirmed’. The incubation periods for diseases are given in the additional information to facilitate the assessment of the epidemiological link.

Possible case

Defined as a case that is classified as possible for reporting purposes. It is usually a case with the clinical criteria as described in the case definition without epidemiological or laboratory evidence of the disease in question. The definition of a possible case has high sensitivity and low specificity. It allows for detection of most cases but some false positives cases will be included into this category.

Probable case

Defined as a case that is classified as probable for reporting purposes. It is usually a case with clinical criteria and an epidemiological link as described in the case definition. Laboratory tests for probable cases are specified only for some diseases.

Confirmed case

Defined as a case that is classified as confirmed for reporting purposes. Confirmed cases should be laboratory confirmed and may fulfil the clinical criteria or not as described in the case definition. The definition of a confirmed case is highly specific and less sensitive; therefore most of the collected cases will be true cases although some will be missed.

The clinical criteria of some diseases do not allude to the fact that many acute cases are asymptomatic, (e.g. hepatitis A, B and C, campylobacter, salmonellosis) although these cases may still be important from a public health perspective on national level.

Confirmed cases will fall in one of the three subcategories listed below. These subcategories will be created during the analysis of data using the variables collected with the case information.

Laboratory-confirmed case with clinical criteria

The case meets the laboratory criteria for case confirmation and the clinical criteria included in the case definition.

Laboratory-confirmed case with unknown clinical criteria

The case meets the laboratory criteria for case confirmation but there is no information available regarding the clinical criteria (e.g. only laboratory report).

Laboratory-confirmed case without clinical criteria

The case meets the laboratory criteria for case confirmation but doesn't meet the clinical criteria in the case definition or is asymptomatic.

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Clinical criteria (AIDS)

Any person who has any of the clinical conditions as defined in the European AIDS case definition for:

— Adults and adolescents ≥ 13 years[5]

— Children < 13 years of age[6]

Laboratory criteria (HIV)

— Adults, adolescents and children aged ≥ 18 months

At least one of the following three:

— Positive result of a HIV screening antibody test or a combined screening test (HIV antibody and HIV p24 antigen) confirmed by a more specific antibody test (e.g. Western blot)

— Positive result of 2 EIA antibody test confirmed by a positive result of a further EIA test

— Positive results on two separate specimens from at least one of the following three:

— Detection of HIV nucleic acid (HIV-RNA, HIV-DNA)

— Demonstration of HIV by HIV p24 antigen test, including neutralisation assay

— Isolation of HIV

— Children aged < 18 months

Positive results on two separate specimens (excluding cord blood) from at least one of the following three:

— Isolation of HIV

— Detection of HIV nucleic acid (HIV-RNA, HIV-DNA)

— Demonstration of HIV by HIV p24 antigen test, including neutralisation assay in a child ≥1 month of age

Epidemiological criteria

NA

Case classification

A. Possible case

NA

B. Probable case

NA

C. Confirmed case

— HIV infection

Any person meeting the laboratory criteria for HIV infection

— AIDS

Any person meeting the clinical criteria for AIDS and the laboratory criteria for HIV infection

ANTHRAX (Bacillus anthracis)

Clinical criteria

Any person with at least one of the following clinical forms:

Cutaneous anthrax

At least one the following two:

— Papular or vesicular lesion
— Depressed black eschar with surrounding oedema

Gastrointestinal anthrax
— Fever or feverishness

AND at least one of the following two:
— Severe abdominal pain
— Diarrhoea

Inhalational anthrax
— Fever or feverishness

AND at least one of the following two:
— Acute respiratory distress
— Radiological evidence of mediastinal widening

Meningeal/meningoencephalitic anthrax
— Fever

AND at least one of the following three:
— Convulsions
— Loss of consciousness
— Meningeal signs

Anthrax septicaemia
Laboratory criteria
— Isolation of *Bacillus anthracis* from a clinical specimen
— Detection of *Bacillus anthracis* nucleic acid in a clinical specimen

Positive nasal swab without clinical symptoms does not contribute to a confirmed diagnosis of a case.

Epidemiological criteria

At least one of the following three epidemiological links:
— Animal to human transmission
— Exposure to a common source
— Exposure to contaminated food/drinking water

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

AVIAN INFLUENZA A/H5 OR A/H5N1 IN HUMANS

Clinical criteria

Any person with one of the following two:
— Fever AND signs and symptoms of acute respiratory infection
— Death from an unexplained acute respiratory illness

Laboratory criteria

At least one of the following three:

— Isolation of influenza A/H5N1 from a clinical specimen

— Detection of influenza A/H5 nucleic acid in a clinical specimen

— Influenza A/H5 specific antibody response (fourfold or greater rise or single high titre)

Epidemiological criteria

At least one of the following four:

— Human to human transmission by having been in close contact (within one metre) to a person reported as probable or confirmed case

— Laboratory exposure: where there is a potential exposure to influenza A/H5N1

— Close contact (within one metre) with an animal with confirmed A/H5N1 infection other than poultry or wild birds (e.g. cat or pig)

— Reside in or have visited an area where influenza A/H5N1 is currently suspected or confirmed[7] AND at least one of the following two:

  — Having been in close contact (within one metre) with sick or dead domestic poultry or wild birds[8] in the affected area

  — Having been in a home or a farm where sick or dead domestic poultry have been reported in the previous month in the affected area

Case classification

A. Possible case

Any person meeting the clinical and the epidemiological criteria

B. Probable case

Any person with a positive test for influenza A/H5 or A/H5N1 performed by a laboratory which is not a National Reference Laboratory participating in the EU Community Network of Reference Laboratories for human influenza (CNRL)

C. Nationally confirmed case

Any person with a positive test for influenza A/H5 or A/H5N1 performed by a National Reference Laboratory participating in the EU Community Network of Reference Laboratories for human influenza (CNRL)

D. WHO confirmed case

Any person with a laboratory confirmation by a WHO Collaborating Centre for H5

BOTULISM (Clostridium botulinum)

Clinical criteria

Any person with at least one of the following clinical forms:

Food-borne and wound botulism

At least one of the following two:

— Bilateral cranial nerve impairment (e.g. diplopia, blurred vision, dysphagia, bulbar weakness)

— Peripheral symmetric paralysis

Infant botulism

Any infant with at least one of the following six:

— Constipation
— Lethargy
— Poor feeding
— Ptosis
— Dysphagia
— General muscle weakness

The type of botulism usually encountered in infants (< 12 months of age) can affect children also over 12 months of age and occasionally adults, with altered gastrointestinal anatomy and microflora.

Laboratory criteria

At least one of the following two:

— Isolation of *C. botulinum* for infant botulism (stool) or wound botulism (wound) (isolation of *C. botulinum* in stool of adults not relevant for the diagnosis of food-borne botulism)
— Detection of botulinum toxin in a clinical specimen

Epidemiological criteria

At least one of the following two epidemiological links:

— Exposure to a common source (e.g. food, sharing of needles or other devices)
— Exposure to contaminated food/drinking water

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

BRUCELLOSIS (Brucella spp.)

Clinical criteria

Any person with fever

AND at least one of following *seven*:

— Sweating (profuse, malodorous, specially nocturnal)
— Chills
— Arthralgia
— Weakness
— Depression
— Headache
— Anorexia

Laboratory criteria

At least one of the following two:

— Isolation of *Brucella spp.* from a clinical specimen

— *Brucella* specific antibody response (Standard Agglutination Test, Complement Fixation, ELISA)

Epidemiological criteria

At least one of the following four epidemiological links:

— Exposure to contaminated food/drinking water
— Exposure to products from a contaminated animal (milk or milk products)
— Animal to human transmission (contaminated secretions or organs e.g. vaginal discharge, placenta)
— Exposure to a common source

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

CAMPYLOBACTERIOSIS (*Campylobacter spp.*)

Clinical criteria

Any person with at least one of the following three:

— Diarrhoea
— Abdominal pain
— Fever

Laboratory criteria

— Isolation of *Campylobacter spp.* from stool or blood

Differentiation of *Campylobacter spp.* should be performed if possible

Epidemiological criteria

At least one of the following five epidemiological links:

— Animal to human transmission
— Human to human transmission
— Exposure to a common source
— Exposure to contaminated food/drinking water
— Environmental exposure

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

CHLAMYDIAL INFECTION(Chlamydia trachomatis)INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)

Clinical criteria

Any person with at least one of the following clinical forms:

Chlamydial infection non-LGV

At least one of the following six:

— Urethritis
— Epididymitis
— Acute salpingitis
— Acute endometritis
— Cervicitis
— Proctitis

In newborn children at least one of the following two:

— Conjunctivitis
— Pneumonia

LGV

At least one of the following five:

— Urethritis
— Genital ulcer
— Inguinal lymphadenopathy
— Cervicitis
— Proctitis

Laboratory criteria

Chlamydial infection non-LGV

At least one of the following three:

— Isolation of *Chlamydia trachomatis* from a specimen of the ano-genital tract or from the conjunctiva
— Demonstration of *Chlamydia trachomatis* by DFA test in a clinical specimen
— Detection of *Chlamydia trachomatis* nucleic acid in a clinical specimen

LGV

At least one of the following two:

— Isolation of *Chlamydia trachomatis* from a specimen of the ano-genital tract or from the conjunctiva
— Detection of *Chlamydia trachomatis* nucleic acid in a clinical specimen

AND

— Identification of serovar (genovar) L1, L2 or L3

Epidemiological criteria

An epidemiological link by Human to human transmission (sexual contact or vertical transmission)

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the laboratory criteria

CHOLERA (*Vibrio cholerae*)
Clinical criteria

Any person with at least one of the following two:
— Diarrhoea
— Vomiting
Laboratory criteria
— Isolation of *Vibrio cholerae* from a clinical specimen

AND
— Demonstration of O1 or O139 antigen in the isolate

AND
— Demonstration of cholera-enterotoxin or the cholera-enterotoxin gene in the isolate
Epidemiological criteria

At least one of the following four epidemiological links:
— Exposure to a common source
— Human to human transmission
— Exposure to contaminated food/drinking water
— Environmental exposure
Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria
VARIANT CREUTZFELDT-JAKOB DISEASE (VCJD)
Preconditions
— Any person with a progressive neuropsychiatric disorder with a duration of illness of at least six months
— Routine investigations do not suggest an alternative diagnosis
— No history of exposure to human pituitary hormones or human dura mater graft
— No evidence of a genetic form of transmissible spongiform encephalopathy
Clinical criteria

Any person with at least four of the following five:
— Early psychiatric symptoms[9]
— Persistent painful sensory symptoms[10]

— Ataxia
— Myoclonus or chorea or dystonia
— Dementia

Diagnostic criteria

Diagnostic criteria for case confirmation:

— Neuropathological confirmation: spongiform change and extensive prion protein deposition with florid plaques throughout the cerebrum and cerebellum

Diagnostic criteria for a probable or a possible case:

— EEG does not show the typical appearance[11] of sporadic CJD[12] in the early stages of the illness
— Bilateral pulvinar high signal on MRI brain scan
— A positive tonsil biopsy[13]

Epidemiological criteria

An epidemiological link by human to human transmission (e.g. blood transfusion)

Case classification

A. Possible case

Any person fulfilling the preconditions

AND

— meeting the clinical criteria

AND

— a negative EEG for sporadic CJD[12]

B. Probable case

Any person fulfilling the preconditions

AND

— meeting the clinical criteria

AND

— a negative EEG for sporadic CJD[12]

AND

— a positive MRI brain scan

OR

Any person fulfilling the preconditions

AND

— a positive tonsil biopsy

C. Confirmed case

Any person fulfilling the preconditions

AND

— meeting the diagnostic criteria for case confirmation

CRYPTOSPORIDIOSIS (Cryptosporidium spp)

Clinical criteria

Any person with at least one of the following two:

— Diarrhoea

— Abdominal pain

Laboratory criteria

At least one of the following four:

— Demonstration of *Cryptosporidium* oocysts in stool

— Demonstration of *Cryptosporidium* in intestinal fluid or small-bowel biopsy specimens

— Detection of *Cryptosporidium* nucleic acid in stool

— Detection of *Cryptosporidium* antigen in stool

Epidemiological criteria

One of the following five epidemiological links:

— Human to human transmission

— Exposure to a common source

— Animal to human transmission

— Exposure to contaminated food/drinking water

— Environmental exposure

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

DIPHTHERIA (Corynebacterium diphtheriae and Corynebacterium ulcerans)

Clinical criteria

Any person with at least one of the following clinical forms:

Respiratory diphtheria:

An upper respiratory tract illness with fever AND one of the following two:

— Croup

OR

— an adherent membrane in at least one of the following three locations:

  — Tonsil

  — Pharynx

  — Nose

Nasal diphtheria:

— Uni- or bilateral nasal discharge initially clear and becoming bloody

Cutaneous diphtheria:

— Skin lesion

Diphtheria of other sites:

— Lesion of conjunctiva or mucous membranes

Laboratory criteria

— Isolation of toxin-producing *C. diphtheriae* or *C. ulcerans* from a clinical specimen

Epidemiological criteria

An epidemiological link by human to human transmission

Case classification

A. Possible case

Any person meeting the clinical criteria for respiratory diphtheria

B. Probable case

Any person meeting the clinical criteria for diphtheria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

ECHINOCOCCOSIS (*Echinococcus* spp)

Clinical criteria

Not relevant for surveillance purposes

Diagnostic criteria

At least one of the following five:

— Histopathology or parasitology compatible with *Echinococcus multilocularis* or *granulosus* (e.g. direct isvisualisation of the protoscolex in cyst fluid)

— Detection of *Echinoccocus granulosus* pathognomonic macroscopic morphology of cyst(s) in surgical specimens

— Typical organ lesions detected by imaging techniques (e.g.: computerised tomography, sonography, MRI) AND confirmed by a serological test

— *Echinococcus* spp. specific serum antibodies by high-sensitivity serological test AND confirmed by a high specificity serological test

— Detection of *Echinococcus multilocularis* or *granulosus* nucleic acid in a clinical specimen

Epidemiological criteria

NA

Case classification

A. Possible case

NA

B. Probable case

NA

C. Confirmed case

Any person meeting the diagnostic criteria

SHIGA/VERO TOXIN PRODUCING *ESCHERICHIA COLI* INFECTION (STEC/VTEC)

Clinical criteria

STEC/VTEC diarrhoea

Any person with at least one of the following two:

— Diarrhoea

— Abdominal pain

HUS

Any person with acute renal failure and at least one of the following two:

— Microangiopatic haemolytic anaemia

— Thrombocytopenia

Laboratory criteria

At least one of the following three:

— Isolation of Shigatoxin/Verotoxin (STEC/VTEC) producing *E. coli*

— Detection of stx1 or stx2 gene(s) nucleic acid

— Detection of free shigatoxins.

Only for HUS the following can be used as laboratory criterion to confirm STEC/VTEC:

— *E. coli* serogroups specific antibody response

Isolation and additional ischaracterisation by serotype, phage type, *eae* genes, and subtypes of stx_1/stx_2 should be performed if possible

Epidemiological criteria

At least one of the following *five epidemiological* links:

— Human to human transmission

— Exposure to a common source

— Animal to human transmission

— Exposure to contaminated food/drinking water

— Environmental exposure

Case classification

A. Possible case of STEC-associated HUS

Any person meeting the clinical criteria for HUS

B. Probable case of STEC/VTEC

Any person meeting the clinical criteria and with an epidemiological link or a laboratory confirmed case without clinical criteria

C. Confirmed case of STEC/VTEC

Any person meeting the clinical and the laboratory criteria

GIARDIASIS (Giardia lamblia)

Clinical criteria

Any person with at least one of the following four:

— Diarrhoea

— Abdominal pain

— Bloating

— Signs of malabsorption (e.g. steatorrhoea, weight loss)

Laboratory criteria

At least one of the following two:

— Demonstration of *Giardia lamblia* cysts or trophozoites in stool, duodenal fluid or small-bowel biopsy

— Demonstration of *Giardia lamblia* antigen in stool

Epidemiological criteria

At least one of the following *four* epidemiological links:

— Exposure to contaminated food/drinking water

— Human to human transmission

— Exposure to a common source

— Environmental exposure

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

GONORRHOEA (*Neisseria gonorrhoeae*)

Clinical criteria

Any person with at least one of the following eight:

— Urethritis

— Acute salpingitis

— Pelvic inflammatory disease

— Cervicitis

— Epididymitis

— Proctitis

— Pharyngitis

— Arthritis

OR

Any newborn child with conjunctivitis

Laboratory criteria

At least one of the following four:

— Isolation of *Neisseria gonorrhoeae* from a clinical specimen

— Detection of *Neisseria gonorrhoeae* nucleic acid in a clinical specimen

— Demonstration of *Neisseria gonorrhoeae* by a non amplified nucleic acid probe test in a clinical specimen

— Microscopic detection of intracellular gram negative diploccocci in an urethral male specimen

Epidemiological criteria

An epidemiological link by human to human transmission (sexual contact or vertical transmission)

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the laboratory criteria

HAEMOPHILUS INFLUENZAE (*Haemophilus influenzae*) MENINGITIS, INVASIVE DISEASE

Clinical criteria

Not relevant for surveillance purposes

Laboratory criteria

Laboratory criteria for case definition

At least one of the following two:

— Isolation of *Haemophilus influenzae* from a normally sterile site

— Detection of *Haemophilus influenzae* nucleic acid from a normally sterile site

Typing of the isolates should be performed, if possible

Epidemiological link

NA

Case Classification

A. Possible case

NA

B. Probable case

NA

C. Confirmed case

Any person meeting the laboratory criteria for case confirmation

HEPATITIS A (Hepatitis A Virus)

Clinical criteria

Any person with a discrete onset of symptoms (e.g. fatigue, abdominal pain, loss of appetite, intermittent nausea and vomiting)

AND

At least one of the following *three*:

— Fever

— Jaundice

— Elevated serum aminotransferase levels

Laboratory criteria

At least one of the following three:

— Detection of hepatitis A virus nucleic acid in serum or stool

— Hepatitis A virus specific antibody response

— Detection of hepatitis A virus antigen in stool

Epidemiological criteria

At least one of the following four:

— Human to human transmission

— Exposure to a common source

— Exposure to contaminated food/drinking water

— Environmental exposure

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

HEPATITIS (Hepatitis B virus)
B,
ACUTE
Clinical criteria

Any person with a discrete onset of symptoms (e.g. fatigue, abdominal pain, loss of appetite, intermittent nausea and vomiting)

AND

At least one of the following *three*:

— Fever

— Jaundice

— Elevated serum aminotransferase levels

Laboratory criteria

Hepatitis B virus core IgM antigen specific antibody response

Laboratory results need to be interpreted according to the vaccination status
Epidemiological criteria

An epidemiological link by human to human transmission (e.g. sexual contact, vertical transmission or blood transmission)
Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

HEPATITIS C (Hepatitis C virus)

Clinical criteria

Not relevant for surveillance purposes

Laboratory criteria

At least one of the following *two*:

— Detection of hepatitis C virus nucleic acid in serum

— Hepatitis C virus specific antibody response confirmed by a different antibody test

Epidemiological criteria

NA

Case classification

A. Possible case

NA

B. Probable case

NA

C. Confirmed case

Any person meeting the laboratory criteria

INFLUENZA (Influenza virus)

Clinical criteria

Any person with at least one of the following clinical forms:

Influenza-like illness (ILI)

— Sudden onset of symptoms

AND

— at least one of the following *four* systemic symptoms:
  — Fever or feverishness
  — Malaise
  — Headache
  — Myalgia

AND

— at least one of the following three respiratory symptoms:
  — Cough
  — Sore throat
  — Shortness of breath

Acute respiratory infection (ARI)

— Sudden onset of symptoms

AND

— At least one of the following *four* respiratory symptoms:
  — Cough
  — Sore throat
  — Shortness of breath

— Coryza

AND

— A clinician's judgement that the illness is due to an infection

Laboratory criteria

At least one the following four:

— Isolation of influenza virus from a clinical specimen
— Detection of influenza virus nucleic acid in a clinical specimen
— Identification of influenza virus antigen by DFA test in a clinical specimen
— Influenza specific antibody response

Sub typing of the influenza isolate should be performed, if possible

Epidemiological criteria

An epidemiological link by human to human transmission

Case classification

A. Possible case

Any person meeting the clinical criteria (ILI or ARI)

B. Probable case

Any person meeting the clinical criteria (ILI or ARI) and with an epidemiological link

C. Confirmed case

Any person meeting the clinical (ILI or ARI) and the laboratory criteria

LEGIONNAIRES' (Legionella spp.)

DISEASE

Clinical criteria

Any person with pneumonia

Laboratory criteria

— Laboratory criteria for case confirmation

At least one of the following *three:*

— Isolation of *Legionella spp*. from respiratory secretions or any normally sterile site
— Detection of *Legionella pneumophila* antigen in urine
— *Legionella pneumophila* serogroup 1 specific antibody response

— Laboratory criteria for a probable case

At least one of the following four:

— Detection of *Legionella pneumophila* antigen in respiratory secretions or lung tissue e.g. by DFA staining using monoclonal-antibody derived reagents
— Detection of *Legionella spp.* nucleic acid in a clinical specimen
— *Legionella pneumophila* non-serogroup 1 or other *Legionella spp.* specific antibody response
— *L. pneumophila* serogroup 1, other serogroups or other *Legionella species:* single high titre in specific serum antibody

Epidemiological criteria

At least one of the following two epidemiological links:

— Environmental exposure

— Exposure to the same common source

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria AND at least one positive laboratory test for a probable case OR an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria for case confirmation

LEPTOSPIROSIS (Leptospira interrogans)

Clinical criteria

Any person with

— Fever

OR

At least two of the following eleven:

— Chills

— Headache

— Myalgia

— Conjunctival suffusion

— Haemorrhages into skin and mucous membranes

— Rash

— Jaundice

— Myocarditis

— Meningitis

— Renal impairment

— Respiratory symptoms such as haemoptysis

Laboratory criteria

At least one of the following *four*:

— Isolation of *Leptospira interrogans* from a clinical specimen

— Detection of *Leptospira interrogans* nucleic acid in a clinical specimen

— Demonstration of *Leptospira interrogans* by immunofluorescence in a clinical specimen

— *Leptospira interrogans* specific antibody response

Epidemiological criteria

At least one of the following three epidemiological links:

— Animal to human transmission

— Environmental exposure

— Exposure to a common source

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

LISTERIOSIS (*Listeria monocytogenes*)
Clinical criteria

Any person with at least one of the following three:

— Listeriosis of newborns defined as

  Stillbirth

  OR

  At least one of the following *five* in the first month of life:
  - — Granulomatosis infantiseptica
  - — Meningitis or meningoencephalitis
  - — Septicaemia
  - — Dyspnoea
  - — Lesions on skin, mucosal membranes or conjunctivae

— Listeriosis in pregnancy defined as at least one of the following three:
  - — Abortion, miscarriage, stillbirth or premature birth
  - — Fever
  - — Influenza-like symptoms

— Other form of listeriosis defined as at least one of the following four:
  - — Fever
  - — Meningitis or meningoencephalitis
  - — Septicaemia
  - — isLocalised infections such as arthritis, endocarditis, and abscesses

Laboratory criteria

At least one of the following *two*:

— Isolation of *Listeria monocytogenes* from a normally sterile site

— Isolation of *Listeria monocytogenes* from a normally non-sterile site in a foetus, stillborn, newborn or the mother at or within 24 hours of birth

Epidemiological criteria

At least one of the following *three* epidemiological links:

— Exposure to a common source

— Human to human transmission (vertical transmission)

— Exposure to contaminated food/drinking water

Additional information

Incubation period 3-70 days, most often 21 days
Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the laboratory criteria

OR

Any mother with a laboratory confirmed listeriosis infection in her foetus, stillborn or newborn

MALARIA (*Plasmodium spp.*)
Clinical criteria

Any person with fever OR a history of fever
Laboratory criteria

At least one of the following three:
— Demonstration of malaria parasites by light microscopy in blood films
— Detection of *Plasmodium* nucleic acid in blood
— Detection of *Plasmodium* antigen

Differentiation of *Plasmodium spp*. should be performed if possible
Epidemiological criteria

NA
Case classification

A. Possible case

NA

B. Probable case

NA

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

MEASLES (Measles virus)
Clinical criteria

Any person with fever

AND
— Maculo-papular rash

AND at least one of the following *three*:
— Cough
— Coryza
— Conjunctivitis
Laboratory criteria

At least one of the following four:

— Isolation of measles virus from a clinical specimen

— Detection of measles virus nucleic acid in a clinical specimen

— Measles virus specific antibody response characteristic for acute infection in serum or saliva

— Detection of measles virus antigen by DFA in a clinical specimen using measles specific monoclonal antibodies

Laboratory results need to be interpreted according to the vaccination status. If recently vaccinated, investigate for wild virus

Epidemiological criteria

An epidemiological link by human to human transmission

Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person not recently vaccinated and meeting the clinical and the laboratory criteria

MENINGOCOCCAL (Neisserial meningitidis) DISEASE, INVASIVE

Clinical criteria

Any person with at least one of the following five:

— Fever

— Meningeal signs

— Petechial rash

— Septic shock

— Septic arthritis

Laboratory criteria

At least one of the following four:

— Isolation of *Neisseria meningitidis* from a normally sterile site, including purpuric skin lesions

— Detection of *Neisseria meningitidis* nucleic acid from a normally sterile site, including purpuric skin lesions

— Detection of *Neisseria meningitidis* antigen in CSF

— Detection of gram negative stained diplococcus in CSF

Epidemiological criteria

An epidemiological link by human to human transmission

Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the laboratory criteria

MUMPS (Mumps virus)
Clinical criteria

Any person with
— Fever

AND

At least two of the following three:
— Sudden onset of tender swelling of the parotid or other salivary glands
— Orchitis
— Meningitis
Laboratory criteria

At least one of the following three:
— Isolation of mumps virus from a clinical specimen
— Detection of mumps virus nucleic acid
— Mumps virus specific antibody response characteristic for acute infection in serum or saliva

Laboratory results need to be interpreted according to the vaccination status
Epidemiological criteria

An epidemiological link by human to human transmission
Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person not recently vaccinated and meeting the laboratory criteria

In case of recent vaccination: any person with detection of wild-type mumps virus strain

PERTUSSIS (Bordetella pertussis)
Clinical criteria

Any person with a cough lasting at least two weeks

AND

at least one of the following three:
— Paroxysms of coughing
— Inspiratory ‘whooping’

— Post-tussive vomiting

OR

Any person diagnosed as pertussis by a physician

OR

Apnoeic episodes in infants
Laboratory criteria

At least one of the following three:
— Isolation of *Bordetella pertussis* from a clinical specimen
— Detection of *Bordetella pertussis* nucleic acid in a clinical specimen
— *Bordetella pertussis* specific antibody response
Epidemiological criteria

An epidemiological link by human to human transmission
Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

PLAGUE(Yersinia pestis)
Clinical criteria

Any person with at least one of the following clinical forms:
Bubonic plague:
— Fever

AND
— Sudden onset of painful lymphadenitis
Septicaemic plague:
— Fever
Pneumonic plague:
— Fever

AND

At least one of the following *three*:
— Cough
— Chest pain
— Haemoptysis
Laboratory criteria

At least one of the following three:
— Isolation of *Yersinia pestis* from a clinical specimen
— Detection of *Yersinia pestis* nucleic acid from a clinical specimen (F1 antigen)

— *Yersinia pestis* anti-F1 antigen specific antibody response

Epidemiological criteria

At least one of the following four epidemiological links:

— Human to human transmission

— Animal to human transmission

— Laboratory exposure (where there is a potential exposure to plague)

— Exposure to a common source

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the laboratory criteria

PNEUMOCOCCAL INVASIVE DISEASE(S) (*Streptococcus pneumoniae*)

Clinical criteria

Not relevant for surveillance purposes

Laboratory criteria

At least one of the following three:

— Isolation of *S. pneumoniae* from a normally sterile site

— Detection of *S. pneumoniae* nucleic acid from a normally sterile site

— Detection of *S. pneumoniae* antigen from a normally sterile site

Epidemiological criteria

NA

Case classification

A. Possible case

NA

B. Probable case

NA

C. Confirmed case

Any person meeting the laboratory criteria

POLIOMYELITIS (Poliovirus)

Clinical criteria

Any person < 15 years of age with acute flaccid paralysis (AFP)

OR

Any person in whom polio is suspected by a physician

Laboratory criteria

At least one of the following three:

— Isolation of a polio virus and intratypic differentiation — Wild polio virus (WPV)

— Vaccine derived poliovirus (VDPV) (for the VDPV at least 85 % similarity with vaccine virus in the nucleotide sequences in the VP1 section)

— Sabin-like poliovirus: intratypic differentiation performed by a WHO-accredited polio laboratory (for the VDPV a >1 % up to 15 % VP1 sequence difference compared with vaccine virus of the same serotype)

Epidemiological criteria

At least one of the following two epidemiological links:

— Human to human transmission

— An history of travel to a polio-endemic area or an area with suspected or confirmed circulation of poliovirus

Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

Q (Coxiella burnetii)

FEVER

Clinical criteria

Any person with at least one of the following three:

— Fever

— Pneumonia

— Hepatitis

Laboratory criteria

At least one of the following three:

— Isolation of *Coxiella burnetii* from a clinical specimen

— Detection of *Coxiella burnetii* nucleic acid in a clinical specimen

— *Coxiella burnetii* specific antibody response (IgG or IgM phase II)

Epidemiological criteria

At least one of the following two epidemiological links:

— Exposure to a common source

— Animal to human transmission

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

RABIES (Lyssa virus)
Clinical criteria

Any person with an acute encephalomyelitis

AND

At least two of the following seven:
— Sensory changes referred to the site of a preceding animal bite
— Paresis or paralysis
— Spasms of swallowing muscles
— Hydrophobia
— Delirium
— Convulsions
— Anxiety
Laboratory criteria

At least one of the following four:
— Isolation of Lyssa virus from a clinical specimen
— Detection of Lyssa virus nucleic acid in a clinical specimen (e.g. saliva or brain tissue)
— Detection of viral antigens by a DFA in a clinical specimen
— Lyssa virus specific antibody response by virus isneutralisation assay in serum or CSF

Laboratory results need to be interpreted according to the vaccination or immunisation status
Epidemiological criteria

At least one of the following three epidemiological links:
— Animal to human transmission (animal with suspected or confirmed infection)
— Exposure to a common source (same animal)
— Human to human transmission (e.g. transplantation of organs)
Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

RUBELLA (Rubella virus)
Clinical criteria

Any person with sudden onset of generalised maculo-papular rash

AND

At least one of the following five:

— Cervical adenopathy
— Sub-occipital adenopathy
— Post-auricular adenopathy
— Arthralgia
— Arthritis

Laboratory criteria

— Laboratory criteria for case confirmation

At least one of the following three:

— Isolation of rubella virus from a clinical specimen
— Detection of rubella virus nucleic acid in a clinical specimen
— Rubella virus specific antibody response (IgG) in serum or saliva
— Laboratory criteria for probable case
— Rubella virus specific antibody response (IgM)[14]

Laboratory results need to be interpreted according to the vaccination status

Epidemiological criteria

An epidemiological link by human to human transmission

Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and with at least one of the following two:

— An epidemiological link
— Meeting the laboratory criteria for a probable case

C. Confirmed case

Any person not recently vaccinated and meeting the laboratory criteria for case confirmation

In case of recent vaccination, a person with detection of wild-type rubella virus strain

RUBELLA, CONGENITAL (including congenital rubella syndrome)

Clinical criteria

Congenital rubella infection (CRI)

No clinical criteria can be defined for CRI

Congenital rubella syndrome (CRS)

Any infant < 1 year of age or any stillborn with:

— At least two of the conditions listed in (A)

OR

— One in category (A) and one in category (B)

(A)

— Cataract(s)
— Congenital glaucoma

— Congenital heart disease
— Loss of hearing
— Pigmentary retinopathy

(B)
— Purpura
— Splenomegaly
— Microcephaly
— Developmental delay
— Meningo-encephalitis
— Radiolucent bone disease
— Jaundice that begins within 24 hours after birth

Laboratory criteria

At least one of the following four:
— Isolation of rubella virus from a clinical specimen
— Detection of Rubella virus nucleic acid
— Rubella virus specific antibody response (IgM)
— Persistence of rubella IgG between 6 and 12 months of age (at least two samples with similar concentration of rubella IgG)

Laboratory results need to be interpreted according to the vaccination status
Epidemiological criteria

Any infant or any stillborn born to a woman with a laboratory confirmed rubella infection during pregnancy by human to human transmission vertical transmission)
Case classification Congenital Rubella

A. Possible case

NA

B. Probable case

Any stillborn or infant either not tested OR with negative laboratory results with at least one of the following two:
— An epidemiological link AND at least one category ‘A’ CRS clinical criteria
— Meeting the clinical criteria for CRS

C. Confirmed case

Any stillborn meeting the laboratory criteria

OR

Any infant meeting the laboratory criteria AND at least one of the following two:
— An epidemiological link
— At least one category ‘A’ CRS clinical criteria

An infant with positive laboratory criteria only without a history of rubella in the mother during the pregnancy and without ‘A’ clinical criteria will therefore be reported as rubella case.

SALMONELLOSIS (Salmonella spp. other than S. Typhi and S. Paratyphi)
Clinical criteria

Any person with at least one of the following four:

— Diarrhoea

— Fever

— Abdominal pain

— Vomiting

Laboratory criteria

— Isolation of *Salmonella* (other than *S. Typhi* and *S. Paratyphi)* from stool or blood

Epidemiological criteria

At least one of the following five epidemiological links:

— Human to human transmission

— Exposure to a common source

— Animal to human transmission

— Exposure to contaminated food/drinking water

— Environmental exposure

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

SEVERE(SARS-coronavirus, SARS-CoV)
ACUTE
RESPIRATORY
SYNDROME —
SARS

Clinical criteria

Any person with fever or a history of fever

AND

At least one of the following *three*:

— Cough

— Difficulty in breathing

— Shortness of breath

AND

At least one of the following four:

— Radiographic evidence of pneumonia

— Radiographic evidence of acute respiratory distress syndrome

— Autopsy findings of pneumonia

— Autopsy findings of acute respiratory distress syndrome

AND

No alternative diagnosis which can fully explain the illness

Laboratory criteria

— Laboratory criteria for case confirmation

At least one of the following three:

— Isolation of virus in cell culture from any clinical specimen and identification of SARS-CoV using method such as RT-PCR

— Detection SARS-CoV nucleic acid in at least one of the following three:

— At least two different clinical specimens (e.g. nasopharyngeal swab and stool)

— The same clinical specimen collected on two or more occasions during the course of the illness (e.g. sequential nasopharyngeal aspirates)

— Two different assays or repeat RT-PCR using a new RNA extract from the original clinical sample on each occasion of testing

— SARS-CoV specific antibody response by one of the following two:

— Seroconversion by ELISA or IFA in acute and convalescent phase serum tested in parallel

— Fourfold or greater rise in antibody titre between acute and convalescent phase sera tested in parallel

— Laboratory criteria for a probable case

At least one of the following two:

— A single positive antibody test for SARS-CoV

— A positive PCR result for SARS-CoV on a single clinical specimen and assay

Epidemiological criteria

At least one of the following three:

— Any person with at least one of the following *three*:

— Employed in an occupation associated with an increased risk of SARS-CoV exposure (e.g. staff in a laboratory working with live SARS-CoV/SARS-CoV-like viruses or storing clinical specimens infected with SARS-CoV; persons with exposure to wildlife or other animals considered a reservoir of SARS-CoV, their excretions or secretions, etc.)

— Close contact[(15)] of one or more persons with confirmed SARS or under investigation for SARS

— History of travel to, or residence in, an area experiencing an outbreak of SARS

— Two or more health-care workers[(16)] with clinical evidence of SARS in the same health-care unit and with onset of illness in the same 10-day period

— Three or more persons (health-care workers and/or patients and/or visitors) with clinical evidence of SARS with onset of illness in the same 10-day period and epidemiologically linked to a healthcare facility

Case classification for the inter-epidemic period

Also applies during an outbreak in a non-affected country or area

A. Possible case

Any person meeting the clinical criteria and with an epidemiological link

B. Probable case

Any person meeting the clinical criteria AND with an epidemiological link AND meeting the laboratory criteria for a probable case

C. Nationally confirmed case

Any person meeting the clinical and the laboratory criteria for case confirmation where the testing has been performed at a national reference laboratory

D. Confirmed case

Any person meeting the clinical and the laboratory criteria for case confirmation where the testing has been performed at a WHO SARS verification and reference laboratory

Case classification during an outbreak

Applies during an outbreak in a country/area where at least one person has been laboratory confirmed by a WHO SARS verification and reference laboratory

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link to a nationally confirmed or a confirmed case

C. Nationally confirmed case

Any person meeting the clinical and the laboratory criteria for case confirmation where the testing has been performed at a national reference laboratory

D. Confirmed case

One of the following three:

— Any person meeting the clinical and the laboratory criteria for case confirmation where the testing has been performed at a WHO SARS verification and reference laboratory
— Any nationally confirmed case with an epidemiological link to a chain of transmission where at least one case has been independently verified by a WHO SARS reference and verification laboratory
— Any person meeting the clinical criteria and with laboratory criteria for probable case with an epidemiological link to a chain of transmission where at least one case has been independently verified by a WHO SARS reference and verification laboratory

SHIGELLOSIS (*Shigella spp.*)

Clinical criteria

Any person with at least one of the following four:

— Diarrhoea
— Fever
— Vomiting
— Abdominal pain

Laboratory criteria

— Isolation of *Shigella spp*. from a clinical specimen

Epidemiological criteria

At least one of the following five epidemiological links:

— Human to human transmission

— Exposure to a common source
— Animal to human transmission
— Exposure to contaminated food/drinking water
— Environmental exposure

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

SMALLPOX (Variola virus)

Clinical criteria

Any person with at least one of the following two:
— Fever

AND

Vesicles or firm pustules rash at the same stage of development with a centrifugal distribution
— Atypical presentations defined as at least one of the following four:
  — Haemorrhagic lesions
  — Flat velvety lesions not progressing to vesicles
  — Variola sine eruptione
  — Milder type

Laboratory criteria

— Laboratory criteria for case confirmation

  At least one of the following two laboratory tests:
  — Isolation of smallpox (variola virus) from a clinical specimen followed by sequencing (designated P4 laboratories only)
  — Detection of Variola virus nucleic acid in a clinical specimen followed by sequencing

Laboratory results need to be interpreted according to the vaccination status
— Laboratory criteria for a probable case
— Identification of orthopox virus particles by EM

Epidemiological criteria

At least one of the following two epidemiological links:
— Human to human transmission
— Laboratory exposure (where there is a potential exposure to Variola virus)

Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and with at least one of the following two:
— An epidemiological link to a confirmed human case by human to human transmission
— Meeting the laboratory criteria for a probable case

C. Confirmed case

Any person meeting the laboratory criteria for case confirmation

During an outbreak: any person meeting the clinical criteria and with an epidemiological link

SYPHILIS (Treponema pallidum)
Clinical criteria
— Primary syphilis

Any person with one or several (usually painless) chancres in the genital, perineal, anal area or mouth or pharyngeal mucosa or elsewhere extragenitally
— Secondary syphilis

Any person with at least one of the following three:
— Diffuse maculo-papular rash often involving palms and soles
— Generalised lymphadenopathy
— Condyloma lata
— Enanthema
— Allopetia diffusa
— Early latent syphilis (< 1 year)

A history of symptoms compatible with those of the earlier stages of syphilis within the previous 12 months
— Late latent syphilis (> 1 year)

Any person meeting laboratory criteria (specific serological tests)
Laboratory criteria

At least one of the following four laboratory tests:
— Demonstration of *Treponema pallidum* in lesion exudates or tissues by dark-field microscopic examination
— Demonstration of *Treponema pallidum* in lesion exudates or tissues by DFA test
— Demonstration of *Treponema* in lesion exudates or tissues by PCR
— Detection of *Treponema pallidum* antibodies by screening test (TPHA, TPPA or EIA) AND additionally detection of Tp-IgM antibodies (by IgM-ELISA, IgM immunoblot or 19S-IgM-FTA-abs) — confirmed by a second IgM assay
Epidemiological criteria
— Primary/secondary syphilis

An epidemiological link by human to human (sexual contact)
— Early latent syphilis (< 1 year)

An epidemiological link by human to human (sexual contact) within the 12 previous months
Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the laboratory criteria for case confirmation

SYPHILIS (Treponema pallidum)
CONGENITAL
AND
NEONATAL
Clinical criteria

Any infant < 2 years of age with at least one of the following 10:

— Hepatospenomegaly
— Mucocutaneous lesions
— Condyloma lata
— Persistent rhinitis
— Jaundice
— Pseudoparalysis (due to periostitis and osteochondritis)
— Central nervous involvement
— Anaemia
— Nephrotic syndrome
— Malnutrition

Laboratory criteria

— Laboratory criteria for case confirmation

  At least one of the following three:

  — Demonstration of *Treponema pallidum* by dark field microscopy in the umbilical cord, the placenta, a nasal discharge or skin lesion material
  — Demonstration of *Treponema pallidum* by DFA-TP in the umbilical cord, the placenta, a nasal discharge or skin lesion material
  — Detection of *Treponema pallidum* — specific IgM (FTA-abs, EIA)

  AND a reactive non treponemal test (VDRL, RPR) in the child's serum

— Laboratory criteria for a probable case

  At least one of the following three:

  — Reactive VDRL-CSF test result
  — Reactive non treponemal and treponemal serologic tests in the mother's serum
  — Infant's non treponemal antibody titre is fourfold or greater than the antibody titre in the mother's serum

Epidemiological criteria

Any infant with an epidemiological link by human to human transmission (vertical transmission)
Case classification

A. Possible case

NA

B. Probable case

Any infant or child meeting the clinical criteria and with at least one of the following two:
— An epidemiological link
— Meeting the laboratory criteria for a probable case

C. Confirmed case

Any infant meeting the laboratory criteria for case confirmation

TETANUS (*Clostridium tetani*)
Clinical criteria

Any person with at least two of the following three:
— Painful muscular contractions primarily of the masseter and neck muscles leading to facial spasms known as trismus and 'risus sardonicus'
— Painful muscular contractions of trunk muscles
— Generalised spasms, frequently position of opisthotonus
Laboratory criteria

At least one of the following two:
— Isolation of *Clostridium tetani* from an infection site
— Detection of tetanus toxin in a serum sample
Epidemiological criteria

NA
Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

TOXOPLASMOSIS, CONGENITAL (*Toxoplasma gondii*)
Clinical criteria

Not relevant for surveillance purposes
Laboratory criteria

At least one of the following four:
— Demonstration of *T. gondii* in body tissues or fluids
— Detection of *T. gondii* nucleic acid in a clinical specimen
— T. gondii specific antibody response (IgM, IgG, IgA) in a newborn
— Persistently stable IgG *T. gondii* titres in an infant (<12 months of age)
Epidemiological criteria

NA
Case classification

A. Possible case

NA

B. Probable case

NA

C. Confirmed case

Any infant meeting the laboratory criteria

TRICHINELLOSIS (*Trichinella* spp.)
Clinical criteria

Any person with at least three of the following six:
— Fever
— Muscle soreness and pain
— Diarrhoea
— Facial oedema
— Eosinophilia
— Subconjunctival, subungual and retinal haemorrhages
Laboratory criteria

At least one of the following two:
— Demonstration of *Trichinella* larvae in tissue obtained by muscle biopsy
— *Trichinella* specific antibody response (IFA test, ELISA or Western Blot)
Epidemiological criteria

At least one of the following two epidemiological links:
— Exposure to contaminated food (meat)
— Exposure to a common source
Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical criteria and the laboratory criteria

TUBERCULOSIS (*Mycobacterium tuberculosis* complex)
Clinical criteria

Any person with the following two:
— Signs, symptoms and/or radiological findings consistent with active tuberculosis in any site

AND
— A clinician's decision to treat the person with a full course of anti-tuberculosis therapy

OR

A case discovered post-mortem with pathological findings consistent with active tuberculosis that would have indicated anti-tuberculosis antibiotic treatment had the patient been diagnosed before dying

Laboratory criteria

— Laboratory criteria for case confirmation

At least one of the following two:

— Isolation of *Mycobacterium tuberculosis* complex (excluding *Mycobacterium bovis*-BCG) from a clinical specimen

— Detection of *Mycobacterium tuberculosis* complex nucleic acid in a clinical specimen AND positive microscopy for acid-fast bacilli or equivalent fluorescent staining bacilli on light microscopy

— Laboratory criteria for a probable case

At least one of the following three:

— Microscopy for acid-fast bacilli or equivalent fluorescent staining bacilli on light microscopy

— Detection of *Mycobacterium tuberculosis* complex nucleic acid in a clinical specimen

— Histological appearance of granulomata

Epidemiological criteria

NA

Case classification

A. Possible case

Any person meeting the clinical criteria

B. Probable case

Any person meeting the clinical criteria and the laboratory criteria for a probable case

C. Confirmed case

Any person meeting the clinical and the laboratory criteria for case confirmation

TULARAEMIA (*Francisella tularensis*)

Clinical criteria

Any person with at least one of the following clinical forms:

— *Ulceroglandular tularaemia*

— Cutaneous ulcer

AND

— Regional lymphadenopathy

— *Glandular tularaemia*

— Enlarged and painful lymph nodes without apparent ulcer

— *Oculoglandular tularaemia*

— Conjunctivitis

AND

— Regional lymphadenopathy

— *Oropharyngeal tularaemia*
  — Cervical lymphadenopathy

  AND

  at least one of the following three:
  — Stomatitis
  — Pharyngitis
  — Tonsillitis
— *Intestinal tularaemia*

  At least one of the following three:
  — Abdominal pain
  — Vomiting
  — Diarrhoea
— *Pneumonic tularaemia*
  — Pneumonia
— *Typhoidal tularaemia*

  At least one of the following two:
  — Fever without early localising signs and symptoms
  — Septicaemia

Laboratory criteria

At least one of the following three:
— Isolation of *Francisella tularensis* from a clinical specimen
— Detection of *Francisella tularensis* nucleic acid in a clinical specimen
— *Francisella tularensis* specific antibody response

Epidemiological criteria

At least one of the following three epidemiological links:
— Exposure to a common source
— Animal to human transmission
— Exposure to contaminated food/drinking water

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

TYPHOID (*Salmonella* Typhi/Paratyphi)
PARATYPHOID
FEVER

Clinical criteria

Any person with at least one of the following two:

— Onset of sustained fever
— At least two of the following four:
  — Headache
  — Relative bradycardia
  — Non productive cough
  — Diarrhoea, constipation, malaise or abdominal pain

Paratyphoid fever has the same symptoms as typhoid fever, however usually a milder course.
Laboratory criteria
— Isolation of *Salmonella* Typhi or Paratyphi from a clinical specimen
Epidemiological criteria

At least one of the following three epidemiological links:
— Exposure to a common source
— Human to human transmission
— Exposure to contaminated food/drinking water
Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria
VIRAL HAEMORRHAGIC FEVERS
Clinical criteria

Any person with at least one of the following two:
— Fever
— Haemorrhagic manifestations in various forms that may lead to multi-organ failure
Laboratory criteria

At least one of the following two:
— Isolation of specific virus from a clinical specimen
— Detection of specific virus nucleic acid in a clinical specimen and genotyping
Epidemiological criteria

At least one of the following:
— Travel in the last 21 days to a region where VHF cases are known or believed to have occurred
— Exposure within the last 21 days to a probable or confirmed case of a Viral Hemorrhagic Fever whose onset of illness was within the last six months
Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

WEST NILE FEVER (West Nile virus infection, WNV)

Clinical criteria

Any person with fever

OR

At least one of the following two:

— Encephalitis

— Meningitis

Laboratory criteria

— Laboratory test for case confirmation

At least one of the following four:

— Isolation of WNV from blood or CSF

— Detection of WNV nucleic acid in blood or CSF

— WNV specific antibody response (IgM) in CSF

— WNV IgM high titre AND detection of WNV IgG, AND confirmation by neutralisation

— Laboratory test for a probable case

WNV specific antibody response in serum

Laboratory results need to be interpreted according to flavivirus vaccination status

Epidemiological criteria

At least one of the following two epidemiological links:

— Animal to human transmission (residing, having visited or having been exposed to mosquito bites in an area where WNV is endemic in horses or birds)

— Human to human transmission (vertical transmission, blood transfusion, transplants)

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria AND with at least one of the following two:

— an epidemiological link

— a laboratory test for a probable case

C. Confirmed case

Any person meeting the laboratory criteria for case confirmation

YELLOW FEVER (Yellow fever virus)

Clinical criteria

Any person with fever

AND

At least one of the following two:

— Jaundice

— Generalised haemorrhage

Laboratory criteria

At least one of the following five:

— Isolation of yellow fever virus from a clinical specimen

— Detection of yellow fever virus nucleic acid

— Detection of yellow fever antigen

— Yellow fever specific antibody response

— Demonstration of typical lesions in post mortem liver histopathology

Laboratory results need to be interpreted according to flavivirus vaccination status

Epidemiological criteria

Travel in the last one week to a region where yellow fever cases are known or believed to have occurred

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person not recently vaccinated meeting the clinical and the laboratory criteria

In case of recent vaccination, a person with detection of wild-type yellow fever virus strain.

YERSINIOSIS (Yersinia enterocolitica, Yersinia pseudotuberculosis)

Clinical criteria

Any person with at least one of the following five:

— Fever

— Diarrhoea

— Vomiting

— Abdominal pain (pseudoappendicitis)

— Tenesmus

Laboratory criteria

— Isolation of human pathogenic *Yersinia enterocolitica* or *Yersinia pseudotuberculosis* from a clinical specimen

Epidemiological criteria

At least one of the following four epidemiological links:

— Human to human transmission

— Exposure to a common source

— Animal to human transmission

— Exposure to contaminated food

Case classification

A. Possible case

NA

B. Probable case

Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

(**1**) OJ L 268, 3.10.1998, p. 1. Decision as last amended by Commission Decision 2007/875/EC (OJ L 344, 28.12.2007, p. 48)

(**2**) OJ L 86, 3.4.2002, p. 44. Decision as amended by Decision 2003/534/EC (OJ L 184, 23.7.2003, p. 35)

(**3**) OJ L 142, 30.4.2004, p. 1

(**4**) OJ L 28, 3.2.2000, p. 50. Decision as last amended by Decision 2007/875/EC.

(**5**) European Centre for the Epidemiological Monitoring of AIDS. 1993 revision of the European AIDS surveillance case definition. AIDS Surveillance in Europe, Quarterly Report 1993; No 37: 23-28

(**6**) European Centre for the Epidemiological Monitoring of AIDS. European case definition for AIDS surveillance in children — revision 1995. HIV/AIDS Surveillance in Europe, Quarterly Report 1995; No 48: 46-53

(**7**) See World isOrganisation for Animal Health — OIE — and European Commission (SANCO) Animal Disease Notification System (ADNS), available at: http://www.oie.int/eng/en_index.htm and http://ec.europa.eu/food/animal/diseases/adns/index_en.htm#)

(**8**) This does not include seemingly well birds that have been killed, for example by hunting.

(**9**) Depression, anxiety, apathy, withdrawal, delusions.

(**10**) This includes both frank pain and/or dysaesthesia.

(**11**) The typical appearance of the EEG in sporadic CJD consists of generalised periodic complexes at approximately one per second. These may occasionally be seen in the late stages of VCJD.

(**12**) The typical appearance of the EEG in sporadic CJD consists of generalised periodic complexes at approximately one per second. These may occasionally be seen in the late stages of VCJD.

(**13**) Tonsil biopsy is not recommended routinely nor in cases with EEG appearances typical of sporadic CJD, but may be useful in suspect cases in which the clinical features are compatible with VCJD and MRI does not show pulvinar high signal.

(**14**) When rubella in pregnancy is suspected, further confirmation of a positive rubella IgM results is required (e.g. a rubella specific IgG avidity test showing a low avidity). In certain situations, such as confirmed rubella outbreaks detection of rubella virus IgM can be considered confirmatory in non-pregnant cases.

(**15**) A close contact is a person who has cared for, lived with, or having had direct contact with the respiratory secretions, body fluids and/or excretions (e.g. faeces) of cases of SARS.

(**16**) In this context the term ‘health-care worker’ includes all hospital staff. The definition of the health care unit in which the cluster occurs will depend on the local situation. Unit size may range from an entire health care facility if small, to a single department or ward of a large tertiary hospital.

Status:
Point in time view as at 28/04/2008.

Changes to legislation:
Commission Decision of 28 April 2008 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document number C(2008) 1589) (Text with EEA relevance) (2008/426/EC) is up to date with all changes known to be in force on or before 09 December 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.