Commission Implementing Decision of 8 August 2012 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 C(2012) 5538) (Text with EEA relevance) (2012/506/EU)

COMMISSION IMPLEMENTING DECISION

of 8 August 2012

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 C(2012) 5538)

(Text with EEA relevance)

(2012/506/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 the 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 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, a scientific opinion on case definitions aiding the Commission and the Member States in the development of intervention strategies in the field of surveillance of and response to communicable diseases.

(3) The case definitions already listed in the Annex to Decision 2002/253/EC for HIV/AIDS, diphtheria, Haemophilus influenzae (invasive disease), hepatitis B and C, meningococcal disease, mumps, legionellosis, congenital rubella, shiga toxin/verocytotoxin producing Escherichia coli infection (STEC/VTEC), salmonellosis and leptospirosis should be updated on the basis of that scientific opinion provided by ECDC.

(4) A generic case definition of antimicrobial resistance, a generic definition of nosocomial infections, a number of specific case definitions of nosocomial infections, and a case

definition for tick-borne encephalitis should also be added to the Annex to Decision 2002/253/EC on the basis of that scientific opinion provided by ECDC.

(5) For the purpose of clarity, it is appropriate to restructure the Annex to Decision 2002/253/EC in order to ensure that case definitions for communicable diseases are in a separate list from those for special health issues, and that, within each list, the case definitions appear in numerical order.

(6) 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, 8 August 2012.

For the Commission

John DALLI

Member of the Commission

ANNEX

1. EXPLANATION OF THE SECTIONS USED IN THE DEFINITION AND CLASSIFICATION OF CASES

Clinical criteria

Clinical criteria 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. They give the general outline of the disease and do not necessarily indicate all the features needed for individual clinical diagnosis.

Laboratory criteria

Laboratory criteria are 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. Laboratory criteria for a probable case are included for some agreed exceptional cases. Those laboratory criteria consist of 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, means one of the following six:

— Human to human transmission	:	the fact that a person 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	:	the fact that a person 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	:	the fact that a person has been exposed to the same common source or vehicle of infection, as a confirmed human case
— Exposure to contaminated food/drinking water	:	the fact that a person has consumed food or drinking water with a laboratory confirmed contamination or has consumed potentially contaminated products from an animal with a laboratory confirmed infection/colonisation
— Environmental exposure	:	the fact that a person has bathed in water or has had contact with a contaminated environmental source that has been laboratory confirmed
— Laboratory exposure	:	the fact that a person has worked 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 are 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

A possible case means a case classified as possible for reporting purposes. It is usually a case meeting the clinical criteria as described in the case definition without epidemiological or laboratory evidence of the disease in question. The definition of a case as possible 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

A probable case means a case 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

A confirmed case means a case classified as confirmed for reporting purposes. Confirmed cases are laboratory confirmed and may or may not fulfil the clinical criteria as described in the case definition. The definition of a case as confirmed 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, campylobacteriosis, salmonellosis) although these cases may still be important from a public health perspective on national level.

Confirmed cases fall in one of the three subcategories listed below. They will be assigned to one of those subcategories during the analysis of data using the variables collected within the context of 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.

2. CASE DEFINITIONS OF COMMUNICABLE DISEASES

2.1. 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 ≥ 15 years

— Children < 15 years of age

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

2.2. 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

2.3. 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 (four-fold 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 1 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 1 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[(4)] AND at least one of the following two:

  — Having been in close contact (within 1 metre) with sick or dead domestic poultry or wild birds[(5)] 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

2.4. 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 *Clostridium botulinum* for infant botulism (stool) or wound botulism (wound) (isolation of *Clostridium 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

2.5. 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

2.6. 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

2.7. 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

2.8. 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

2.9. CREUTZFELDT-JAKOB DISEASE, VARIANT (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[6]

— Persistent painful sensory symptoms[7]

— 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[8] of sporadic CJD[9] in the early stages of the illness

— Bilateral pulvinar high signal on MRI brain scan

— A positive tonsil biopsy[10]

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[11]

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

2.10. 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

2.11. DIPHTHERIA (*Corynebacterium diphtheriae, Corynebacterium ulcerans* and *Corynebacterium pseudotuberculosis*)

Clinical Criteria

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

An upper respiratory tract illness with laryngitis or nasopharyngitis or tonsillitis

AND

an adherent membrane/pseudomembrane
Mild Respiratory Diphtheria:

An upper respiratory tract illness with laryngitis or nasopharyngitis or tonsillitis

WITHOUT

an adherent membrane/pseudomembrane.
Cutaneous Diphtheria:

Skin lesion
Diphtheria of other sites:

Lesion of conjunctiva or mucous membranes

Laboratory Criteria

Isolation of toxin-producing *Corynebacterium diphtheriae, Corynebacterium ulcerans* or *Corynebacterium pseudotuberculosis* from a clinical specimen.

Epidemiological Criteria

At least one of the following epidemiological links:

— Human to human transmission

— Animal to human transmission

Case Classification

A. **Possible case**

Any person meeting the clinical criteria for classical respiratory diphtheria

B. **Probable case**

Any person meeting the clinical criteria for diphtheria (Classic Respiratory Diphtheria, Mild Respiratory Diphtheria, Cutaneous Diphtheria, Diphtheria of other sites) with an epidemiological link to a human confirmed case or with an epidemiological link to animal to human transmission

C. **Confirmed case**

Any person meeting the laboratory criteria AND at least one of the clinical forms

2.12. 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 visualisation 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

2.13. 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

2.14. 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 a 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

2.15. HAEMOPHILUS INFLUENZAE, INVASIVE DISEASE (*Haemophilus influenzae*)

Clinical Criteria

Not relevant for surveillance purposes

Laboratory Criteria

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

Epidemiological Criteria NA

Case Classification

A. **Possible case** NA

B. **Probable case** NA

C. **Confirmed case**

Any person meeting the laboratory criteria

2.16. 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

2.17. HEPATITIS B (Hepatitis B virus)

Clinical Criteria

Not relevant for surveillance purposes

Laboratory Criteria

Positive results of at least one or more of the following tests or combination of tests:

— IgM hepatitis B core antibody (anti-HBc IgM)
— Hepatitis B surface antigen (HBsAg)
— Hepatitis B e antigen (HBeAg)
— Hepatitis B nucleic acid (HBV-DNA)

Epidemiological Criteria

Not relevant for surveillance purposes

Case Classification

A. **Possible case** NA

B. **Probable case** NA

C. **Confirmed case**

Any person meeting the laboratory criteria

2.18. HEPATITIS C (Hepatitis C virus)

Clinical Criteria

Not relevant for surveillance purposes

Laboratory Criteria

At least one of the following three:

— Detection of hepatitis C virus nucleic acid (HCV RNA)
— Detection of hepatitis C virus core antigen (HCV-core)
— Hepatitis C virus specific antibody (anti-HCV) response confirmed by a confirmatory (e.g. immunoblot) antibody test in persons older than 18 months without evidence of resolved infection)

Epidemiological Criteria NA

Case Classification

A. **Possible case** NA

B. **Probable case** NA

C. **Confirmed case**

Any person meeting the laboratory criteria

2.19. 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

2.20. INFLUENZA A(H1N1)

Clinical criteria

Any person with one of the following three:

— fever > 38 °C AND signs and symptoms of acute respiratory infection

— pneumonia (severe respiratory illness)
— death from an unexplained acute respiratory illness

Laboratory criteria

At least one of the following tests:

— RT-PCR
— viral culture (requiring BSL 3 facilities)
— four-fold rise in novel influenza virus A(H1N1) specific neutralising antibodies (implies the need for paired sera, from acute phase illness and then at convalescent stage 10-14 days later minimum)

Epidemiological criteria

At least one of the following three in the seven days before disease onset:

— a person who was a close contact to a confirmed case of novel influenza A(H1N1) virus infection while the case was ill
— a person who has travelled to an area where sustained human-to-human transmission of novel influenza A(H1N1) is documented
— a person working in a laboratory where samples of the novel influenza A(H1N1) virus are tested

Case classification

A. **Case under investigation**

Any person meeting the clinical and epidemiological criteria

B. **Probable case**

Any person meeting the clinical AND epidemiological criteria AND with a laboratory result showing positive influenza A infection of an unsubtypable type

C. **Confirmed case**

Any person meeting the laboratory criteria for confirmation

2.21. LEGIONNAIRES' DISEASE (*Legionella* spp.)

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
— Significant rise in specific antibody level to *Legionella pneumophila* serogroup 1 in paired serum samples

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 respiratory secretions, lung tissue or any normally sterile site

— Significant rise in specific antibody level to *Legionella pneumophila* other than serogroup 1 or other *Legionella* spp. in paired serum samples
— Single high level of specific antibody to *Legionella pneumophila* serogroup 1 in serum

Epidemiological Criteria NA

Case Classification

A. **Possible case** NA

B. **Probable case**

Any person meeting the clinical criterion AND at least one laboratory criterion for a probable case

C. **Confirmed case**

Any person meeting the clinical criterion AND at least one laboratory criterion for a confirmed case

2.22. LEPTOSPIROSIS (*Leptospira* spp.)

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* or any other pathogenic *Leptospira* spp. from a clinical specimen
— Detection of *Leptospira interrogans* or any other pathogenic *Leptospira* spp. nucleic acid in a clinical specimen
— Demonstration of *Leptospira interrogans* or any other pathogenic *Leptospira* spp. by immunofluorescence in a clinical specimen
— *Leptospira interrogans* or any other pathogenic *Leptospira* spp. 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

2.23. 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
  — Localised 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

2.24. 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

2.25. 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

2.26. MENINGOCCOCAL DISEASE, INVASIVE (*Neisseria meningitidis*)

Clinical Criteria

Any person with at least one of the following symptoms:

— Meningeal signs
— Haemorrhagic rash
— Septic shock
— Septic arthritis

Laboratory Criteria

At least one of the following four:

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

2.27. MUMPS (Mumps virus)

Clinical Criteria

Any person with

— Fever

AND

At least one of the following three:

— Sudden onset of unilateral or bilateral tender swelling of the parotid or other salivary glands without other apparent cause

— 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

2.28. 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

2.29. 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

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

Clinical Criteria

Not relevant for surveillance purposes

Laboratory Criteria

At least one of the following three:

— Isolation of *Streptococcus pneumoniae* from a normally sterile site

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

— Detection of *Streptococcus 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

2.31. POLIOMYELITIS (Polio virus)

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

2.32. Q FEVER (*Coxiella burnetii*)

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

2.33. 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 neutralisation 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

2.34. 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[(13)])

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

2.35. 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 of the conditions listed in the 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 of the conditions listed in the category 'A' CRS clinical criteria

2.36. SALMONELLOSIS (*Salmonella* spp. other than *Salmonella typhi* and *Salmonella 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 *Salmonella typhi* and *Salmonella paratyphi*) from stool, urine, body site (e.g. infected wound) or any normally sterile body fluids and tissues (e.g. blood, CSF, bone, synovial fluid, etc.)

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

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

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
    - Four-fold 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[14] 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[15] 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

2.38. SHIGA TOXIN/VEROCYTO-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 four:

— Isolation of an *Escherichia coli* strain that produces Shigatoxin (Stx) or harbours *stx1* or *stx2* gene(s)

— Isolation of non-sorbitol-fermenting (NSF) *Escherichia coli* O157 (without Stx or *stx* gene testing)

— Direct detection of *stx1* or *stx2* gene(s) nucleic acid (without strain isolation)

— Direct detection of free Stx in faeces (without strain isolation)

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

— *Escherichia coli* serogroup-specific (LPS) antibody response

Isolation of an STEC/VTEC strain and additional characterisation by serotype, phage type, *eae* genes, and subtypes of *stx1/stx2* 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

C. **Confirmed case of STEC/VTEC**

Any person meeting the clinical and the laboratory criteria

2.39. 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

2.40. 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

2.41. 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 five:

— 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

2.42. SYPHILIS, CONGENITAL AND NEONATAL (*Treponema pallidum*)

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 four-fold 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

2.43. 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

2.44. TICK-BORNE ENCEPHALITIS (TBE virus)

Clinical Criteria

Any person with symptoms of inflammation of the CNS (e.g. meningitis, meningo-encephalitis, encephalomyelitis, encephaloradiculitis)

Laboratory Criteria[16]

— Laboratory criteria for case confirmation:

At least one of the following five:

— TBE specific IgM AND IgG antibodies in blood
— TBE specific IgM antibodies in CSF
— Sero-conversion or four-fold increase of TBE-specific antibodies in paired serum samples
— Detection of TBE viral nucleic acid in a clinical specimen,
— Isolation of TBE virus from clinical specimen

— Laboratory criteria for a probable case:

Detection of TBE-specific IgM-antibodies in a unique serum sample

Epidemiological Criteria

Exposure to a common source (unpasteurised dairy products)

Case Classification

A. **Possible case** NA

B. **Probable case**

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

OR

Any person meeting the clinical criteria and with an epidemiological link

C. **Confirmed case**

Any person meeting the clinical and laboratory criteria for case confirmation

2.45. TOXOPLASMOSIS, CONGENITAL (*Toxoplasma gondii*)

Clinical Criteria

Not relevant for surveillance purposes

Laboratory Criteria

At least one of the following four:

— Demonstration of *Toxoplasma gondii* in body tissues or fluids
— Detection of *Toxoplasma gondii* nucleic acid in a clinical specimen
— *Toxoplasma gondii* specific antibody response (IgM, IgG, IgA) in a newborn
— Persistently stable IgG *Toxoplasma 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

2.46. 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

2.47. 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

2.48. 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

2.49. TYPHOID/PARATYPHOID FEVER (*Salmonella typhi/paratyphi*)

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

2.50. VIRAL HAEMORRHAGIC FEVERS (VHF)

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 VHF 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

2.51. 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

2.52. 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 1 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

2.53. 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

3. **CASE DEFINITIONS OF SPECIAL HEALTH ISSUES**

3.1. GENERAL CASE DEFINITION OF NOSOCOMIAL INFECTION (OR ‘HEALTHCARE-ASSOCIATED INFECTION’)

A nosocomial infection associated to the current hospital stay is defined as infection that matches one of the case definitions AND

— the onset of symptoms was on Day 3 or later (day of admission = Day 1) of the current hospital admission OR
— the patient underwent surgery on day 1 or day 2 and develops symptoms of a Surgical Site Infection before day 3 OR
— an invasive device was placed on day 1 or day 2 resulting in an HAI before day 3

A nosocomial infection associated to a previous hospital stay is defined as infection that matches one of the case definitions

AND

— the patient presents with an infection but has been readmitted less than two days after a previous admission to an acute care hospital

OR

— the patient has been admitted with an infection that meets the case definition of a Surgical Site Infection i.e. the SSI occurred within 30 days of the operation (or in the case of surgery involving an implant was a deep or organ/space SSI that developed within a year of the operation) and the patient either has symptoms that meet the case definition and/or is on antimicrobial treatment for that infection

OR

— the patient has been admitted (or develops symptoms within two days) with *Clostridium difficile* infection less than 28 days from a previous discharge from an acute care hospital.

For the purpose of point prevalence surveys, an active nosocomial infection present on the day of the survey is defined as an infection for which signs and symptoms of the infection are present on the survey date or signs and symptoms were present in the past and the patient is (still) receiving treatment for that infection on the survey date. The presence of symptoms and signs should be verified until the start of the treatment in order to determine whether the treated infection matches one of the case definitions of nosocomial infection

3.1.1. *BJ: BONE AND JOINT INFECTION*

BJ-BONE: Osteomyelitis

Osteomyelitis must meet at least one of the following criteria:

— Patient has organisms cultured from bone

— Patient has evidence of osteomyelitis on direct examination of the bone during a surgical operation or histopathologic examination

— Patient has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), localised swelling, tenderness, heat, or drainage at suspected site of bone infection

AND at least one of the following:

— organisms cultured from blood

— positive blood antigen test (e.g. *Haemophilus.influenzae, Streptococcus pneumoniae*)

— radiographic evidence of infection (e.g. abnormal findings on x-ray, CT scan, MRI, radiolabel scan [gallium, technetium, etc.]).

Note reporting instruction:

Report mediastinitis following cardiac surgery that is accompanied by osteomyelitis as surgical site infection-organ/space (SSI-O).

BJ-JNT: Joint or bursa

Joint or bursa infections must meet at least one of the following criteria:

— Patient has organisms cultured from joint fluid or synovial biopsy

— Patient has evidence of joint or bursa infection seen during a surgical operation or histopathologic examination

— Patient has at least two of the following signs or symptoms with no other recognised cause: joint pain, swelling, tenderness, heat, evidence of effusion or limitation of motion

AND at least one of the following:

— organisms and white blood cells seen on Gram’s stain of joint fluid

— positive antigen test on blood, urine, or joint fluid

— cellular profile and chemistries of joint fluid compatible with infection and not explained by an underlying rheumatologic disorder
— radiographic evidence of infection (e.g. abnormal findings on x-ray, CT scan, MRI, radiolabel scan [gallium, technetium, etc.])

BJ-DISC: Disc space infection

Vertebral disc space infection must meet at least one of the following criteria:
— Patient has organisms cultured from vertebral disc space tissue obtained during a surgical operation or needle aspiration
— Patient has evidence of vertebral disc space infection seen during a surgical operation or histopathologic examination
— Patient has fever (> 38 °C) with no other recognised cause or pain at the involved vertebral disc space
— AND radiographic evidence of infection, (e.g. abnormal findings on x-ray, CT scan, MRI, radiolabel scan [gallium, technetium, etc.]).

Patient has fever (> 38 °C) with no other recognised cause and pain at the involved vertebral disc space
— AND positive antigen test on blood or urine (e.g. *Haemophilus influenzae, Streptococcus pneumoniae, Neisseria meningitidis*, or Group B *Streptococcus*).

3.1.2. *BSI: BLOODSTREAM INFECTION*

BSI: Laboratory-confirmed bloodstream infection

One positive blood culture for a recognised pathogen

OR

Patient has at least one of the following signs or symptoms: fever (> 38 °C), chills, or hypotension

AND Two positive blood cultures for a common skin contaminant (from two separate blood samples, usually within 48 hours)

Skin contaminants = coagulase-negative staphylococci, *Micrococcus* spp., *Propionibacterium acnes, Bacillus* spp., *Corynebacterium* spp.

Source of bloodstream infection:

— Catheter-related : the same micro-organism was cultured from the catheter or symptoms improve within 48 hours after removal of the catheter (C-PVC: peripheral catheter, C-CVC: central venous catheter (note: report C-CVC or C-PVC BSI as CRI3-CVC or CRI3-PVC respectively if microbiologically confirmed, see CRI3 definition)).
— Secondary to another infection : the same micro-organism was isolated from another infection site or strong clinical evidence exists that bloodstream infection was secondary to another infection site, invasive diagnostic procedure or foreign body
  — Pulmonary (S-PUL)
  — Urinary tract infection (S-UTI)
  — Digestive tract infection (S-DIG)
  — SSI (S-SSI): surgical site infection
  — Skin and soft tissue (S-SST)
  — Other (S-OTH)

— Unknown origin (UO) : None of the above, bloodstream infection of unknown origin (verified during survey and no source found)
— Unknown (UNK) : No information available about the source of the bloodstream infection or information missing

3.1.3. *CNS: CENTRAL NERVOUS SYSTEM INFECTION*

CNS-IC: Intracranial infection (brain abscess, subdural or epidural infection, encephalitis)

Intracranial infection must meet at least one of the following criteria:
— Patient has organisms cultured from brain tissue or dura
— Patient has an abscess or evidence of intracranial infection seen during a surgical operation or histopathologic examination
— Patient has at least two of the following signs or symptoms with no other recognised cause: headache, dizziness, fever (> 38 °C), localising neurologic signs, changing level of consciousness, or confusion

AND at least one of the following:
— organisms seen on microscopic examination of brain or abscess tissue obtained by needle aspiration or by biopsy during a surgical operation or autopsy
— positive antigen test on blood or urine
— radiographic evidence of infection, (e.g. abnormal findings on ultrasound, CT scan, MRI, radionuclide brain scan, or arteriogram)
— diagnostic single antibody titer (IgM) or four-fold increase in paired sera (IgG) for pathogen

AND if diagnosis is made antemortem, physician institutes appropriate antimicrobial therapy.
Note reporting instruction:

If meningitis and a brain abscess are present together, report the infection as IC

CNS-MEN: Meningitis or ventriculitis

Meningitis or ventriculitis must meet at least one of the following criteria:
— Patient has organisms cultured from cerebrospinal fluid (CSF)
— Patient has at least one of the following signs or symptoms with no other recognised cause: fever (> 38 °C), headache, stiff neck, meningeal signs, cranial nerve signs, or irritability

AND at least one of the following:
— increased white cells, elevated protein, and/or decreased glucose in CSF
— organisms seen on Gram's stain of CSF
— organisms cultured from blood
— positive antigen test of CSF, blood, or urine
— diagnostic single antibody titer (IgM) or four-fold increase in paired sera (IgG) for pathogen

AND if diagnosis is made antemortem, physician institutes appropriate antimicrobial therapy.
Note reporting instructions:
— Report CSF shunt infection as SSI if it occurs ≤ 1 year of placement; if later or after manipulation/access of the shunt, report as CNS-MEN
— Report meningoencephalitis as MEN
— Report spinal abscess with meningitis as MEN

CNS-SA: Spinal abscess without meningitis

An abscess of the spinal epidural or subdural space, without involvement of the cerebrospinal fluid or adjacent bone structures, must meet at least one of the following criteria:

— Patient has organisms cultured from abscess in the spinal epidural or subdural space

— Patient has an abscess in the spinal epidural or subdural space seen during a surgical operation or at autopsy or evidence of an abscess seen during a histopathologic examination

— Patient has at least one of the following signs or symptoms with no other recognised cause: fever (> 38 °C), back pain, focal tenderness, radiculitis, paraparesis, or paraplegia

AND at least one of the following:

— organisms cultured from blood

— radiographic evidence of a spinal abscess (e.g. abnormal findings on myelography, ultrasound, CT scan, MRI, or other scans [gallium, technetium, etc.])

AND if diagnosis is made antemortem, physician institutes appropriate antimicrobial therapy
Note reporting instruction:

Report spinal abscess with meningitis as meningitis (CNS-MEN)

3.1.4. *CRI: CATHETER-RELATED INFECTION*[17]

CRI1-CVC: Local CVC-related infection (no positive blood culture)

— quantitative CVC culture ≥ 10^3 CFU/ml or semi-quantitative CVC culture > 15 CFU

— AND pus/inflammation at the insertion site or tunnel

CRI1-PVC: Local PVC-related infection (no positive blood culture)

— quantitative PVC culture ≥ 10^3 CFU/ml or semi-quantitative PVC culture > 15 CFU

— AND pus/inflammation at the insertion site or tunnel

CRI2-CVC: General CVC-related infection (no positive blood culture)

— quantitative CVC culture ≥ 10^3 CFU/ml or semi-quantitative CVC culture > 15 CFU

— AND clinical signs improve within 48 hours after catheter removal

CRI2-PVC: General PVC-related infection (no positive blood culture)

— quantitative PVC culture ≥ 10^3 CFU/ml or semi-quantitative PVC culture > 15 CFU

— AND clinical signs improve within 48 hours after catheter removal

CRI3-CVC: microbiologically confirmed CVC-related bloodstream infection

— BSI occurring 48 hours before or after catheter removal

AND positive culture with the same micro-organism of either:

— quantitative CVC culture ≥ 10^3 CFU/ml or semi-quantitative CVC culture > 15 CFU

— quantitative blood culture ratio CVC blood sample/peripheral blood sample > 5

— differential delay of positive blood cultures: CVC blood sample culture positive two hours or more before peripheral blood culture (blood samples drawn at the same time)

— positive culture with the same micro-organism from pus from insertion site

CRI3-PVC: microbiologically confirmed PVC-related bloodstream infection

BSI occurring 48 hours before or after catheter removal

AND positive culture with the same micro-organism of either:

— quantitative PVC culture ≥ 10^3 CFU/ml or semi-quantitative PVC culture > 15 CFU

— positive culture with the same micro-organism from pus from insertion site

3.1.5. *CVS: CARDIOVASCULAR SYSTEM INFECTION*

CVS-VASC: Arterial or venous infection

Arterial or venous infection must meet at least one of the following criteria:

— Patient has organisms cultured from arteries or veins removed during a surgical operation

— AND blood culture not done or no organisms cultured from blood

— Patient has evidence of arterial or venous infection seen during a surgical operation or histopathologic examination

— Patient has at least one of the following signs or symptoms with no other recognised cause: fever (> 38 °C), pain, erythema, or heat at involved vascular site

— AND more than 15 colonies cultured from intravascular cannula tip using semiquantitative culture method

— AND blood culture not done or no organisms cultured from blood

— Patient has purulent drainage at involved vascular site

— AND blood culture not done or no organisms cultured from blood

Note reporting instructions:

Report infections of an arteriovenous graft, shunt, or fistula or intravascular cannulation site without organisms cultured from blood as CVS-VASC

CVS-ENDO: Endocarditis

Endocarditis of a natural or prosthetic heart valve must meet at least one of the following criteria:

— Patient has organisms cultured from valve or vegetation

— Patient has two or more of the following signs or symptoms with no other recognised cause: fever (> 38 °C), new or changing murmur, embolic phenomena, skin manifestations (e.g. petechiae, splinter haemorrhages, painful subcutaneous nodules), congestive heart failure, or cardiac conduction abnormality

AND at least one of the following:

— organisms cultured from two or more blood cultures

— organisms seen on Gram's stain of valve when culture is negative or not done

— valvular vegetation seen during a surgical operation or autopsy

— positive antigen test on blood or urine (e.g. *Haemophilus influenzae, Streptococcuspneumoniae, Neisseria meningitidis*, or Group B *Streptococcus*)

— evidence of new vegetation seen on echocardiogram

AND if diagnosis is made antemortem, physician institutes appropriate antimicrobial therapy

CVS-CARD: Myocarditis or pericarditis

Myocarditis or pericarditis must meet at least one of the following criteria:

— Patient has organisms cultured from pericardial tissue or fluid obtained by needle aspiration or during a surgical operation

— Patient has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), chest pain, paradoxical pulse, or increased heart size

AND at least one of the following:

— abnormal EKG consistent with myocarditis or pericarditis

— positive antigen test on blood (e.g. *Haemophilus influenzae, Streptococcus pneumoniae*)

— evidence of myocarditis or pericarditis on histologic examination of heart tissue

— four-fold rise in type-specific antibody with or without isolation of virus from pharynx or faeces

— pericardial effusion identified by echocardiogram, CT scan, MRI, or angiography

CVS-MED: Mediastinitis

Mediastinitis must meet at least one of the following criteria:

— Patient has organisms cultured from mediastinal tissue or fluid obtained during a surgical operation or needle aspiration

— Patient has evidence of mediastinitis seen during a surgical operation or histopathologic examination

— Patient has at least one of the following signs or symptoms with no other recognised cause: fever (> 38 °C), chest pain, or sternal instability

AND at least one of the following:

— purulent discharge from mediastinal area

— organisms cultured from blood or discharge from mediastinal area

— mediastinal widening on x-ray

Note reporting instruction:

Report mediastinitis following cardiac surgery that is accompanied by osteomyelitis as SSI-O

3.1.6. *EENT: EYE, EAR, NOSE, THROAT, OR MOUTH INFECTION*

EENT-CONJ: Conjunctivitis

Conjunctivitis must meet at least one of the following criteria:

— Patient has pathogens cultured from purulent exudate obtained from the conjunctiva or contiguous tissues, such as eyelid, cornea, meibomian glands, or lacrimal glands

— Patient has pain or redness of conjunctiva or around eye

AND at least one of the following:

— WBCs and organisms seen on Gram's stain of exudates

— purulent exudates

— positive antigen test (e.g. ELISA or IF for *Chlamydia trachomatis*, herpes simplex virus, adenovirus) on exudate or conjunctival scraping

— multinucleated giant cells seen on microscopic examination of conjunctival exudate or scrapings

— positive viral culture

— diagnostic single antibody titer (IgM) or four-fold increase in paired sera (IgG) for pathogen

Note reporting instructions:

— Report other infections of the eye as EYE

— Do not report chemical conjunctivitis caused by silver nitrate (AgNO3) as a health care-associated infection

— Do not report conjunctivitis that occurs as a part of a more widely disseminated viral illness (such as measles, chickenpox, or a URI)

EENT-EYE: Eye, other than conjunctivitis

An infection of the eye, other than conjunctivitis, must meet at least one of the following criteria:

— Patient has organisms cultured from anterior or posterior chamber or vitreous fluid

— Patient has at least two of the following signs or symptoms with no other recognised cause: eye pain, visual disturbance, or hypopyon

AND at least one of the following:

— physician diagnosis of an eye infection

— positive antigen test on blood (e.g. *Haemophilus influenzae, Streptococcus pneumoniae*)

— organisms cultured from blood

EENT-EAR: Ear mastoid

Ear and mastoid infections must meet at least one of the following criteria:

Otitis externa must meet at least one of the following criteria:

— Patient has pathogens cultured from purulent drainage from ear canal

— Patient has at least one of the following signs or symptoms with no other recognised cause: fever (> 38 °C), pain, redness, or drainage from ear canal

— AND organisms seen on Gram's stain of purulent drainage

Otitis media must meet at least one of the following criteria:

— Patient has organisms cultured from fluid from middle ear obtained by tympanocentesis or at surgical operation

— Patient has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), pain in the eardrum, inflammation, retraction or decreased mobility of eardrum, or fluid behind eardrum

Otitis interna must meet at least one of the following criteria:

— Patient has organisms cultured from fluid from inner ear obtained at surgical operation

— Patient has a physician diagnosis of inner ear infection

Mastoiditis must meet at least one of the following criteria:

— Patient has organisms cultured from purulent drainage from mastoid

— Patient has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), pain, tenderness, erythema, headache, or facial paralysis

AND at least one of the following:

— organisms seen on Gram's stain of purulent material from mastoid

— positive antigen test on blood

EENT-ORAL: Oral cavity (mouth, tongue, or gums)

Oral cavity infections must meet at least one of the following criteria:

— Patient has organisms cultured from purulent material from tissues of oral cavity

— Patient has an abscess or other evidence of oral cavity infection seen on direct examination, during a surgical operation, or during a histopathologic examination

— Patient has at least one of the following signs or symptoms with no other recognised cause: abscess, ulceration, or raised white patches on inflamed mucosa, or plaques on oral mucosa

AND at least one of the following:

— organisms seen on Gram's stain

— positive KOH (potassium hydroxide) stain

— multinucleated giant cells seen on microscopic examination of mucosal scrapings

— positive antigen test on oral secretions

— diagnostic single antibody titer (IgM) or four-fold increase in paired sera (IgG) for pathogen

— physician diagnosis of infection and treatment with topical or oral antifungal therapy

Note reporting instruction:

Report health care-associated primary herpes simplex infections of the oral cavity as ORAL; recurrent herpes infections are not healthcare-associated

EENT-SINU: Sinusitis

Sinusitis must meet at least one of the following criteria:

— Patient has organisms cultured from purulent material obtained from sinus cavity

— Patient has at least one of the following signs or symptoms with no other recognised cause: fever (> 38 °C), pain or tenderness over the involved sinus, headache, purulent exudate, or nasal obstruction

AND at least one of the following:

— positive transillumination

— positive radiographic examination (including CT scan)

EENT-UR: Upper respiratory tract, pharyngitis, laryngitis, epiglottitis

Upper respiratory tract infections must meet at least one of the following criteria:

— Patient has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), erythema of pharynx, sore throat, cough, hoarseness, or purulent exudate in throat

AND at least one of the following:

— organisms cultured from the specific site

— organisms cultured from blood

— positive antigen test on blood or respiratory secretions

— diagnostic single antibody titer (IgM) or four-fold increase in paired sera (IgG) for pathogen

— physician diagnosis of an upper respiratory infection

Patient has an abscess seen on direct examination, during a surgical operation, or during a histopathologic examination

3.1.7. *GI: GASTROINTESTINAL SYSTEM INFECTION*

GI-CDI: *Clostridium difficile* infection

A *Clostridium difficile* infection (previously also referred to as *Clostridium difficile* associated diarrhoea or CDAD) must meet at least one of the following criteria:

— Diarrhoeal stools or toxic megacolon, and a positive laboratory assay for *Clostridium difficile* toxin A and/or B in stools

— Pseudomembranous colitis revealed by lower gastro-intestinal endoscopy

— Colonic histopathology characteristic of *Clostridium difficile* infection (with or without diarrhoea) on a specimen obtained during endoscopy, colectomy or autopsy

GI-GE: Gastroenteritis (excl. CDI)

Gastroenteritis must meet at least one of the following criteria:

— Patient has an acute onset of diarrhoea (liquid stools for more than 12 hours) with or without vomiting or fever (> 38 °C) and no likely non-infectious cause (e.g. diagnostic tests, therapeutic regimen other than antimicrobial agents, acute exacerbation of a chronic condition, or psychological stress)

— Patient has at least two of the following signs or symptoms with no other recognised cause: nausea, vomiting, abdominal pain, fever (> 38 °C), or headache

AND at least one of the following:

— an enteric pathogen is cultured from stool or rectal swab

— an enteric pathogen is detected by routine or electron microscopy
— an enteric pathogen is detected by antigen or antibody assay on blood or faeces
— evidence of an enteric pathogen is detected by cytopathic changes in tissue culture (toxin assay)
— diagnostic single antibody titer (IgM) or four-fold increase in paired sera (IgG) for pathogen

GI-GIT: Gastrointestinal tract (oesophagus, stomach, small and large bowel, and rectum) excluding gastroenteritis and appendicitis

Gastrointestinal tract infections, excluding gastroenteritis and appendicitis, must meet at least one of the following criteria:

— Patient has an abscess or other evidence of infection seen during a surgical operation or histopathologic examination
— Patient has at least two of the following signs or symptoms with no other recognised cause and compatible with infection of the organ or tissue involved: fever (> 38 °C), nausea, vomiting, abdominal pain, or tenderness

AND at least one of the following:

— organisms cultured from drainage or tissue obtained during a surgical operation or endoscopy or from a surgically placed drain
— organisms seen on Gram's or KOH stain or multinucleated giant cells seen on microscopic examination of drainage or tissue obtained during a surgical operation or endoscopy or from a surgically placed drain
— organisms cultured from blood
— evidence of pathologic findings on radiographic examination
— evidence of pathologic findings on endoscopic examination (e.g. *Candida* spp. esophagitis or proctitis)

GI-HEP: Hepatitis

Hepatitis must meet the following criterion:

Patient has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), anorexia, nausea, vomiting, abdominal pain, jaundice, or history of transfusion within the previous 3 months

AND at least one of the following:

— positive antigen or antibody test for hepatitis A, hepatitis B, hepatitis C, or delta hepatitis
— abnormal liver function tests (e.g. elevated ALT/AST, bilirubin)
— cytomegalovirus (CMV) detected in urine or oropharyngeal secretions

Note reporting instructions:

— Do not report hepatitis or jaundice of non-infectious origin (alpha-1 antitrypsin deficiency, etc.)
— Do not report hepatitis or jaundice that results from exposure to hepatotoxins (alcoholic or acetaminophen-induced hepatitis, etc.)
— Do not report hepatitis or jaundice that results from biliary obstruction (cholecystitis)

GI-IAB: Intraabdominal, not specified elsewhere including gallbladder, bile ducts, liver (excluding viral hepatitis), spleen, pancreas, peritoneum, subphrenic or subdiaphragmatic space, or other intraabdominal tissue or area not specified elsewhere

Intraabdominal infections must meet at least one of the following criteria:

— Patient has organisms cultured from purulent material from intraabdominal space obtained during a surgical operation or needle aspiration
— Patient has abscess or other evidence of intraabdominal infection seen during a surgical operation or histopathologic examination
— Patient has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), nausea, vomiting, abdominal pain, or jaundice

AND at least one of the following:
— organisms cultured from drainage from surgically placed drain (e.g. closed suction drainage system, open drain, T-tube drain)
— organisms seen on Gram's stain of drainage or tissue obtained during surgical operation or needle aspiration
— organisms cultured from blood and radiographic evidence of infection (e.g. abnormal findings on ultrasound, CT scan, MRI, or radiolabel scans [gallium, technetium, etc.] or on abdominal x-ray)

Note reporting instruction:

Do not report pancreatitis (an inflammatory syndrome characterised by abdominal pain, nausea, and vomiting associated with high serum levels of pancreatic enzymes) unless it is determined to be infectious in origin

3.1.8. *LRI: LOWER RESPIRATORY TRACT INFECTION, OTHER THAN PNEUMONIA*

LRI-BRON: Bronchitis, tracheobronchitis, bronchiolitis, tracheitis, without evidence of pneumonia

Tracheobronchial infections must meet at least one of the following criteria:

Patient has no clinical or radiographic evidence of pneumonia

AND patient has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), cough, new or increased sputum production, rhonchi, wheezing

AND at least one of the following:
— positive culture obtained by deep tracheal aspirate or bronchoscopy
— positive antigen test on respiratory secretions

Note reporting instruction:

Do not report chronic bronchitis in a patient with chronic lung disease as an infection unless there is evidence of an acute secondary infection, manifested by change in organism

LRI-LUNG: Other infections of the lower respiratory tract

Other infections of the lower respiratory tract must meet at least one of the following criteria:
— Patient has organisms seen on smear or cultured from lung tissue or fluid, including pleural fluid
— Patient has a lung abscess or empyema seen during a surgical operation or histopathologic examination
— Patient has an abscess cavity seen on radiographic examination of lung

Note reporting instruction:

Report lung abscess or empyema without pneumonia as LUNG

3.1.9. *NEO: SPECIFIC NEONATAL CASE DEFINITIONS*

NEO-CSEP: Clinical Sepsis

ALL of the 3 following criteria:

— Supervising physician started appropriate antimicrobial therapy for sepsis for at least five days.
— No detection of pathogens in blood culture or not tested
— No obvious infection at another site

AND two of the following criteria (without other apparent cause):
— Fever (> 38 °C) or temperature instability (frequent post-set of the incubator) or hypothermia (< 36,5 °C)
— Tachycardia (> 200/min) or new/increased bradycardia (< 80/min)
— Capillary refilling time (CRT) > 2 s
— New or increased apnoea (s) (> 20 s)
— Unexplained metabolic acidosis
— New-onset hyperglycaemia (> 140 mg/dl)
— Another sign of sepsis (skin colour (only if the CRT is not used), laboratory signs (CRP, interleukin), increased oxygen requirement (intubation), unstable general condition of the patient, apathy)

NEO-LCBI: Laboratory-confirmed BSI
— at least two of: temperature > 38 °C or < 36,5 °C or temperature instability, tachycardia or bradycardia, apnoea, extended capillary refilling time (CRT), metabolic acidosis, hyperglycaemia, other sign of BSI such as apathy

AND
— a recognised pathogen other than coagulase-negative staphylococci (CNS) cultured from blood or cerebrospinal fluid (CSF; this is included because meningitis in this age group is usually haematogenous, so positive CSF can be regarded as evidence of BSI even if blood cultures are negative or were not taken)

Note reporting instructions:
— in order to be consistent with BSI reporting in adults (including secondary BSI), the criterion ‘the organism is not related to an infection at another site’ was removed from the Neo-KISS definition for the purposes of the EU PPS
— report the origin of the neonatal BSI in the field BSI origin
— if both the case definitions for NEO-LCBI and NEO-CNSB are matched, report NEO-LCBI

NEO-CNSB: Laboratory-confirmed BSI with coagulase-negative staphylococci (CNS)
— at least two of: temperature > 38 °C or < 36,5 °C or temperature instability, tachycardia or bradycardia, apnoea, extended recapillarisation time, metabolic acidosis, hyperglycaemia, other sign of BSI such as apathy
— AND CNS is cultured from blood or catheter tip
— AND patient has one of: C-reactive protein > 2,0 mg/dl, immature/total neutrophil ratio (I/T ratio) > 0,2, leukocytes < 5/nl, platelets < 100/nl

Note reporting instructions:
— in order to be consistent with BSI reporting in adults (including secondary BSI), the criterion ‘the organism is not related to an infection at another site’ was removed from the Neo-KISS definition for the purposes of the EU PPS
— report the origin of the neonatal BSI in the field BSI origin
— if both the case definitions for NEO-LCBI and NEO-CNSB are matched, report NEO-LCBI

NEO-PNEU: Pneumonia
— respiratory compromise
— AND new infiltrate, consolidation or pleural effusion on chest X ray

— AND at least four of: temperature > 38 °C or < 36,5 °C or temperature instability, tachycardia or bradycardia, tachypnoea or apnoea, dyspnoea, increased respiratory secretions, new onset of purulent sputum, isolation of a pathogen from respiratory secretions, C-reactive protein > 2,0 mg/dl, I/T ratio > 0,2

NEO-NEC: Necrotising enterocolitis

— Histopathological evidence of necrotising enterocolitis

OR

— at least one characteristic radiographic abnormality (pneumoperitoneum, pneumatosis intestinalis, unchanging 'rigid' loops of small bowel) plus at least two of the following without other explanation: vomiting, abdominal distension, prefeeding residuals, persistent microscopic or gross blood in stools

3.1.10. *PN: PNEUMONIA*

Two or more serial chest X-rays or CT-scans with a suggestive image of pneumonia for patients with underlying cardiac or pulmonary disease. In patients without underlying cardiac or pulmonary disease one definitive chest X-ray or CT-scan is sufficient

AND at least one of the following symptoms

Fever > 38 °C with no other cause

Leucopoenia (< 4 000 WBC/mm^3) or leucocytosis (≥ 12 000 WBC/mm^3)

AND at least one of the following (or at least two if clinical pneumonia only = PN 4 and PN 5)

— New onset of purulent sputum, or change in character of sputum (colour, odour, quantity, consistency)
— Cough or dyspnoea or tachypnea
— Suggestive auscultation (rales or bronchial breath sounds), ronchi, wheezing
— Worsening gas exchange (e.g. O_2 desaturation or increased oxygen requirements or increased ventilation demand)

and according to the used diagnostic method

(a) **Bacteriologic diagnostic performed by:**

Positive quantitative culture from minimally contaminated LRT[(18)] specimen (PN 1)

— Broncho-alveolar lavage (BAL) with a threshold of ≥ 10^4 CFU/ml[(19)] or ≥ 5 % of BAL obtained cells contains intracellular bacteria on direct microscopic exam (classified on the diagnostic category BAL)
— Protected brush (PB Wimberley) with a threshold of ≥ 10^3 CFU/ml
— Distal protected aspirate (DPA) with a threshold of ≥ 10^3 CFU/ml

Positive quantitative culture from possibly contaminated LRT specimen (PN 2)

— Quantitative culture of LRT specimen (e.g. endotracheal aspirate) with a threshold of 10^6 CFU/ml

(b) **Alternative microbiology methods (PN 3)**

— Positive blood culture not related to another source of infection
— Positive growth in culture of pleural fluid
— Pleural or pulmonary abscess with positive needle aspiration
— Histologic pulmonary exam shows evidence of pneumonia

— Positive exams for pneumonia with virus or particular germs (e.g. *Legionella, Aspergillus*, mycobacteria, mycoplasma, *Pneumocystis jirovecii*)
— Positive detection of viral antigen or antibody from respiratory secretions (e.g. EIA, FAMA, shell vial assay, PCR)
— Positive direct exam or positive culture from bronchial secretions or tissue
— Seroconversion (e.g. influenza viruses, *Legionella, Chlamydia*)
— Detection of antigens in urine (*Legionella*)

(c) **Others**
— Positive sputum culture or non-quantitative LRT specimen culture (PN 4)
— No positive microbiology (PN 5)

Note: PN 1 and PN 2 criteria were validated without previous antimicrobial therapy

Intubation-associated pneumonia (IAP)

A pneumonia is defined as intubation-associated (IAP) if an invasive respiratory device was present (even intermittently) in the 48 hours preceding the onset of infection

Note: Pneumonia for which intubation was started on the day of onset without additional information on the sequence of the events is not considered as IAP

3.1.11. *REPR: REPRODUCTIVE TRACT INFECTION*

REPR-EMET: Endometritis

Endometritis must meet at least one of the following criteria:
— Patient has organisms cultured from fluid or tissue from endometrium obtained during surgical operation, by needle aspiration, or by brush biopsy
— Patient has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), abdominal pain, uterine tenderness, or purulent drainage from uterus

Note reporting instruction:

Report postpartum endometritis as a health care-associated infection unless the amniotic fluid is infected at the time of admission or the patient was admitted 48 hours after rupture of the membrane

REPR-EPIS: Episiotomy

Episiotomy infections must meet at least one of the following criteria:
— Postvaginal delivery patient has purulent drainage from the episiotomy
— Postvaginal delivery patient has an episiotomy abscess

REPR-VCUF: Vaginal cuff

Vaginal cuff infections must meet at least one of the following criteria:
— Posthysterectomy patient has purulent drainage from the vaginal cuff
— Posthysterectomy patient has an abscess at the vaginal cuff
— Posthysterectomy patient has pathogens cultured from fluid or tissue obtained from the vaginal cuff

Note reporting instruction:

Report vaginal cuff infections as SSI-O

REPR-OREP: Other infections of the male or female reproductive tract (epididymis, testes, prostate, vagina, ovaries, uterus, or other deep pelvic tissues, excluding endometritis or vaginal cuff infections)

Other infections of the male or female reproductive tract must meet at least one of the following criteria:

— Patient has organisms cultured from tissue or fluid from affected site

— Patient has an abscess or other evidence of infection of affected site seen during a surgical operation or histopathologic examination

— Patient has two of the following signs or symptoms with no other recognised cause: fever (> 38 °C), nausea, vomiting, pain, tenderness, or dysuria

AND at least one of the following:

— organisms cultured from blood

— physician diagnosis

Note reporting instructions:

— Report endometritis as EMET

— Report vaginal cuff infections as VCUF

3.1.12. *SSI: SURGICAL SITE INFECTION*

Note: All definitions are to be assumed to be confirmed for the purposes of surveillance reporting.

Superficial incisional (SSI-S)

Infection occurs within 30 days after the operation AND infection involves only skin and subcutaneous tissue of the incision AND at least one of the following:

— Purulent drainage with or without laboratory confirmation, from the superficial incision

— Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision

— At least one of the following signs or symptoms of infection: pain or tenderness, localised swelling, redness, or heat AND superficial incision is deliberately opened by surgeon, unless incision is culture-negative

— Diagnosis of superficial incisional SSI made by a surgeon or attending physician

Deep incisional (SSI-D)

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place AND the infection appears to be related to the operation AND infection involves deep soft tissue (e.g. fascia, muscle) of the incision AND at least one of the following:

— Purulent drainage from the deep incision but not from the organ/space component of the surgical site

— A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (> 38 °C), localised pain or tenderness, unless incision is culture-negative

— An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiological examination

— Diagnosis of deep incisional SSI made by a surgeon or attending physician

Organ/Space (SSI-O)

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place AND the infection appears to be related to the operation AND infection involves any part of the anatomy (e.g. organs and spaces) other than the incision which was opened or manipulated during an operation AND at least one of the following:

— Purulent drainage from a drain that is placed through a stab wound into the organ/space

— Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space

— An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiological examination

— Diagnosis of organ/space SSI made by a surgeon or attending physician

3.1.13. *SST: SKIN AND SOFT TISSUE INFECTION*

SST-SKIN: Skin infection

Skin infections must meet at least one of the following criteria:

— Patient has purulent drainage, pustules, vesicles, or boils

— Patient has at least two of the following signs or symptoms with no other recognised cause: pain or tenderness, localised swelling, redness, or heat

AND at least one of the following:

— organisms cultured from aspirate or drainage from affected site; if organisms are normal skin flora (e.g. diphtheroids [*Corynebacterium* spp.], *Bacillus* [not *B.anthracis*] spp., *Propionibacterium* spp., coagulase-negative staphylococci [including *Staphylococcusepidermidis*], viridans group streptococci, *Aerococcus* spp., *Micrococcus* spp.), they must be a pure culture

— organisms cultured from blood

— positive antigen test performed on infected tissue or blood (e.g. herpes simplex, varicella zoster, *Haemophilus influenzae, Neisseria meningitidis*)

— multinucleated giant cells seen on microscopic examination of affected tissue

— diagnostic single antibody titer (IgM) or four-fold increase in paired sera (IgG) for pathogen

Note reporting instructions:

— Report infected decubitus ulcers as DECU

— Report infected burns as BURN

— Report breast abscesses or mastitis as BRST

SST-ST: Soft tissue (necrotising fascitis, infectious gangrene, necrotising cellulitis, infectious myositis, lymphadenitis, or lymphangitis)

Soft tissue infections must meet at least one of the following criteria:

— Patient has organisms cultured from tissue or drainage from affected site

— Patient has purulent drainage at affected site

— Patient has an abscess or other evidence of infection seen during a surgical operation or histopathologic examination

— Patient has at least two of the following signs or symptoms at the affected site with no other recognised cause: localised pain or tenderness, redness, swelling, or heat

AND at least one of the following:

— organisms cultured from blood

— positive antigen test performed on blood or urine (e.g. *Haemophilus influenzae, Streptococcus pneumoniae, Neisseria meningitidis*, Group B *Streptococcus, Candida* spp.)

— diagnostic single antibody titer (IgM) or four-fold increase in paired sera (IgG) for pathogen

Note reporting instructions:

— Report infected decubitus ulcers as DECU

— Report infection of deep pelvic tissues as OREP

SST-DECU: Decubitus ulcer, including both superficial and deep infections

Decubitus ulcer infections must meet the following criterion:

— Patient has at least two of the following signs or symptoms with no other recognised cause: redness, tenderness, or swelling of decubitus wound edges

AND at least one of the following:

— organisms cultured from properly collected fluid or tissue

— organisms cultured from blood

SST-BURN: Burn

Burn infections must meet at least one of the following criteria:

— Patient has a change in burn wound appearance or character, such as rapid eschar separation, or dark brown, black, or violaceous discoloration of the eschar, or oedema at wound margin

AND histologic examination of burn biopsy shows invasion of organisms into adjacent viable tissue

Patient has a change in burn wound appearance or character, such as rapid eschar separation, or dark brown, black, or violaceous discoloration of the eschar, or oedema at wound margin

AND at least one of the following:

— organisms cultured from blood in the absence of other identifiable infection

— isolation of herpes simplex virus, histologic identification of inclusions by light or electron microscopy, or visualisation of viral particles by electron microscopy in biopsies or lesion scrapings

Patient with a burn has at least two of the following signs or symptoms with no other recognised cause: fever (> 38 °C) or hypothermia (< 36 °C), hypotension, oliguria (< 20 cc/hr), hyperglycaemia at previously tolerated level of dietary carbohydrate, or mental confusion

AND at least one of the following:

— histologic examination of burn biopsy shows invasion of organisms into adjacent viable tissue

— organisms cultured from blood

— isolation of herpes simplex virus, histologic identification of inclusions by light or electron microscopy, or visualisation of viral particles by electron microscopy in biopsies or lesion scrapings

SST-BRST: Breast abscess or mastitis

A breast abscess or mastitis must meet at least one of the following criteria:

— Patient has a positive culture of affected breast tissue or fluid obtained by incision and drainage or needle aspiration

— Patient has a breast abscess or other evidence of infection seen during a surgical operation or histopathologic examination

— Patient has fever (> 38 °C) and local inflammation of the breast

AND physician diagnosis of breast abscess

3.1.14. *SYS: SYSTEMIC INFECTION*

SYS-DI: Disseminated infection

Disseminated infection is infection involving multiple organs or systems, without an apparent single site of infection, usually of viral origin, and with signs or symptoms with no other recognised cause and compatible with infectious involvement of multiple organs or systems
Note reporting instructions:

— Use this code for viral infections involving multiple organ systems (e.g. measles, mumps, rubella, varicella, erythema infectiosum). These infections often can be identified by clinical criteria alone. Do not use this code for healthcare-associated infections with multiple metastatic sites, such as with bacterial endocarditis; only the primary site of these infections should be reported

— Do not report fever of unknown origin (FUO) as DI

— Report viral exanthemas or rash illness as DI

SYS-CSEP: Clinical sepsis in adults and children

Patient has at least one of the following

— clinical signs or symptoms with no other recognised cause

— fever (> 38 °C)

— hypotension (systolic pressure < 90 mm/Hg)

— or oliguria (20 cm^3(ml)/hr)

And blood culture not done or no organisms or antigen detected in blood

And no apparent infection at another site

And physician institutes treatment for sepsis
Note reporting instructions:

— Do not use this code unless absolutely needed

— For CSEP in neonates, use NEO-CSEP case definition (see below)

3.1.15. *UTI: URINARY TRACT INFECTION*

UTI-A: microbiologically confirmed symptomatic UTI

Patient has at least one of the following signs or symptoms with no other recognised cause: fever (> 38 °C), urgency, frequency, dysuria, or suprapubic tenderness

AND

patient has a positive urine culture, that is, ≥ 10^5 microorganisms per ml of urine with no more than two species of microorganisms.

UTI-B: not microbiologically confirmed symptomatic UTI

Patient has at least two of the following with no other recognised cause: fever (> 38 °C), urgency, frequency, dysuria, or suprapubic tenderness

AND

at least one of the following:

— Positive dipstick for leukocyte esterase and/or nitrate

— Pyuria urine specimen with ≥ 10^4 WBC/ml or ≥ 3 WBC/high-power field of unspun urine

— Organisms seen on Gram stain of unspun urine

— At least two urine cultures with repeated isolation of the same uropathogen (gram-negative bacteria or *Staphylococcus saprophyticus*) with ≥ 10^2 colonies/ml urine in non-voided specimens

— $\leq 10^5$ colonies/ml of a single uropathogen (gram-negative bacteria or *Staphylococcus saprophyticus*) in a patient being treated with effective antimicrobial agent for a urinary infection
— Physician diagnosis of a urinary tract infection
— Physician institutes appropriate therapy for a urinary infection

Asymptomatic bacteriuria should not be reported, but bloodstream infections secondary to asymptomatic bacteriuria are reported as BSI with source (origin) S-UTI

A urinary tract infection (UCA-UTI) is defined as catheter-associated if an indwelling urinary catheter was present (even intermittently) in the seven days preceding the onset of infection

3.2. GENERIC CASE DEFINITION OF ANTIMICROBIAL RESISTANCE

Definition

A microorganism is defined as clinically susceptible, clinically intermediate or clinically resistant to an antimicrobial agent according to the EUCAST clinical breakpoints, i.e. clinical MIC breakpoints and their inhibition zone diameter correlates[20]

Clinically Susceptible (S)

— a micro-organism is defined as susceptible by a level of antimicrobial activity associated with a high likelihood of therapeutic success
— a micro-organism is categorised as susceptible (S) by applying the appropriate breakpoint in a defined phenotypic test system
— this breakpoint may be altered with legitimate changes in circumstances

Clinically Intermediate (I)

— a micro-organism is defined as intermediate by a level of antimicrobial agent activity associated with uncertain therapeutic effect. It implies that an infection due to the isolate may be appropriately treated in body sites where the drugs are physically concentrated or when a high dosage of drug can be used; it also indicates a buffer zone that should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations
— a micro-organism is categorised as intermediate (I) by applying the appropriate breakpoints in a defined phenotypic test system
— these breakpoints may be altered with legitimate changes in circumstances

Clinically Resistant (R)

— a micro-organism is defined as resistant by a level of antimicrobial activity associated with a high likelihood of therapeutic failure
— a micro-organism is categorised as resistant (R) by applying the appropriate breakpoint in a defined phenotypic test system
— this breakpoint may be altered with legitimate changes in circumstances

Clinical breakpoints are presented as S≤x mg/L; I>x, ≤y mg/L; R>y mg/L

Microorganisms and corresponding antimicrobial agents (bug-drug combinations) relevant for surveillance in humans are defined in the relevant surveillance protocols

(**1**) OJ L 268, 3.10.1998, p. 1.

(**2**) OJ L 86, 3.4.2002, p. 44.

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

(**4**) See World Organisation 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#)

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

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

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

(**8**) 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.

(**9**) See footnote 5.

(**10**) 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.

(**11**) See footnote 5.

(**12**) See footnote 5.

(**13**) 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.

(**14**) 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.

(**15**) 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.

(**16**) Serological results should be interpreted according to the vaccination status and previous exposure to other flaviviral infections. Confirmed cases in such situations should be validated by serum neutralisation assay or other equivalent assays.

(**17**) CVC = central vascular catheter, PVC = peripheral vascular catheter
central vascular catheter colonisation should not be reported. A CRI3 (-CVC or -PVC) is also a bloodstream infection with source C-CVC or C-PVC respectively; however when a CRI3 is reported, the BSI should not be reported in the point prevalence survey; microbiologically confirmed catheter-related BSI should be reported as CRI3.

(**18**) LRT = Lower Respiratory Tract.

(**19**) CFU = Colony Forming Units.

(**20**) http://www.eucast.org/clinical_breakpoints/

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
Commission Implementing Decision of 8 August 2012 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 C(2012) 5538) (Text with EEA relevance) (2012/506/EU) is up to date with all changes known to be in force on or before 01 July 2024. 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.