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COMMISSION IMPLEMENTING REGULATION (EU) 2026/2097

of 18 September 2026

**on the communicable diseases and related special health issues subject to epidemiological surveillance
and the corresponding case definitions, and repealing Implementing Decision (EU) 2018/945**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU ⁽¹⁾, and in particular Article 13(10), points (a) and (b), thereof,

Whereas:

- (1) Commission Implementing Decision (EU) 2018/945 ⁽²⁾ establishes a list of communicable diseases and related special health issues to be covered by epidemiological surveillance. In addition, it sets out the case definitions for the purposes of submitting data for the epidemiological surveillance of those communicable diseases. That Implementing Decision was adopted on the basis of Decision No 1082/2013/EU of the European Parliament and of the Council ⁽³⁾, which has now been repealed by Regulation (EU) 2022/2371.
- (2) The list of communicable diseases and related special health issues established by Implementing Decision (EU) 2018/945 should be updated to reflect changes in disease epidemiology and the public health needs and priorities of the Union and the Member States. The updated list should cover certain communicable diseases and related special health issues in accordance with the criteria for the selection of communicable diseases and related special health issues for epidemiological surveillance set out in Section 1 of Annex I to Regulation (EU) 2022/2371.
- (3) In addition, the list of case definitions, currently set out in Implementing Decision (EU) 2018/945, should be updated in the light of new scientific information and evolving laboratory diagnostic criteria and practices.
- (4) Antimicrobial resistance is estimated to cost millions of lives globally every year. As the strongest determinant of antimicrobial resistance, antimicrobial consumption has been under voluntary surveillance at Union level for over 20 years and should therefore also be included in Annex I to this Regulation as a special health issue subject to epidemiological surveillance.
- (5) Coronavirus disease 2019 (COVID-19) caused a pandemic with very high morbidity and mortality and should therefore be subject to epidemiological surveillance at Union level. The surveillance of COVID-19 should be integrated with the sentinel syndromic and virologic surveillance of influenza and respiratory syncytial virus to ensure standardised surveillance of respiratory viral infections more independently of changing testing and control policies.
- (6) Hantavirus infection is a zoonosis causing a few thousand cases in the Union every year. It may present as a viral haemorrhagic fever and should be subject to epidemiological surveillance at Union level to enable early warning, faster diagnosis, and more effective response in neighbouring Member States.
- (7) Any zoonotic influenza virus (an animal-hosted type A influenza virus that crosses the species barrier to infect humans) may cause a pandemic in the future, hence any human infection with such a virus should be subject to epidemiological surveillance at Union level. In Annex I to this Regulation, 'Zoonotic influenza' should therefore replace the 'influenza A/H5N1' as currently listed in Implementing Decision (EU) 2018/945.

⁽¹⁾ OJ L 314, 6.12.2022, p. 26, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>.

⁽²⁾ Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions (OJ L 170, 6.7.2018, p. 1, ELI: http://data.europa.eu/eli/dec_impl/2018/945/oj).

⁽³⁾ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1, ELI: <http://data.europa.eu/eli/dec/2013/1082/oj>).

- (8) Rabies virus and other lyssaviruses can cause central nervous disease in humans. It is therefore appropriate to expand 'rabies', as currently listed in Implementing Decision (EU) 2018/945, to 'rabies and other lyssavirus infections' in Annex I to this Regulation.
- (9) Mpox clade II caused a global epidemic in 2022 predominantly among gay, bisexual and other men who have sex with men (MSM). Mpox clade I is prevalent in sub-Saharan Africa and is spreading in sexual networks affecting both men and women. Cases infected outside Europe have been detected in the Union and the countries in the European Economic Area and resulted in some onward transmission through household transmission or heterosexual contact. In late 2025, clade I started to spread also among MSM in the Union with cases acquired in the country of residence or through travel to other Member States or to the countries in the European Economic Area. Mpox should therefore be subject to event-based surveillance at Union level to detect any upsurge in cases in at-risk populations or the general population.
- (10) Respiratory syncytial virus (RSV) infection causes a considerable number of hospitalisations among young children and the elderly and should therefore be subject to epidemiological surveillance at Union level. Like COVID-19, the surveillance of RSV infection should be integrated with the sentinel syndromic and virologic surveillance of influenza. Routine surveillance of RSV infection is also expected to contribute to measuring the impact of RSV vaccines.
- (11) According to the criteria for the selection of communicable diseases and related special health issues for epidemiological surveillance as set out in Section 1 of Annex I to Regulation (EU) 2022/2371, the following diseases should no longer be subject to epidemiological surveillance at Union level:
- Cryptosporidiosis is a common but predominantly mild gastrointestinal infection that may cause local water-borne outbreaks but has no cross-border public health dimension that would justify continued surveillance at Union level,
 - Like Cryptosporidiosis, Giardiasis tends to cause local outbreaks of self-limited diarrhoea,
 - Lyme neuroborreliosis is difficult to diagnose and only accounts for a small fraction of Lyme disease. Routine surveillance of Lyme neuroborreliosis at Union level is therefore not suitable for estimating and monitoring the burden of Lyme disease,
 - Severe acute respiratory syndrome (SARS) caused a large outbreak of severe respiratory infection which ended in 2004, but no further cases have been reported since,
 - Thanks to decades of routine childhood vaccination in the Union, Tetanus has become exceedingly rare. It is not transmitted from person to person. Discontinuing tetanus surveillance at Union level therefore poses no major public health risks,
 - Cases of typhoid and paratyphoid fever are mostly imported from outside the Union and are relatively mild and easily treatable by antibiotics. Their continued surveillance at Union level adds little public health value.
- (12) In accordance with Article 9 of Regulation (EC) No 851/2004 of the European Parliament and of the Council ^(*), the European Centre for Disease Prevention and Control has provided, at the Commission's request, scientific assistance on the establishment of case definitions for antimicrobial consumption, arenavirus infection, Crimean-Congo haemorrhagic fever, filovirus infection, Hantavirus infection, healthcare-associated COVID-19, Lyssavirus infection, mpox, respiratory viral infections (influenza-like illness, acute respiratory infection, severe acute respiratory infection, COVID-19, seasonal influenza, zoonotic influenza, and RSV infection), Rift Valley fever. The assistance also included the revision of the case definitions for botulism, chikungunya virus disease, chlamydial infection including chlamydial lymphogranuloma venerum, cholera, variant Creutzfeldt-Jakob disease, dengue, gonococcal infection, hepatitis B, hepatitis C, Legionnaires' disease, malaria, measles, plague, Q fever, rubella, Shiga toxin-producing *E. coli* infection, shigellosis, smallpox, syphilis and congenital syphilis, tick-borne encephalitis, tuberculosis, tularaemia, West Nile virus infection, intestinal yersiniosis, Zika virus disease, antimicrobial resistance and healthcare-associated infections. The respective case definitions should be amended accordingly.

^(*) 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 (OJ L 142, 30.4.2004, p. 1, ELI: <http://data.europa.eu/eli/reg/2004/851/oj>).

- (13) This Regulation replaces Implementing Decision (EU) 2018/945 which should be repealed.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Committee on serious cross-border threats to health established under Article 29 of Regulation (EU) 2022/2371.
- (15) The competent authorities of the Member States should be given until 1 July 2028 in order to prepare themselves to apply the rules laid down in this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The communicable diseases and related special health issues referred to in Article 2(1), points (a)(i) and (a)(ii), of Regulation (EU) 2022/2371 that are to be covered by the network for epidemiological surveillance of communicable diseases and related special health issues referred to in Article 13(1) of that Regulation are listed in Annex I.

Article 2

For the purposes of the epidemiological surveillance of the communicable diseases and related special health issues listed in Annex I, the case definitions set out in Annex II shall apply.

Article 3

Implementing Decision (EU) 2018/945 is repealed.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2028.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 September 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Communicable diseases and related special health issues subject to epidemiological surveillance, as referred to in Article 1

1. DISEASES

Anthrax

Arenavirus infection, excluding lymphocytic choriomeningitis

Botulism

Brucellosis

Campylobacteriosis

Chikungunya virus disease

Chlamydial infection, including Chlamydial lymphogranuloma (venereum) (LGV)

Cholera

Coronavirus disease 2019 (COVID-19)

Variant Creutzfeldt-Jakob disease

Crimean-Congo haemorrhagic fever

Dengue

Diphtheria

Echinococcosis

Filovirus infection

Gonococcal infection

Haemophilus influenzae infection, invasive disease

Hantavirus infection

Acute hepatitis A

Hepatitis B

Hepatitis C

Human immunodeficiency virus (HIV) infection and Acquired immunodeficiency syndrome (AIDS)

Influenza, seasonal

Influenza, zoonotic

Legionnaires' disease

Leptospirosis

Listeriosis

Malaria

Measles

Meningococcal infection, invasive disease

Mpox

Mumps

Pertussis

Plague

Streptococcus pneumoniae infection, invasive disease

Acute poliomyelitis

Q fever
Rabies and other lyssavirus infections
Respiratory syncytial virus (RSV) infection
Rift Valley fever
Rubella
Congenital rubella syndrome
Salmonella enteritis
Shiga toxin-producing *E. coli* infection (STEC), including haemolytic-uraemic syndrome (HUS)
Shigellosis
Smallpox
Syphilis
Congenital syphilis
Tick-borne encephalitis, both Central European and Far Eastern
Congenital toxoplasmosis
Trichinellosis
Tuberculosis
Tularaemia
West Nile virus infection
Yellow fever
Yersiniosis, intestinal
Zika virus disease

2. SPECIAL HEALTH ISSUES

Antimicrobial resistance (including antimicrobial consumption)
Healthcare-associated infections

ANNEX II

Case definitions for the communicable diseases and related special health issues subject to epidemiological surveillance, as referred to in Article 2**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 constitute 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 methods is sufficient 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 laboratory testing 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 shall be 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 (or, for some diseases, a person suspected to have been exposed due to their travel history) 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 suspected infection or 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 suspected infection or colonisation;
- Environmental exposure: the fact that a person has bathed in water or has had contact with a contaminated environmental source that has been confirmed by a laboratory;
- Laboratory exposure: the fact that a person has worked in a laboratory where there is a potential for exposure.

A person shall be considered epidemiologically linked to a confirmed case if at least one case in the chain of transmission is confirmed by a laboratory. In case of an outbreak of faeco-oral or airborne transmitted infections, a case may be considered epidemiologically linked without establishing the chain of transmission.

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 (for example, biting, touching) or indirect contact to infected materials or objects (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: transmission by infected mosquitoes, ticks, 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 shall be classified as 'possible', 'probable' and 'confirmed'. The incubation periods for diseases are given in the additional information to facilitate the assessment of the epidemiological link.

POSSIBLE CASE

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 confirmed by a laboratory 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 (for example, hepatitis A, B and C, campylobacteriosis, salmonellosis) although these cases may still be important from a public health perspective on national level.

DISCARDED CASE

Any person meeting the clinical criteria

AND

At least one of the following three:

- despite an adequate specimen collected and tested by a proficient laboratory, the case does not meet the case definition laboratory criteria for the disease in question;
- the case is epidemiologically linked to a laboratory-confirmed case or outbreak of another communicable disease than the disease in question;
- another disease aetiology is confirmed in the case, even if the case is epidemiologically linked to a laboratory-confirmed case or another epidemiologically linked case of the disease in question.

Note: For some of the conditions under surveillance, the structure of the case definitions does not follow the typical structure of the case definition such as in the cases of variant Creutzfeldt-Jakob disease (vCJD), healthcare-associated infections and antimicrobial resistance.

2. ABBREVIATION LIST

1. AFP: acute flaccid paralysis
2. AIDS: acquired immune deficiency syndrome
3. AMR: antimicrobial resistance
4. Anti-HBc: hepatitis B core antibody
5. anti-HCV: hepatitis C virus specific antibody
6. ARI: acute respiratory infection
7. BAL: broncho-alveolar lavage
8. BCG: Bacille de Calmette et Guérin
9. BJ: bone and joint infection
10. BJ-BONE: osteomyelitis
11. BJ-DISC: disc space infection
12. BJ-JNT: joint or bursa infection
13. BoNT: botulinum neurotoxin
14. BSI: bloodstream infection
15. C-CVC: catheter-related — central venous catheter
16. CDAD: *Clostridioides difficile* associated diarrhoea
17. CFU: colony-forming unit
18. CMV: cytomegalovirus
19. CNS: central nervous system
20. CNS-IC: central nervous system infection — intracranial infection
21. CNS-MEN: central nervous system infection — meningitis or ventriculitis
22. CNS-SA: central nervous system infection — spinal abscess without meningitis
23. C-PVC: catheter-related — peripheral venous catheter
24. CRI: catheter-related infection
25. CRS: Congenital rubella syndrome
26. CRT: capillary refilling time
27. CSF: Cerebrospinal fluid
28. CT scan: computed tomography scan

29. CVS: cardiovascular system infection
30. CVS-CARD: cardiovascular system infection — myocarditis or pericarditis
31. CVS-ENDO: cardiovascular system infection — endocarditis
32. CVS-MED: cardiovascular system infection — mediastinitis
33. CVS-VASC: cardiovascular system infection — arterial or venous infection
34. DFA: direct fluorescent antibody
35. DFA-TP: direct fluorescent antibody test for *Treponema pallidum*
36. DNA: deoxyribonucleic acid
37. DPA: distal protected aspirate
38. EARS-Net: European Antimicrobial Resistance Surveillance Network
39. ECDC: European Centre for Disease Prevention and Control
40. ECOFFs: epidemiological cut-off values
41. EEG: electroencephalography
42. EENT: eye, ear, nose, throat, or mouth infection
43. EENT-CONJ: eye, ear, nose, throat, or mouth infection — conjunctivitis
44. EENT-EAR: eye, ear, nose, throat, or mouth infection — ear and mastoid
45. EENT-EYE: eye, ear, nose, throat, or mouth infection — eye, other than conjunctivitis
46. EENT-ORAL: eye, ear, nose, throat, or mouth infection — oral cavity (mouth, tongue, or gums)
47. EENT-SINU: eye, ear, nose, throat, or mouth infection — sinusitis
48. EENT-UR: eye, ear, nose, throat, or mouth infection — upper respiratory tract, pharyngitis, laryngitis, epiglottitis
49. EFNS: European Federation of Neurological Societies
50. EIA: enzyme immunoassay
51. ELISA: enzyme-linked immunosorbent assay
52. EM: electron microscopy
53. ERLI-Net: European Reference Laboratory Network for Human Influenza
54. EUCAST: European Committee on Antimicrobial Susceptibility Testing
55. FAMA: fluorescent antibody to membrane antigen
56. FTA-abs: fluorescent treponemal antibody absorption

57. FUO: fever of unknown origin
58. GI: gastrointestinal system infection
59. GI-CDI: gastrointestinal system infection — *Clostridioides difficile* infection
60. GI-GE: gastrointestinal system infection — gastroenteritis (excl. CDI)
61. GI-GIT: gastrointestinal system infection — gastrointestinal tract (esophagus, stomach, small and large bowel, and rectum) excluding gastroenteritis and appendicitis
62. GI-HEP: gastrointestinal system infection — hepatitis
63. GI-IAB: gastrointestinal system infection — 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
64. HAI: healthcare-associated infections
65. HbeAg: hepatitis B e antigen
66. HbsAg: hepatitis B surface antigen
67. HBV-DNA: hepatitis B deoxyribonucleic acid
68. HCV-core: hepatitis C virus core antigen
69. HCV-RNA: hepatitis C virus ribonucleic acid
70. HIV: human immunodeficiency virus
71. HUS: haemolytic-uraemic syndrome
72. IAP: intubation-associated pneumonia
73. IF: immunofluorescence
74. IFA: indirect fluorescent antibody
75. IgG: immunoglobulin G
76. IgM: immunoglobulin M
77. ILI: influenza-like illness
78. LGV: lymphogranuloma (venereum)
79. LPS: lipopolysaccharides
80. LRI: lower respiratory tract infection, other than pneumonia
81. LRI-BRON: lower respiratory tract infection — bronchitis, tracheobronchitis, bronchiolitis, tracheitis, without evidence of pneumonia
82. TBE: Tick-borne encephalitis
83. vCJD: variant Creutzfeldt-Jakob disease

3. CASE DEFINITIONS OF COMMUNICABLE DISEASES

3.1. ANTHRAX

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

At least one of the following two:

- Isolation of *Bacillus anthracis* from a clinical specimen;
- Detection of *Bacillus anthracis* nucleic acid in a clinical specimen.

Positive nasal swab without clinical symptoms shall 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 with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

3.2. ARENAVIRUS INFECTION**Clinical criteria**

- Clinical manifestations compatible with arenavirus infection (for example, fever, gastrointestinal symptoms, haemorrhagic manifestations, neurological manifestations)

Laboratory criteria*Probable case*

- Detection of anti-arenavirus IgM antibodies in a single serum sample.

Confirmed case

At least one of the following four:

- Isolation and identification of arenavirus from a clinical specimen;
- Detection of arenavirus nucleic acid from a clinical specimen;
- Detection of arenavirus antigen from a clinical specimen;
- Detection of acute infection through serological methods: arenavirus-specific seroconversion OR four-fold antibody titre increase in paired serum samples OR low-avidity IgG antibodies in a serum sample.

Identification of the virus species should be performed, if possible.

Epidemiological criteria

At least one of the following three:

- Residing in, or having visited within the four-week period prior to the onset of symptoms, an area where arenavirus transmission has previously occurred;
- Having been exposed to arenavirus infectious material during an occupation (for example laboratory work);
- Having had contact with possibly infected rodents, their excreta or fomites within the four-week period prior to the onset of symptoms in an area where arenavirus transmission has previously occurred.

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the laboratory criteria for a probable case AND at least one of the following two:
 - clinical criteria;
 - epidemiological criteria.
- C. Confirmed case
 - Any person meeting the laboratory criteria for a confirmed case.

3.3. BOTULISM

Clinical criteria

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

Food-borne, wound and iatrogenic botulism

At least one of the following two:

- Bilateral cranial nerve impairment (for example, diplopia, blurred vision, dysphagia, bulbar weakness);
- Peripheral symmetric paralysis.

Infant botulism

Any infant with at least one of the following six:

- Constipation;
- Lethargy;
- Difficulty in sucking or feeding;
- Ptosis;
- Dysphagia;
- General muscle weakness.

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

Laboratory criteria

At least one of the following three:

- Isolation of BoNT-producing clostridia (for example, *Clostridium botulinum*, *C. baratii*, *C. butyricum*) for infant botulism (stool) or wound botulism (wound);
- Detection of botulinum neurotoxins in a clinical specimen;
- Detection of genes encoding for botulinum neurotoxins in a clinical specimen.

Epidemiological criteria

At least one of the following three epidemiological links:

- Exposure to a common source (for example, food, sharing of needles or other devices);
- Exposure to contaminated food/drinking water;
- Exposure to botulinum neurotoxin for cosmetic or medical reasons.

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the clinical criteria with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

3.4. BRUCELLOSIS

Clinical criteria

Any person with fever

AND at least one of the following seven:

- Sweating (profuse, malodorous, specially nocturnal);
- Chills;
- Arthralgia;
- Weakness;
- Depression;
- Headache;
- Anorexia.

Laboratory criteria

At least one of the following three:

- Isolation of human pathogenic *Brucella* spp. from a clinical specimen;
- Human pathogenic *Brucella* specific antibody response (standard agglutination test, complement fixation, ELISA);
- Detection of human pathogenic *Brucella* spp. nucleic acid in a clinical specimen.

Epidemiological criteria

At least one of the following five 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, for example, vaginal discharge, placenta);
- Exposure to a common source;
- Laboratory exposure.

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the clinical criteria with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

3.5. CAMPYLOBACTERIOSIS

Clinical criteria

Any person with at least one of the following three:

- Diarrhoea;
- Abdominal pain;
- Fever.

Laboratory criteria

At least one of the following two:

- Isolation of human pathogenic *Campylobacter* spp. from a clinical specimen;
- Detection of *Campylobacter* spp. nucleic acid in a clinical specimen.

Note: Antimicrobial susceptibility testing of *Campylobacter* spp. should be performed on a representative subset of isolates.

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 with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

Antimicrobial resistance

The results of antimicrobial susceptibility tests shall be reported according to the methods and criteria agreed between the ECDC and the Member States as specified in the EU protocol for harmonised monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates (<https://ecdc.europa.eu/en/publications-data/eu-protocol-harmonised-monitoring-antimicrobial-resistance-human-salmonella-and-0>).

3.6. CHIKUNGUNYA VIRUS DISEASE

Clinical criteria

- Clinical manifestations compatible with chikungunya virus disease (for example, fever, rash, joint pain).

Laboratory criteria

Probable case

- Detection of anti-chikungunya virus IgM antibodies in a single serum sample.

Confirmed case

At least one of the following four:

- Isolation and identification of chikungunya virus from a clinical specimen;
- Detection of chikungunya viral antigen from a clinical specimen;
- Detection of chikungunya viral nucleic acid from a clinical specimen;
- Detection of acute infection through serological methods (for example, IgM antibodies in a single serum sample, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample), AND confirmation of the specificity of antibodies by simultaneous neutralisation assays with serologically cross-reacting viruses, or with other equivalently discriminatory method.

Epidemiological criteria

At least one of the following two:

- Residing in, or having visited within the two-week period prior to the onset of symptoms, an area where chikungunya virus transmission has previously occurred;
- Having received substances of human origin from a donor who has resided or visited (within the four-week period before donation) an area where chikungunya virus disease has previously been detected.

Case classification

A. Possible case NA

B. Probable case

Any person meeting the laboratory criteria for a probable case AND at least one of the following two:

- clinical criteria;
- epidemiological criteria.

C. Confirmed case

Any person meeting the laboratory criteria for a confirmed case.

Note: Serological results should be interpreted according to previous exposure to other alphaviral infections. Confirmed cases in such situations should be validated by serum neutralisation assay or other equivalent assays.

3.7. CHLAMYDIAL INFECTION, INCLUDING CHLAMYDIAL 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 ten:

- Urethritis;
- Epididymitis;
- Pelvic inflammatory disease;
- Acute salpingitis;
- Acute endometritis;
- Cervicitis;

- Proctitis;
- Purulent conjunctivitis;
- Reactive arthritis;
- Perihepatitis.

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/Proctocolitis.

Laboratory criteria

Chlamydial infection non-LGV

At least one of the following three:

- Detection of *Chlamydia trachomatis* nucleic acid in a clinical specimen;
- Isolation of *Chlamydia trachomatis* from a clinical specimen;
- Detection of *Chlamydia trachomatis* by direct fluorescent antibody (DFA) test in a clinical specimen.

LGV

At least one of the following two:

- Detection of *Chlamydia trachomatis* nucleic acid in a clinical specimen;
- Isolation of *Chlamydia trachomatis* from a clinical specimen;

AND

Identification of a *Chlamydia trachomatis* strain.

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 with an epidemiological link.
- C. Confirmed case
Any person meeting the laboratory criteria.

3.8. CHOLERA

Clinical criteria

Any person with at least one of the following two:

- Diarrhoea;
- Vomiting.

Laboratory criteria

At least one of the following two:

- Isolation of *Vibrio cholerae* from a clinical specimen;
- Detection of *Vibrio cholerae* nucleic acid in a clinical specimen;

AND

At least one of the following two:

- Demonstration of O1 or O139 antigen in the isolate;
- Detection of the O1 or O139 gene(s) in the isolate or clinical specimen;

AND

- Demonstration of cholera-enterotoxin production or detection of the cholera-enterotoxin gene in the isolate or clinical specimen.

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 with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

3.9. VARIANT CREUTZFELDT-JAKOB DISEASE (vCJD)

Preconditions

- Any person with a progressive neuropsychiatric disorder with a duration of illness of at least 6 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 ⁽¹⁾;
- Persistent painful sensory symptoms ⁽²⁾;
- Ataxia;
- Myoclonus or chorea or dystonia;
- Dementia.

Diagnostic criteria*Confirmed case*

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

Probable or possible case

- EEG does not show the typical appearance of sporadic CJD ⁽³⁾ in the early stages of the illness;
- Bilateral pulvinar high signal on MRI brain scan;
- A positive tonsil biopsy ⁽⁴⁾.

Epidemiological criteria

An epidemiological link by human-to-human transmission (for example, blood transfusion).

Case classification**A. Possible case**

Any person fulfilling the preconditions AND

- meeting the clinical criteria AND
- a negative EEG for sporadic CJD ⁽⁵⁾.

B. Probable case

Any person fulfilling the preconditions AND

- meeting the clinical criteria AND
- a negative EEG for sporadic CJD AND
- a positive MRI brain scan

OR

Any person fulfilling the preconditions AND

- a positive tonsil biopsy.

⁽¹⁾ Depression, anxiety, apathy, withdrawal, delusions.

⁽²⁾ This includes both frank pain and/or dysaesthesia.

⁽³⁾ 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.

⁽⁴⁾ 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. Tonsil biopsy testing should be based on immunohistochemistry or Western Blot.

⁽⁵⁾ 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.

- C. Confirmed case
Any person fulfilling the preconditions AND
meeting the diagnostic criteria for case confirmation.

3.10. CRIMEAN-CONGO HAEMORRHAGIC FEVER (CCHF)

Clinical criteria

- Clinical manifestations compatible with Crimean-Congo haemorrhagic fever (for example, fever, photophobia, abdominal pain, diarrhoea, vomiting, haemorrhagic manifestations).

Laboratory criteria

Probable case

- Detection of anti-CCHF virus IgM antibodies in a single serum sample.

Confirmed case

At least one of the following:

- Isolation and identification of CCHF virus from a clinical specimen;
- Detection of CCHF viral nucleic acid from a clinical specimen;
- Detection of acute infection through serological methods (for example, IgM antibodies in a single serum sample, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample), AND confirmation of the specificity of antibodies by simultaneous neutralisation assays with serologically cross-reacting viruses, or with other equivalently discriminatory method.

Epidemiological criteria

- Residing in or having visited within the two-week period prior to the onset of symptoms an area where CCHF virus transmission has previously occurred;
- Having received substances of human origin from a donor who has resided or visited (within the four-week period before donation) an area where CCHF virus transmission has previously occurred;
- Having been exposed to CCHF infectious material during an occupation (for example laboratory work).

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the laboratory criteria for a probable case AND at least one of the following two:
- clinical criteria;
- epidemiological criteria.
- C. Confirmed case
Any person meeting the laboratory criteria for a confirmed case.

3.11. DENGUE

Clinical criteria

- Clinical manifestations compatible with dengue (for example, fever, severe headache, retro-orbital pain, myalgia, arthralgia, rash).

Laboratory criteria*Probable case*

- Detection of anti-dengue virus IgM antibodies in a single serum sample.

Confirmed case

At least one of the following four:

- Isolation and identification of a dengue virus from a clinical specimen;
- Detection of dengue viral nucleic acid from a clinical specimen;
- Detection of dengue viral antigen from a clinical specimen;
- Detection of acute infection through serological methods (for example, IgM antibodies in a single serum sample, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample), AND confirmation of the specificity of antibodies by simultaneous neutralisation assays with serologically cross-reacting viruses, or with other equivalently discriminatory method.

Epidemiological criteria

At least one of the following three:

- Residing in, or having visited within the two-week period prior to the onset of symptoms, an area where dengue virus transmission has previously been detected;
- Sexual contact with a probable or confirmed case of dengue;
- Having received substances of human origin from a donor who has resided or visited (within the four-week period before donation) an area where dengue has previously been detected.

Case classification

A. Possible case NA

B. Probable case

Any person meeting the laboratory criteria for a probable case AND the clinical criteria AND the epidemiological criteria.

C. Confirmed case

Any person meeting the laboratory criteria for a confirmed case.

Note: Serological results should be interpreted according to previous exposure to other flaviviral infections and the flavivirus vaccination status.

3.12. DIPHTHERIA

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 classic 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.

3.13. ECHINOCOCCOSIS

Clinical criteria

Not relevant for surveillance purposes.

Diagnostic criteria

At least one of the following four:

- Typical organ lesions detected by imaging techniques (ultrasound, MRI, CT scan) AND seropositivity by two assays based on different antigens (or a single highly sensitive and specific Western blot);
- Histopathology or parasitology compatible with *Echinococcus multilocularis* or *granulosus* (for example, direct visualisation of the protoscolex in cyst fluid);
- Detection of *Echinococcus granulosus* pathognomonic macroscopic morphology of cyst(s) in surgical specimens OR pathognomonic morphology features on ultrasound;
- 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.

3.14. FILOVIRUS INFECTION

Clinical criteria

Clinical manifestations compatible with filovirus infection (for example, fever, gastrointestinal symptoms, haemorrhagic manifestations, central nervous system manifestations).

Laboratory criteria*Probable case*

Detection of acute infection through serological methods (for example, IgM antibodies in a single serum sample, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample).

Confirmed case

At least one of the following three:

- Isolation and identification of filovirus from a clinical specimen;
- Detection of filovirus nucleic acid from a clinical specimen;
- Detection of filovirus antigen from a clinical specimen.

Identification of the virus species should be performed, if possible.

Epidemiological criteria

At least one of the following two:

- Having been exposed within the four-week period prior to the onset of symptoms to a case of filovirus infection;
- Having been exposed to filovirus infectious material during an occupation (for example laboratory work).

Case classification

A. Possible case NA

B. Probable case

Any person meeting the laboratory criteria for a probable case AND at least one of the following two:

- clinical criteria;
- epidemiological criteria.

C. Confirmed case

Any person meeting the laboratory criteria for a confirmed case.

3.15. GONOCOCCAL INFECTION

Clinical criteria

Any person with at least one of the following eleven:

- Urethritis;
- Acute salpingitis;
- Pelvic inflammatory disease;
- Cervicitis;
- Epididymitis;
- Proctitis;

- Pharyngitis;
- Arthritis;
- Purulent conjunctivitis;
- Perihepatitis;
- Bartholinitis;

OR

Any newborn child with conjunctivitis.

Laboratory criteria

At least one of the following three:

- Isolation of *Neisseria gonorrhoeae* from a clinical specimen;
- Detection of *Neisseria gonorrhoeae* nucleic acid in a clinical specimen;
- Microscopic detection of intracellular Gram-negative diplococci in a urethral specimen from a male.

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 with an epidemiological link.
- C. Confirmed case
Any person meeting the laboratory criteria.

Antimicrobial resistance and reporting of treatment failures

For cases ascertained by culture, the results of antimicrobial susceptibility tests shall be reported according to the methods and criteria agreed between the ECDC and the Member States as specified in the ECDC reporting protocol for gonococcal antimicrobial resistance surveillance which is available to participating Member States.

Cases of possible or confirmed *Neisseria gonorrhoeae* treatment failure shall be reported to ECDC in accordance with the most current case definitions and following the instructions in the 'Response plan to control and manage the threat of multi- and extensively drug-resistant gonorrhoea in Europe' (<https://www.ecdc.europa.eu>) through the European surveillance portal for infectious diseases (EpiPulse).

3.16. HAEMOPHILUS INFLUENZAE INFECTION, INVASIVE DISEASE

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.

3.17. HANTAVIRUS INFECTION

Clinical criteria

Clinical manifestations compatible with hantavirus infection (for example, fever, haemorrhagic manifestations, impaired renal function, pulmonary manifestations).

Laboratory criteria*Probable case*

Detection of anti-hantavirus IgM antibodies in a single serum sample.

Confirmed case

At least one of the following four:

- Isolation and identification of hantavirus from a clinical specimen;
- Detection of hantavirus nucleic acid in a clinical specimen;
- Detection of hantavirus antigen from a clinical specimen;
- Detection of acute infection through hantavirus-specific IgM and IgG antibodies in a single serum sample OR through seroconversion in paired serum samples.

Identification of the virus species should be performed, if possible.

Epidemiological criteria

At least one of the following within two months before onset of symptoms:

- Having had contact with possibly infected rodents, their excreta or fomites;
- Having been exposed to hantavirus infectious material during an occupation (for example laboratory work).

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the laboratory criteria for a probable case AND at least one of the following two:
 - clinical criteria;
 - epidemiological criteria.
- C. Confirmed case
Any person meeting the laboratory criteria for a confirmed case.

3.18. ACUTE HEPATITIS A

Clinical criteria

Any person with a discrete onset of symptoms (for example, 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 with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

3.19. HEPATITIS B

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.

Note: When reporting cases of hepatitis B, the Member States should distinguish between acute and chronic disease according to ECDC requirements.

3.20. HEPATITIS C

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 antigen);
- Hepatitis C virus specific antibody (anti-HCV) response confirmed by a confirmatory antibody test (for example, immunoblot) in persons older than 18 months, excluding persons known to have a resolved prior infection and persons that are also tested for HCV RNA and/or HCV core antigen with an undetectable result.

Epidemiological criteria NA**Case classification**

A. Possible case NA

B. Probable case NA

C. Confirmed case

Any person meeting the laboratory criteria.

Note: When reporting cases of hepatitis C, the Member States should distinguish between acute and chronic disease according to ECDC requirements.

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

Clinical criteria (AIDS)

Any person who has any of the following clinical conditions:

- Bacterial infections, multiple or recurrent, in a child under 13 years of age;
- Candidiasis of bronchi, trachea, or lungs;
- Candidiasis, oesophageal;
- Coccidioidomycosis, disseminated or extrapulmonary;
- Cryptococcosis, extrapulmonary;
- Cryptosporidiosis, intestinal with diarrhoea (> 1 month duration);
- Cytomegalovirus disease (other than liver, spleen, or lymph nodes) in a patient over one month of age;

- Cytomegalovirus retinitis (with loss of vision);
- Herpes simplex: chronic ulcer(s) (> 1 month duration); or bronchitis, pneumonitis, or oesophagitis in a patient over one month of age;
- Histoplasmosis, disseminated or extrapulmonary;
- Isosporiasis, intestinal with diarrhoea (> 1 month duration);
- *Mycobacterium avium* complex or *M. kansasii*, disseminated or extrapulmonary;
- *Mycobacterium tuberculosis*, pulmonary in an adult or adolescent (aged 13 years or over);
- *Mycobacterium tuberculosis*, extrapulmonary;
- *Mycobacterium*, other or unidentified species, disseminated or extrapulmonary;
- *Pneumocystis carinii* pneumonia;
- Pneumonia, recurrent, in an adult or adolescent (aged 13 years or over);
- Progressive multifocal leukoencephalopathy;
- Salmonella (non-typhoid) septicaemia, recurrent;
- Toxoplasmosis of the brain in a patient over one month of age;
- Cervical cancer, invasive, in an adult or adolescent (aged 13 years or over);
- Encephalopathy, HIV-related;
- Kaposi's sarcoma;
- Lymphoid interstitial pneumonia in a child under 13 years of age;
- Lymphoma, Burkitts (or equivalent term);
- Lymphoma, immunoblastic (or equivalent term);
- Lymphoma, primary, of brain;
- Wasting syndrome due to HIV;
- Opportunistic infection(s), not specified;
- Lymphoma(s), not specified.

Laboratory criteria (HIV)

- Adults, adolescents and children aged ≥ 18 months

At least one of the following three:

- Positive result of an HIV screening antibody test or a combined screening test (HIV antibody and HIV p24 antigen) confirmed by a more specific antibody test (for example, Western blot);
- Positive result of two EIA antibody tests 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 proviral 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 proviral DNA);
- Demonstration of HIV by HIV p24 antigen test, including neutralisation assay in a child $\geq$ 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.

3.22. LEGIONNAIRES' DISEASE

Clinical criteria

Any person with pneumonia

Laboratory criteria

Laboratory criteria for case confirmation

At least one of the following four:

- Isolation of *Legionella* spp. from respiratory secretions or any normally sterile site;
- Detection of *Legionella* antigen in urine;
- Detection of *Legionella pneumophila* nucleic acid in lower respiratory secretions, lung tissue or any normally sterile site;
- 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 three:

- Detection of nucleic acid of unspecified *Legionella* spp. or other species than *Legionella pneumophila* in lower 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.

Differentiation of *Legionella* spp. should be performed, if possible.

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.

3.23. LEPTOSPIROSIS

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 with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

3.24. LISTERIOSIS

Clinical criteria

Any person with at least one of the following five:

- Fever;
- Meningitis, meningoen­cephalitis, or encephalitis;
- Influenza-like symptoms;
- Septicaemia;
- Localised infections such as arthritis, endocarditis, endophthalmitis, and abscesses.

Listeriosis in pregnancy:

- Pregnancy-related consequences of *Listeria* infection defined as: miscarriage, stillbirth or premature birth;
- Listeriosis of newborns defined as one of the following:
 - Stillbirth (foetal death after 20 weeks of gestation);
 - Premature birth (before 37 gestational weeks).

OR

At least one of the following five in the first month of life (neonatal listeriosis):

- Meningitis or meningoen­cephalitis;
- Septicaemia;
- Dyspnoea;
- Granulomatosis infantiseptica;
- Lesions on skin, mucosal membranes or conjunctivae.

Laboratory criteria

At least one of the following two:

- Isolation of *Listeria monocytogenes* or detection of nucleic acid of *Listeria monocytogenes* from a normally sterile site;
- In a pregnancy-associated case also: Isolation of *Listeria monocytogenes* or detection of nucleic acid from *Listeria monocytogenes* in a normally non-sterile site (for example, placental tissue, amniotic fluid, meconium, vaginal swab) or from a foetus, stillborn, newborn or the mother.

Epidemiological criteria

At least one of the following four epidemiological links:

- Exposure to a common source;
- Human-to-human transmission (vertical transmission);
- Exposure to contaminated food;
- Animal-to-human transmission.

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the clinical criteria with an epidemiological link.
- C. Confirmed case
Any person meeting the laboratory criteria for a normal sterile site OR
In a pregnancy-associated case (mother or newborn in the first month of life) meeting the laboratory criteria, only the mother is to be reported as a case.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

3.25. MALARIA

Clinical criteria

Not relevant for surveillance purposes.

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 laboratory criteria for a confirmed case.

3.26. MEASLES

Clinical criteria

Any person suspected of having measles infection by a healthcare worker

OR

Any person with fever AND

- Maculo-papular (non-vesicular) rash;

AND at least one of the following *three*:

- Cough;
- Coryza;
- Conjunctivitis.

Laboratory criteria

At least one of the following *four*:

- Measles IgM antibody detection;
- Detection of measles virus nucleic acid in an adequate clinical specimen;
- Measles IgG seroconversion or significant rise in measles IgG antibody titre in paired specimens tested in parallel;
- Isolation of measles virus from a clinical specimen.

In elimination settings, additional testing may be considered in certain situations to exclude false-positive IgM results. Laboratory results need to be interpreted according to the timing of specimen collection and to the vaccination status. Please refer to the WHO Manual for the Laboratory Surveillance of Measles and Rubella Viruses (2018). If recently vaccinated, investigate for wild virus and rule out the possibility of a vaccine-associated reaction.

Epidemiological criteria

A case that was geographically and temporally related with a laboratory-confirmed case or another epidemiologically linked measles case with dates of rash onset occurring 7–23 days apart.

Discarded case criteria

Any person meeting the clinical criteria

AND

At least one of the following *three*:

- Despite an adequate specimen collected and tested by a proficient laboratory, the case does not meet the measles case definition laboratory criteria;
- The case is epidemiologically linked to a laboratory-confirmed case or outbreak of another communicable disease that is not measles;
- Another disease aetiology is confirmed in the case, even if the case is epidemiologically linked to a laboratory-confirmed measles case or another epidemiologically linked case.

Case classification

A. Possible case

Any person meeting the clinical criteria and in whom laboratory confirmation or epidemiological linkage to a laboratory-confirmed case or another epidemiologically linked case was not possible.

B. Probable case

Any person meeting the clinical criteria and epidemiological criteria, but in whom laboratory confirmation was not possible.

C. Confirmed case

Any person meeting the clinical and the laboratory criteria who was not recently vaccinated.

In case of recent vaccination, a person meeting the clinical criteria with detection of wild-type measles virus strain shall be considered as a confirmed case.

- D. Discarded case
Any person meeting the discarded case criteria.

Note: Whenever possible, suspected cases of measles shall be laboratory tested at a proficient laboratory using an adequate specimen collected during the proper time period. Please refer to the WHO Manual for the Laboratory Surveillance of Measles and Rubella Viruses (2018). In instances where this is not possible, effort shall be made to identify an epidemiological link to a laboratory-confirmed measles case or another epidemiologically linked case.

3.27. MENINGOCOCCAL INFECTION, INVASIVE DISEASE

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 with an epidemiological link.
- C. Confirmed case
Any person meeting the laboratory criteria.

3.28. MPOX

Clinical criteria

Clinical manifestations compatible with mpox (for example, acute skin rash, mucosal lesions, lymphadenopathy).

Laboratory criteria

Probable case

At least one of the following three:

- Detection of orthopoxvirus viral nucleic acid from a clinical specimen (for example, orthopoxvirus-specific PCR without monkeypoxvirus-specific PCR or sequencing);

- Detection of orthopoxvirus infection by electron microscopy or by antigen detection methods;
- Detection of acute infection through serological methods (for example, anti-orthopoxvirus IgM antibodies in a single serum sample, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample).

Confirmed case

At least one of the following two:

- Isolation and identification of monkeypox virus from a clinical specimen;
- Detection of monkeypox viral nucleic acid from a clinical specimen.

Epidemiological criteria

At least one of the following two within the three-week period before onset of symptoms:

- Epidemiological link to a probable or confirmed case of mpox;
- Residing in or having visited an area with documented on-going transmission of monkeypox virus.

Case classification

A. Possible case NA

B. Probable case

Any person meeting the laboratory criteria for a probable case AND at least one of the following two:

- clinical criteria,
- epidemiological criteria.

C. Confirmed case

Any person meeting the laboratory criteria for a confirmed case.

Note: Orthopoxvirus-specific PCR and monkeypox virus-specific PCR on a blood specimen may be unreliable and should also not be used alone as a first-line diagnostic test. Serological results should be interpreted according to previous exposure to smallpox/mpox vaccination or other known exposure to orthopoxviruses.

3.29. MUMPS

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 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.

3.30. 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.

Notes: All individuals including adults, adolescents or vaccinated children can present with atypical symptoms. Characteristics of cough should be investigated, particularly whether the cough is paroxysmal in nature, increases during the night and occurs in the absence of fever.

Laboratory criteria

At least one of the following three:

- (i) Isolation of *Bordetella pertussis* from a clinical specimen;
- (ii) Detection of *Bordetella pertussis* nucleic acid in a clinical specimen;
- (iii) *Bordetella pertussis*-specific antibody response.

Direct diagnosis (i)-(ii): *Bordetella pertussis* and its nucleic acid are best isolated/detected from nasopharyngeal samples.

Indirect diagnosis (iii): if possible, ELISA should be performed using highly purified pertussis toxin and WHO reference sera as a standard. Results should be interpreted according to pertussis vaccination status. If vaccinated within the last few years before specimen collection, the titre of specific antibodies against *Bordetella pertussis* toxin may be a consequence of, or modified by, previous vaccination.

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 with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

3.31. PLAGUE

Clinical criteria

Not relevant for surveillance purposes.

Laboratory criteria

At least one of the following three:

- Isolation and identification of *Yersinia pestis* from a clinical specimen;
- Detection of *Yersinia pestis* nucleic acid from a clinical specimen;
- *Yersinia pestis* anti-F1-antigen-specific antibody response.

Epidemiological criteria NA**Case classification**

- A. Possible case NA
- B. Probable case NA
- C. Confirmed case
Any person meeting the laboratory criteria.

3.32. *STREPTOCOCCUS PNEUMONIAE* INFECTION, INVASIVE DISEASE**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.

Antimicrobial resistance

The results of antimicrobial susceptibility tests shall be reported according to the methods and criteria agreed between the ECDC and the Member States as specified by the ECDC's European Antimicrobial Resistance Surveillance Network (EARS-Net). The criteria for reporting are published each year as part of the antimicrobial resistance reporting protocol. See: The European Surveillance system. Antimicrobial resistance reporting protocol. European Antimicrobial Resistance Surveillance Network (EARS-Net). www.ecdc.europa.eu.

3.33. ACUTE POLIOMYELITIS

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;
- A 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 with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

3.34. Q FEVER

Clinical criteria

Clinical manifestations compatible with acute Q fever (for example, fever, pneumonia, hepatitis).

Laboratory criteria

At least one of the following three:

- Isolation and identification 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

Exposure to the same source (for example, infected animals or their birth products) as a confirmed case or to *Coxiella burnetii* infectious material.

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the clinical criteria and the epidemiological criteria.
- C. Confirmed case
Any person meeting the clinical criteria and the laboratory criteria.

3.35. RABIES AND OTHER LYSSAVIRUS INFECTIONS

Clinical criteria

Not relevant for surveillance purposes.

Laboratory criteria

At least one of the following four:

- Isolation and identification of Lyssavirus from a clinical specimen;
- Detection of Lyssa virus nucleic acid in a clinical specimen;
- Detection of lyssavirus antigens in a clinical specimen;
- Demonstration of typical lesions in post-mortem brain histopathology.

Identification of the virus species 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 laboratory criteria.

3.36. RESPIRATORY VIRAL INFECTIONS (INFLUENZA, CORONAVIRUS DISEASE 2019, RESPIRATORY SYNCYTIAL VIRUS INFECTION)

SYNDROMES*Acute respiratory infection (ARI)*

Sudden onset of symptoms and at least one of the following:

- Cough;
- Sore throat;
- Shortness of breath;
- Coryza;

AND

a clinician's judgement that the illness is due to an infection.

Influenza-like illness (ILI)

An acute respiratory infection (ARI) with at least one of the following four systemic symptoms:

- Measured fever or self-reported feverishness;
- Malaise;
- Headache;
- Myalgia.

Severe acute respiratory infection (SARI)

An acute respiratory infection (ARI) which:

- Requires hospitalisation

OR

- In infants less than 6 months of age, presents with at least one of the following two:
 - Apnoea, defined as temporary cessation of breathing from any cause,
 - Sepsis, defined as:
 - fever (37,5 °C or above) or hypothermia (less than 35,5 °C), AND
 - shock (lethargy, fast breathing, cold skin, prolonged capillary refill, fast weak pulse), AND
 - being seriously ill with no apparent cause.

INFLUENZA IN HUMANS, SEASONAL

Clinical criteria

At least one of the following:

- ARI;
- ILI;
- SARI.

Laboratory criteria

At least one of the following:

- Detection of influenza virus nucleic acid in a clinical specimen;
- Identification of influenza virus antigen in a clinical specimen (antigen tests used in healthcare and other settings where testing can be performed by trained or professional staff, for example pharmacies);
- Isolation of influenza virus from a clinical specimen.

Epidemiological criteria

Contact with a confirmed human case.

Case classification

- A. Possible case:
Any person meeting the clinical criteria (ARI, ILI or SARI).
- B. Probable case:
Any person meeting the clinical criteria (ARI, ILI or SARI) and the epidemiological criterion.
- C. Confirmed case:
Any person meeting the laboratory criteria.

INFLUENZA IN HUMANS, ZOONOTIC

Zoonotic influenza in humans is an infection caused by an influenza virus that is primarily adapted to non-human animal hosts (such as birds, pigs, horses) and is not circulating in the human population but can cause a human infection through direct or indirect exposure to infected animals or contaminated environments.

Clinical criteria

At least one of the following:

- ARI;
- ILI;
- SARI;
- Conjunctivitis;
- Neurological presentation (for example encephalitis);
- Other severe or unusual clinical presentations not explained by an alternative diagnosis.

Laboratory criteria

At least one of the following:

- Isolation of a zoonotic influenza virus from a clinical specimen;
- Specific antibody response to a zoonotic influenza virus (four-fold or greater rise);
- Detection of a zoonotic influenza virus nucleic acid in a clinical specimen (in case of nucleic acid positivity only, clinical, and/or epidemiological, and/or other laboratory criteria shall be verified to rule out sample contamination).

Epidemiological criteria

In the 14 days prior to symptom onset, at least one of the following:

- Close contact with a probable or confirmed human case of zoonotic influenza;
- Close contact with an animal in which zoonotic influenza A virus has been confirmed;
- Presence in a setting (for example, home, farm, market, workplace) in which zoonotic influenza A virus has been confirmed in animals or the environment;
- Laboratory exposure to zoonotic influenza virus.

Case classification

- A. Possible case NA
- B. Probable case:
Any person meeting the clinical AND the epidemiological criteria
OR
Any person meeting the epidemiological criteria AND detection of untyped non-seasonal influenza A – (pending confirmation).
- C. Confirmed case:
Any person meeting the laboratory criteria (laboratory confirmation performed by a national reference laboratory for influenza or European Union reference laboratory or WHO Collaborating Centre or other WHO reference laboratory.).

CORONAVIRUS DISEASE 2019 (COVID-19) IN HUMANS

Clinical criteria

At least one of the following:

- ARI;
- ILI;
- SARI.

Laboratory criteria

At least one of the following:

- Detection of SARS-CoV-2 nucleic acid in a clinical specimen;
- Identification of SARS-CoV-2 antigen in a clinical specimen (antigen tests used in healthcare and other settings where testing can be performed by trained or professional staff, for example pharmacies);
- Isolation of SARS-CoV-2 from a clinical specimen.

Epidemiological criteria

Contact with a confirmed human case in the 14 days prior to onset of symptoms.

Case classification

- A. Possible case:
Any person meeting the clinical criteria (ARI, ILI or SARI).
- B. Probable case:
Any person meeting the clinical criteria (ARI, ILI or SARI) and the epidemiological criterion.
- C. Confirmed case:
Any person meeting the laboratory criteria.

RESPIRATORY SYNCYTIAL VIRUS (RSV) INFECTION IN HUMANS

Clinical criteria

At least one of the following:

- ARI;
- ILI;
- SARI.

Laboratory criteria

At least one of the following:

- Detection of RSV nucleic acid in a clinical specimen;
- Identification of RSV antigen in a clinical specimen (antigen tests used in healthcare and other settings where testing can be performed by trained or professional staff, for example pharmacies);
- Isolation of RSV from a clinical specimen.

Epidemiological criteria

Contact with a confirmed human case.

Case classification

- A. Possible case:
Any person meeting the clinical criteria (ARI, ILI or SARI).
- B. Probable case:
Any person meeting the clinical criteria (ARI, ILI or SARI) and the epidemiological criterion.
- C. Confirmed case:
Any person meeting the laboratory criteria.

3.37. RIFT VALLEY FEVER

Clinical criteria

Clinical manifestations compatible with Rift Valley fever (for example, fever, jaundice, gastrointestinal symptoms, haemorrhagic manifestations, ocular manifestations).

Laboratory criteria*Probable case*

Detection of anti-Rift Valley fever virus (RVFV) IgM antibodies in a single serum sample.

Confirmed case

At least one of the following four:

- Isolation and identification of RVFV from a clinical specimen;
- Detection of RVFV nucleic acid from a clinical specimen;
- Detection of RVFV antigen from a clinical specimen;
- Detection of acute infection through serological methods (for example, IgM antibodies in a single serum sample, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample), AND confirmation of the specificity of antibodies by simultaneous neutralisation assays with serologically cross-reacting viruses, or with other equivalently discriminatory method.

Epidemiological criteria

At least one of the following three:

- Residing in, or having visited within the two-week period prior to the onset of symptoms, an area where RVFV transmission has previously occurred;
- Having been exposed to RVFV infectious material during an occupation (for example laboratory work);
- Having had contact with biological material of possibly infected animals in an area where RVFV transmission has previously occurred.

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the laboratory criteria for a probable case AND at least one of the following two:
 - clinical criteria;
 - epidemiological criteria.
- C. Confirmed case
Any person meeting the laboratory criteria for a confirmed case.

3.38. RUBELLA

Clinical criteria

Any person suspected of having rubella infection by a healthcare worker

OR

Any person with sudden onset of generalised maculo-papular (non-vesicular) rash

AND

At least one of the following three:

- Lymphadenopathy (for example, cervical, sub-occipital or post-auricular adenopathy);
- Arthralgia;
- Arthritis.

Laboratory criteria

At least one of the following four:

- Isolation of rubella virus from a clinical specimen;
- Detection of rubella virus nucleic acid in an adequate clinical specimen;
- Rubella IgM antibody detection;
- Rubella IgG seroconversion or significant rise in rubella IgG antibody titre in paired specimens tested in parallel.

In elimination settings, additional testing may be considered in certain situations to exclude false-positive IgM results. Laboratory results need to be interpreted according to the timing of specimen collection and to the vaccination status. Please refer to the WHO Manual for the Laboratory Surveillance of Measles and Rubella Viruses (2018). If recently vaccinated, investigate for wild virus.

Epidemiological criteria

A person who was geographically and temporally related to a laboratory-confirmed case or another epidemiologically linked rubella case with the dates of rash onset occurring 12 to 23 days apart.

Discarded case criteria

Any person meeting the clinical criteria;

AND

At least one of the following three:

- Despite an adequate specimen collected and tested by a proficient laboratory, the case does not meet the rubella case definition laboratory criteria;
- The case is epidemiologically linked to a laboratory-confirmed case or outbreak of another communicable disease that is not rubella;
- Another disease aetiology is confirmed in the case, even if the case is epidemiologically linked to a laboratory-confirmed rubella case or another epidemiologically linked case.

Case classification**A. Possible case**

Any person meeting the clinical criteria and in whom laboratory confirmation or epidemiological linkage to a laboratory-confirmed case or another epidemiologically linked case was not possible.

B. Probable case

Any person meeting the clinical criteria and epidemiological criteria, but in whom laboratory confirmation was not possible.

C. Confirmed case

Any person meeting the clinical criteria and the laboratory criteria who has not been recently vaccinated.

In case of recent vaccination, a person meeting the clinical criteria with detection of wild-type rubella virus strain shall be considered as a confirmed case.

D. Discarded

Any person meeting the discarded case criteria.

Note: When rubella in pregnancy is suspected, further confirmation of a positive rubella IgM result is required for case management (for example, a rubella-specific IgG avidity test, rubella IgM and comparison of rubella IgG levels on paired sera conducted in a reference laboratory).

3.39. CONGENITAL RUBELLA SYNDROME**Clinical criteria***Congenital rubella infection*

No clinical criteria can be defined for congenital rubella infection.

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 shall 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.

3.40. *SALMONELLA* ENTERITIS**Clinical criteria**

Any person with at least one of the following four:

- Diarrhoea;
- Fever;
- Abdominal pain;
- Vomiting.

Laboratory criteria

At least one of the following two:

- Isolation of *Salmonella* (other than *S. Typhi* or *S. Paratyphi*) in a clinical specimen;
- Detection of nucleic acid from *Salmonella* (other than *S. Typhi* or *S. Paratyphi*) in a clinical specimen.

Note: Antimicrobial susceptibility testing of *Salmonella enterica* should be performed on a representative subset of isolates.

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 with an epidemiological link.

C. Confirmed case

Any person meeting the clinical and the laboratory criteria.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

Antimicrobial resistance

The results of antimicrobial susceptibility tests shall be reported according to the methods and criteria agreed between the ECDC and the Member States as specified in the EU protocol for harmonised monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates (<https://ecdc.europa.eu/en/publications-data/eu-protocol-harmonised-monitoring-antimicrobial-resistance-human-salmonella-and-0>).

3.41. SHIGA TOXIN-PRODUCING *E. COLI* INFECTION (STEC), INCLUDING HAEMOLYTIC-URAEMIC SYNDROME (HUS)**Clinical criteria***STEC 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:

- Microangiopathic haemolytic anaemia;
- Thrombocytopenia.

Laboratory criteria

At least one of the following two:

- Detection of *stx1* or *stx2* gene(s) nucleic acid in the *Escherichia coli* isolate or the clinical specimen;
- Detection of Shiga toxin in the *Escherichia coli* isolate or the clinical specimen.

Only for HUS, the following can be used as a laboratory criterion to confirm STEC:

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

For a probable case:

- Isolation of non-sorbitol-fermenting (NSF) *Escherichia coli* O157 (without testing for the toxin or toxin-producing genes).

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
Any person meeting the clinical criteria with an epidemiological link
OR
Any person meeting the clinical criteria and the laboratory criterion for a probable case.
- C. Confirmed case of STEC
Any person meeting the clinical criteria and the laboratory criteria for a confirmed case.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

3.42. SHIGELLOSIS

Clinical criteria

Any person with at least one of the following four:

- Diarrhoea;
- Fever;
- Vomiting;
- Abdominal pain.

Laboratory criteria

For a confirmed case:

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

For a probable case:

- Detection of *Shigella* spp. nucleic acid in a clinical specimen

Note: Antimicrobial susceptibility testing of *Shigella* should be performed, if possible.

Epidemiological criteria

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

- 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 with an epidemiological link

OR

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

C. Confirmed case

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

OR

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

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

Antimicrobial resistance

The results of antimicrobial susceptibility tests shall be reported according to the methods and criteria agreed between the ECDC and the Member States.

3.43. SMALLPOX

Clinical criteria

Not relevant for surveillance purposes.

Laboratory criteria

At least one of the following two:

- Isolation of variola virus (*Orthopoxvirus variola*) from a clinical specimen followed by sequencing;
- Detection of variola virus nucleic acid in a clinical specimen followed by sequencing.

Epidemiological criteria NA**Case classification**

- A. Possible case NA
- B. Probable case NA
- C. Confirmed case
Any person meeting the laboratory criteria.

3.44. SYPHILIS (EXCLUDING CONGENITAL SYPHILIS)

Clinical criteria*Primary syphilis*

Any person with one or several (usually painless) ulcerative lesions (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;
- Diffuse alopecia.

Early latent syphilis (< 12 months)

No symptoms at the time of diagnosis and a history of symptoms compatible with those of the earlier stages of syphilis within the previous 12 months.

Note that ocular and neurological manifestations may occur at any stage of syphilis. Note that cases of late latent syphilis (> 12 months) are not subject to Union surveillance.

Laboratory criteria

At least one of the following four:

- Detection of *Treponema pallidum* by dark-field microscopic examination in a clinical specimen;
- Detection of *Treponema pallidum* by direct fluorescent antibody (DFA) test in a clinical specimen;
- Detection of *Treponema pallidum* nucleic acid in a clinical specimen;
- Detection of *Treponema pallidum* antibodies by screening test (TPHA, TPPA or EIA) AND additionally detection of either TP-IgM antibodies (for example, IgM-ELISA or immunoblot or 19S-IgM-FTA-abs) OR non-treponemal antibodies (for example, RPR, VDRL).

Epidemiological criteria*Primary/secondary syphilis*

An epidemiological link by human-to-human transmission (sexual contact).

Early latent syphilis

An epidemiological link by human-to-human transmission (sexual contact) within the 12 previous months.

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the clinical criteria with an epidemiological link.
- C. Confirmed case
Any person meeting the laboratory criteria for case confirmation.

3.45. CONGENITAL SYPHILIS

Clinical criteria

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

- Hepatomegaly/Hepatosplenomegaly;
- Mucocutaneous lesions;
- Condyloma lata;
- Persistent rhinitis;
- Jaundice;
- Pseudoparalysis (due to periostitis and osteochondritis);
- Central nervous involvement;
- Anaemia;
- Nephrotic syndrome;
- Malnutrition;
- Generalised lymphadenopathy.

Laboratory criteria*Confirmed case*

At least one of the following four:

- Detection of *Treponema pallidum* by dark-field microscopic examination in a clinical specimen;
- Detection of *Treponema pallidum* by direct fluorescent antibody (DFA) test in a clinical specimen;
- Detection of *Treponema pallidum* nucleic acid in a clinical specimen;
- Detection of *Treponema pallidum*-specific IgM (FTA-abs, EIA).

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

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 at birth 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.

3.46. TICK-BORNE ENCEPHALITIS (TBE)

For the purpose of this document, 'tick-borne encephalitis' refers both to Central European tick-borne encephalitis and Far Eastern tick-borne encephalitis.

Clinical criteria

Clinical manifestations compatible with tick-borne encephalitis (for example, fever, symptoms of inflammation of the central nervous system)

Laboratory criteria*Probable case*

Detection of anti-TBE virus IgM-antibodies in a single serum sample.

Confirmed case

At least one of the following six:

- Isolation and identification of TBE virus from a clinical specimen;
- Detection of TBE viral nucleic acid in a clinical specimen;
- Detection of TBE virus antigen in a clinical specimen;
- Detection of TBE virus-specific IgM AND IgG antibodies in blood;
- Detection of TBE virus-specific IgM antibodies in CSF;
- Detection of acute infection through serological methods in CSF or serum (for example, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample), AND confirmation of the specificity of antibodies by simultaneous neutralisation assays with serologically cross-reacting viruses, or with other equivalently discriminatory methods.

Epidemiological criteria

At least one of the following two:

- Exposure to the same vehicle of infection (for example, unpasteurised milk and milk products) as a confirmed case;
- Residing in, or having visited within the four-week period prior to the onset of symptoms, an area where tick-borne viral encephalitis has previously occurred.

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the laboratory criteria for a probable case AND the clinical criteria AND the epidemiological criteria.
- C. Confirmed case
Any person meeting the laboratory criteria for a confirmed case.

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

3.47. CONGENITAL TOXOPLASMOSIS

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.

3.48. TRICHINELLOSIS

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 with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical criteria and the laboratory criteria.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

3.49. TUBERCULOSIS

Clinical criteria

Any person with the following:

- 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 treatment OR

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

Laboratory criteria*Confirmed case*

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 at time of diagnosis with any of the WHO-recommended tests according to the most updated WHO recommendations (<https://www.who.int/publications/i/item/9789240030589>).

Probable case

At least one of the following:

- Detection of acid-fast bacilli by microscopy (including fluorescence microscopy);
- 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 criteria and the laboratory criteria for case confirmation.

Antimicrobial resistance

The results of phenotypic antimicrobial susceptibility tests and/or genotypic methods shall be reported according to the methods and criteria agreed between the ECDC and the Member States as specified by the European Reference Laboratory Network for Tuberculosis and the European Tuberculosis Surveillance Network and published in the reporting protocol for tuberculosis surveillance.

3.50. TULARAEMIA

Clinical criteria

Clinical manifestations compatible with tularaemia (for example, fever, lymphadenopathy, gastrointestinal symptoms, pneumonia, septicaemia, stomatitis, cutaneous ulcer, conjunctivitis).

Laboratory criteria

At least one of the following three:

- Isolation and identification of *Francisella tularensis* from a clinical specimen;
- Detection of *Francisella tularensis* nucleic acid in a clinical specimen;
- *Francisella tularensis*-specific antibody response.

Epidemiological criteria

Exposure to the same source (for example, infected animals, food or water contaminated with *Francisella tularensis*) as a confirmed case or to *Francisella tularensis* infectious material.

Case classification

- A. Possible case NA
- B. Probable case
Any person meeting the clinical criteria and the epidemiological criteria.
- C. Confirmed case
Any person meeting the clinical and laboratory criteria.

3.51. WEST NILE VIRUS INFECTION (WNV)

Clinical criteria

Clinical manifestations compatible with West Nile virus infection (for example, fever, encephalitis, meningitis).

Laboratory criteria*Probable case*

At least one of the following three:

- Detection of anti-WNV IgM antibodies in serum or CSF;
- Detection of seroconversion or four-fold antibody titre increase in paired serum samples;
- Detection of flavivirus nucleic acid in a clinical specimen, if WNV-specific assay is not available (for example, NAT/PCR screening of blood donations).

Confirmed case

At least one of the following four:

- Isolation and identification of WNV from a clinical specimen;
- Detection of WNV nucleic acid in a clinical specimen;
- Detection of acute infection through serological methods in CSF or serum (for example, IgM antibodies in a single serum sample, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample), AND confirmation of the specificity of antibodies by simultaneous neutralisation assays with serologically cross-reacting viruses, or with other equivalently discriminatory method;
- WNV-specific antigen detection (postmortem immunohistochemistry (IHC)).

Epidemiological criteria

At least one of the following four epidemiological links:

- Residing in, or having visited within the four-week period prior to the onset of symptoms or prior to the detection of the infection during the WNV transmission season, an area where WNV has been previously detected in humans or animals;
- Having received substances of human origin from a donor who has resided or visited (within the four-week period before donation) during the WNV transmission season an area where WNV has been previously detected;
- Having been exposed to WNV infectious material during an occupation (for example laboratory work);
- Having been exposed to WNV through vertical transmission.

Case classification

A. Possible case NA

B. Probable case

Any person meeting the laboratory criteria for a probable case AND the clinical criteria AND the epidemiological criteria.

C. Confirmed case

Any person meeting the laboratory criteria for case confirmation.

Note: Serological results should be interpreted according to previous exposure to other flaviviral infections and the flavivirus vaccination status.

3.52. YELLOW FEVER

Clinical criteria

Clinical manifestations compatible with yellow fever (for example, fever, jaundice, haemorrhagic manifestations).

Laboratory criteria*Probable case*

At least one of the following two:

- Detection of anti-yellow fever virus IgM antibodies in a single serum sample (not applicable in case of recent yellow fever vaccination);
- Demonstration of typical lesions in post-mortem liver histopathology.

Confirmed case

At least one of the following four:

- Isolation and identification of yellow fever virus from a clinical specimen (in case of recent vaccination, a person with detection of wild-type yellow fever virus strain);
- Detection of yellow fever virus nucleic acid in a clinical specimen (in case of recent vaccination, a person with detection of wild-type yellow fever virus strain);
- Detection of yellow fever antigen in a clinical specimen (not applicable in case of recent yellow fever vaccination);
- Detection of acute infection through serological methods (for example, IgM antibodies in a single serum sample, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample), AND confirmation of the specificity of antibodies (not applicable in case of recent yellow fever vaccination).

Epidemiological criteria

At least one of the following two:

- Residing in, or having visited within the two-week period prior to the onset of symptoms, an area where yellow fever virus transmission has previously been detected;
- Having received substances of human origin from a donor who has resided or visited (within the four-week period before donation) an area where yellow fever virus transmission has previously been detected.

Case classification

A. Possible case NA

B. Probable case

Any person meeting the laboratory criteria for a probable case AND the clinical criteria AND the epidemiological criteria.

C. Confirmed case

Any person meeting the laboratory criteria for a confirmed case.

Note: Serological results should be interpreted according to previous exposure to other flaviviral infections and the flavivirus vaccination status. In case of recent yellow fever vaccination without travel history to a yellow-fever-affected area, if strain determination is not possible, this should be considered as a vaccine-strain of yellow fever virus.

3.53. YERSINIOSIS, INTESTINAL

Clinical criteria

Any person with at least one of the following five:

- Fever;
- Diarrhoea;
- Vomiting;
- Abdominal pain (pseudoappendicitis);
- Rectal tenesmus.

Laboratory criteria

At least one of the following two:

- Isolation of human pathogenic *Yersinia enterocolitica* or *Yersinia pseudotuberculosis* from a clinical specimen;
- Detection of *Y. enterocolitica* or *Y. pseudotuberculosis* virulence genes in 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 with an epidemiological link.
- C. Confirmed case
Any person meeting the clinical and the laboratory criteria.

Note: If the national surveillance system is not capturing clinical symptoms, all laboratory-confirmed individuals shall be reported as confirmed cases.

3.54. ZIKA VIRUS DISEASE**Clinical criteria**

Clinical manifestations compatible with Zika virus disease (for example, rash, fever, a foetus or newborn with microcephaly or intracranial calcifications or other central nervous system abnormalities).

Laboratory criteria*Probable case*

Detection of anti-Zika virus IgM antibodies in a single serum sample.

Confirmed case

At least one of the following five:

- Isolation and identification of Zika virus from a clinical specimen;
- Detection of Zika virus nucleic acid in a clinical specimen;
- Detection of Zika virus antigen in a clinical specimen;
- Detection of acute infection through serological methods (for example, IgM antibodies in a single serum sample, seroconversion or four-fold antibody titre increase in paired serum samples, low-avidity IgG antibodies in a serum sample), AND confirmation of the specificity of antibodies by simultaneous neutralisation assays with serologically cross-reacting viruses, or with another equivalently discriminatory method;
- Detection of anti-Zika virus IgM antibodies in amniotic fluid or cerebrospinal fluid of a foetus or newborn with microcephaly or intracranial calcifications or other central nervous system abnormalities.

Epidemiological criteria

At least one of the following four:

- Residing in, or having visited within the two-week period prior to the onset of symptoms, an area where Zika virus transmission has previously been detected;
- Having received substances of human origin from a donor who has resided or visited (within the four-week period before donation) an area where Zika virus transmission has previously been detected;
- Sexual contact within the two-week period prior to the onset of symptoms with a probable or confirmed case of Zika virus infection;
- Mother having had a probable or confirmed Zika virus infection during pregnancy.

Case classification

A. Possible case NA

B. Probable case

A person meeting the laboratory criteria for a probable case AND the clinical criteria AND the epidemiological criteria

OR

A foetus or newborn with microcephaly or intracranial calcifications or other central nervous system abnormalities with a mother meeting at least one of the epidemiological criteria.

C. Confirmed case

A person meeting the laboratory criteria for a confirmed case.

Note: Serological results should be interpreted according to previous exposure to other flaviviral infections and the flavivirus vaccination status.

4. CASE DEFINITIONS OF SPECIAL HEALTH ISSUES

4.1. ANTIMICROBIAL RESISTANCE (INCLUDING ANTIMICROBIAL CONSUMPTION IN HUMANS)

4.1.1. GENERAL CASE DEFINITION FOR PATHOGENS (OTHER THAN THOSE LISTED IN ANNEX I) FOR WHICH ANTIMICROBIAL RESISTANCE IS A CONCERN

Clinical criteria

Not relevant for surveillance purposes.

Laboratory criteria

At least one microbiological culture (blood, CSF) positive for *Staphylococcus aureus* or *Klebsiella pneumoniae* complex or *Escherichia coli* or *Enterococcus faecium* or *Enterococcus faecalis* or *Pseudomonas aeruginosa* or *Acinetobacter* species or *Streptococcus pneumoniae* or *Candidozyma auris*.

Epidemiological criteria

Not relevant for surveillance purposes.

Case classification

A. Possible case NA

B. Probable case NA

C. Confirmed case

Antimicrobial resistance

The results of antimicrobial susceptibility tests shall be reported according to the methods and criteria agreed between ECDC and Member States as specified by ECDC's European Antimicrobial Resistance Surveillance Network (EARS-Net; the criteria for reporting are published each year as part of the antimicrobial resistance reporting protocol. See: Antimicrobial resistance (AMR) reporting protocol. EARS-Net. www.ecdc.europa.eu). The reported data shall cover bloodstream and CSF isolates (invasive isolates), such as:

- *Staphylococcus aureus*: resistance/susceptibility to meticillin and other anti-staphylococcal beta-lactams;
- Enterobacterales (such as *Klebsiella pneumoniae* complex and *Escherichia coli*): resistance/susceptibility to third generation cephalosporins and carbapenems, as well as, when available, novel antimicrobial agents and colistin;
- *Acinetobacter* species (including *Acinetobacter baumannii* complex): resistance/susceptibility to carbapenems, and in carbapenem-resistant isolates, resistance/susceptibility to novel antimicrobial agents;
- *Pseudomonas aeruginosa*: resistance/susceptibility to carbapenems, and in carbapenem-resistant isolates, resistance/susceptibility to novel antimicrobial agents;
- *Enterococcus faecium* and *Enterococcus faecalis*: resistance/susceptibility to glycopeptides.

4.1.2. GENERIC CASE DEFINITIONS AND CLASSIFICATION OF ANTIMICROBIAL RESISTANCE TO ANTIMICROBIAL AGENTS

Clinical resistance to antimicrobial agents

Definition

A micro-organism is classified as clinically 'susceptible, standard dosing regimen', clinically 'susceptible, increased exposure', or clinically resistant to an antimicrobial agent by applying the appropriate EUCAST clinical breakpoints (http://www.eucast.org/clinical_breakpoints/) in a standardised methodology (or a methodology calibrated to a standardised methodology), i.e. clinical minimum inhibitory concentration (MIC) breakpoints and their inhibition zone diameter correlates. Exposure is a function of how the mode of administration, dose, dosing interval, infusion time, as well as distribution and excretion of the antimicrobial agent will influence the infecting organism at the site of infection. Breakpoints may be altered with legitimate changes in circumstances. Equivalent quantitative antimicrobial susceptibility testing (AST) methods may be used instead of MIC or disk diffusion, if endorsed by EUCAST.

Classification

Clinically Susceptible, standard dosing regimen (S)

- a micro-organism is defined as 'susceptible, standard dosing regimen' (S), when there is a high likelihood of therapeutic success using a standard dosing regimen of the agent.

Clinically Susceptible, increased exposure (I)

- a micro-organism is defined as 'susceptible, increased exposure' (I), when there is a high likelihood of therapeutic success because exposure to the agent is increased by adjusting the dosing regimen or by its concentration at the site of infection.

Clinically Resistant (R)

- a micro-organism is defined as 'resistant' (R), when there is a high likelihood of therapeutic failure even when there is increased exposure.

Clinical breakpoints are presented as:

- S: MIC $\leq$ x mg/L; disk diffusion zone diameter $\geq$ σ mm
- I: MIC $>$ x, $\leq$ y mg/L; disk diffusion zone diameter $\geq$ ρ mm, $<$ σ mm
- R: MIC $>$ y mg/L; disk diffusion zone diameter $<$ ρ mm

Pandrug-resistant (PDR)

- for *Staphylococcus aureus*, *Enterococcus* species, Enterobacterales including *Klebsiella pneumoniae* complex and *Escherichia coli*, *Pseudomonas aeruginosa* and *Acinetobacter* species, an isolate is defined as pandrug-resistant (PDR) based on the fact that it is resistant to all antimicrobial agents, as in the international expert proposal for interim standard definitions for acquired resistance ⁽⁶⁾;
- an isolate is defined as confirmed PDR, when it is either 'resistant' (R) or 'susceptible, increased exposure' (I), to all agents in all antimicrobial categories, confirmed by a reference or other clinical microbiology laboratory testing a supplemental panel of antimicrobial agents beyond those routinely tested, in accordance with the definitions by microorganism in the international expert proposal for interim standard definitions for acquired resistance ⁽⁷⁾;
- an isolate is defined as possibly PDR, when it is either 'resistant' (R) or 'susceptible, increased exposure' (I), to all the antimicrobial agents tested in the laboratory;
- an isolate is defined as not PDR, when it is 'susceptible, standard dosing regimen' (S), to at least one of the tested antimicrobial agents.

Microbiological resistance to antimicrobial agents

Phenotypic definition

A microorganism is classified as having a wild-type phenotype or a non-wild-type phenotype for a species according to the EUCAST epidemiological cut-off concentrations (ECOFFs) in a standardised methodology (or a methodology calibrated to a standardised methodology) (http://www.eucast.org/ast_of_bacteria/; http://www.eucast.org/mic_distributions_and_ecoffs/) based on species-specific MIC distributions and their inhibition zone diameter correlates.

Phenotypic classification

Wild-type (WT) phenotype

- a microorganism is defined as wild-type (WT) for a species or species complex, when it is devoid of phenotypically- detectable acquired resistance mechanism.

Non-wild-type (NWT) phenotype

- a microorganism is defined as non-wild-type (NWT) for a species, when it expresses at least one phenotypically-detectable acquired resistance mechanism.

ECOFFs are presented as (http://www.eucast.org/ast_of_bacteria/):

- WT: ECOFF $\leq$ x mg/L; disk diffusion zone diameter $\geq$ σ mm
- NWT: ECOFF $>$ x mg/L; disk diffusion diameter $<$ σ mm

Identification of an acquired antimicrobial resistance mechanism (for example, drug inactivating enzyme, modification of drug target protein type, efflux pump).

Expression of an acquired antimicrobial resistance mechanism by a microorganism can be determined *in vitro* and the type of mechanism identified using standardised methodology according to the EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance (https://www.eucast.org/fileadmin/eucast/pdf/eucast_guidelines/EUCAST_detection_of_resistance_mechanisms_170711.pdf).

⁽⁶⁾ Magiorakos AP, et al. 'Multidrug-resistant, extensively drug-resistant and pandrug-resistant bacteria: an international expert proposal for interim standard definitions for acquired resistance', Clin Microbiol Infect. 2012 Mar;18(3):268-81. <http://www.sciencedirect.com/science/article/pii/S1198743X14616323>.

⁽⁷⁾ Idem.

Genotypic definition

A microorganism is classified as harbouring or lacking a genetic determinant or combination of determinants conferring to it a non-wild type susceptibility phenotype in relation to an antimicrobial agent (transferable gene or core gene mutation). The presence of a genetic determinant or combination of determinants conferring to it a non-wild type susceptibility phenotype in relation to one or several antimicrobial agents can be shown by detecting and identifying the corresponding nucleic acid sequence(s) in a bacterial genome.

Genotypic classification

Genotypes are reported as:

- Positive: presence of [name of resistance gene or core gene mutation];
- Negative: absence of [name of resistance gene] or detection of a wild-type core gene sequence.

4.1.3. ANTIMICROBIAL CONSUMPTION IN HUMANS

Member States shall report national surveillance data on antimicrobial consumption in humans according to the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system (https://atcddd.fhi.no/atc_ddd_index/) and with the methods and criteria agreed between the ECDC and Member States as specified by the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) of the ECDC. The criteria for reporting are published each year as part of the Antimicrobial consumption reporting protocol (Antimicrobial consumption (AMC) reporting protocol. European Surveillance of Antimicrobial Consumption Network (ESAC-Net), www.ecdc.europa.eu). Data shall include antimicrobial consumption for both the community and the hospital sector, which shall be reported separately.

4.2. GENERAL CASE DEFINITION OF HEALTHCARE-ASSOCIATED INFECTION (HAI)

A healthcare-associated infection associated with the current hospital stay is defined as an 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 OR
- onset of symptoms on Day 1 or Day 2 in a newborn OR
- the patient was diagnosed with COVID-19 and the onset of symptoms (or first positive test if asymptomatic) was on Day 3 or later (day of admission = Day 1) of the current admission.

A healthcare-associated infection associated with a previous hospital stay is defined as an infection that matches one of the case definitions:

AND

- the patient presents with an infection but has been readmitted less than 48 hours 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 90 days 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 2 days) with *Clostridioides difficile* infection less than 28 days from a previous discharge from an acute care hospital,

OR

- the patient has COVID-19 on admission (or onset before Day 3) and was (re-)admitted fewer than 48 hours after a stay of more than seven days in the same or another healthcare facility.

Note: For the purpose of point prevalence surveys, an active healthcare-associated 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 healthcare-associated infection. Adapted definitions for healthcare-associated infections in long-term care facilities and intensive care units are available from <https://www.ecdc.europa.eu/en/publications-data/protocol-point-prevalence-surveys-healthcare-associated-infections-4-0> and <https://www.ecdc.europa.eu/en/publications-data/protocol-surveillance-healthcare-associated-infections-and-prevention-indicators>, respectively.

4.2.1. BJ: BONE AND JOINT INFECTION

BJ-BONE: Osteomyelitis

Osteomyelitis shall 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 2 of the following signs or symptoms with no other recognised cause: fever ($> 38^{\circ}\text{C}$), localised swelling, tenderness, heat, or drainage at suspected site of bone infection.

AND at least 1 of the following:

- organisms cultured from blood;
- positive blood antigen test (for example, *Haemophilus influenzae*, *Streptococcus pneumoniae*);
- radiographic evidence of infection (for example, 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 shall 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 (for example, abnormal findings on X-ray, CT scan, MRI, radiolabel scan (gallium, technetium, etc.)).

BJ-DISC: Disc space infection

Vertebral disc space infection shall 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 ($> 38^{\circ}\text{C}$) with no other recognised cause or pain at the involved vertebral disc space

AND radiographic evidence of infection (for example, abnormal findings on X-ray, CT scan, MRI, radiolabel scan (gallium, technetium, etc.));

- Patient has fever ($> 38^{\circ}\text{C}$) with no other recognised cause and pain at the involved vertebral disc space

AND positive antigen test on blood or urine (for example, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Neisseria meningitidis*, or Group B *Streptococcus*).

4.2.2. 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 ($> 38^{\circ}\text{C}$), chills, or hypotension

AND

Two positive blood cultures for a common skin contaminant (from 2 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.

4.2.3. COV: COVID-19 (SARS-COV-2 INFECTION)

Patient has documentation in the medical record of any laboratory confirmation test for COVID-19 (viral RNA target or antigenic detection from an oropharyngeal or nasal swab or any other appropriate clinical specimen)

AND

COV-ASY: *asymptomatic COVID-19*

- Patient has no signs or symptoms compatible with COVID-19.

COV-MM: *mild/moderate COVID-19*

- Patient has any sign or symptom compatible with COVID-19, without need for oxygen therapy and oxygen saturation level $\geq 92\%$.

COV-SEV: *severe COVID-19*

- Patient has signs or symptoms compatible with COVID-19 with need for oxygen therapy for shortness of breath due to COVID-19 and/or oxygen saturation level $< 92\%$.

Signs and symptoms compatible with COVID-19: Fever, cough, fatigue, shortness of breath, anorexia, myalgias, loss of smell (anosmia), loss of taste (ageusia). Other non-specific symptoms, such as sore throat, nasal congestion, headache, diarrhoea, nausea and vomiting, have also been reported. Additional neurological manifestations reported include dizziness, agitation, weakness, seizures, or findings suggestive of stroke, including trouble with speech or vision, sensory loss, or problems with balance in standing or walking. Older people and immunosuppressed patients in particular may present with atypical symptoms such as fatigue, reduced alertness, reduced mobility, diarrhoea, loss of appetite, confusion, and absence of fever. Symptoms such as dyspnoea, fever, gastrointestinal (GI) symptoms or fatigue due to physiologic adaptations in pregnant women, adverse pregnancy events, or other diseases such as malaria, may overlap with symptoms of COVID-19. Children might not have reported fever or cough as frequently as adults. (Source: WHO. Living guidance for clinical management of COVID-19. 23 November 2021. Available from <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2>).

4.2.4. CNS: CENTRAL NERVOUS SYSTEM INFECTION

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

Intracranial infection shall 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 2 of the following signs or symptoms with no other recognised cause: headache, dizziness, fever ($> 38^{\circ}\text{C}$), localising neurologic signs, changing level of consciousness, or confusion.

AND at least 1 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 (for example, abnormal findings on ultrasound, CT scan, MRI, radionuclide brain scan, or arteriogram);
- Diagnostic single antibody titre (IgM) or 4-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 shall meet at least one of the following criteria:

- Patient has organisms cultured from cerebrospinal fluid (CSF);
- Patient has at least 1 of the following signs or symptoms with no other recognised cause: fever ($> 38^{\circ}\text{C}$), 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 titre (IgM) or 4-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 ≤ 90 days of placement; if > 90 days or after manipulation/access of the shunt, report as CNS-MEN if the infection meets the general case definition of HAI;
- 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, shall 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 1 of the following signs or symptoms with no other recognised cause: fever ($> 38^{\circ}\text{C}$), back pain, focal tenderness, radiculitis, paraparesis, or paraplegia.

AND at least 1 of the following:

- Organisms cultured from blood;
- Radiographic evidence of a spinal abscess (for example, 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).

4.2.5. CRI: CATHETER-RELATED INFECTION

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

- Quantitative CVC culture $\geq 10^3$ CFU/ml or semi-quantitative CVC culture > 15 CFU,
- AND pus/inflammation at the insertion site or tunnel.

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

- Quantitative PVC culture $\geq 10^3$ 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 $\geq 10^3$ 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 $\geq 10^3$ 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 within 48 hours before or after catheter removal AND
- Positive culture with the same micro-organism of quantitative CVC culture $\geq 10^3$ CFU/ml or semi-quantitative CVC culture > 15 CFU OR
- BSI occurring with or without catheter removal, and at least one of:
 - Quantitative blood culture ratio CVC blood sample/peripheral blood sample > 5 ;
 - Differential delay of positivity of blood cultures: CVC blood sample culture positive 2 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 within 48 hours before or after catheter removal (if any) AND positive culture with the same micro-organism of either:

- Quantitative PVC culture $\geq 10^3$ CFU/ml or semi-quantitative PVC culture > 15 CFU, or
- Positive culture with the same micro-organism from pus from insertion site.

Note reporting instructions

Central vascular catheter colonisation shall 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 shall not be reported in the point prevalence survey; microbiologically confirmed catheter-related BSI shall be reported as CRI3.

4.2.6. CVS: CARDIOVASCULAR SYSTEM INFECTION

CVS-VASC: Arterial or venous infection

Arterial or venous infection shall 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 1 of the following signs or symptoms with no other recognised cause: fever ($> 38^{\circ}\text{C}$), 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. Report CVS-VASC matching the third criterion as CRI1 or CRI2, as appropriate.

CVS-ENDO: Endocarditis

Endocarditis of a natural or prosthetic heart valve shall 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 ($> 38^{\circ}\text{C}$), new or changing murmur, embolic phenomena, skin manifestations (for example, petechiae, splinter hemorrhages, 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 (for example, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *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 shall 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 ($> 38^{\circ}\text{C}$), 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 (for example, *Haemophilus influenzae*, *Streptococcus pneumoniae*);
- Evidence of myocarditis or pericarditis on histologic examination of heart tissue;
- 4-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 shall 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 ($> 38^{\circ}\text{C}$), chest pain, or sternal instability.

AND at least 1 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

4.2.7. EENT: EYE, EAR, NOSE, THROAT, OR MOUTH INFECTION

EENT-CONJ: *Conjunctivitis*

Conjunctivitis shall 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 1 of the following:
 - WBCs and organisms seen on Gram's stain of exudates;
 - Purulent exudates;
 - Positive antigen test (for example, 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 titre (IgM) or 4-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 (AgNO_3) 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, shall meet at least one of the following criteria:

- Patient has organisms cultured from anterior or posterior chamber or vitreous fluid;
- Patient has at least 2 of the following signs or symptoms with no other recognised cause: eye pain, visual disturbance, or hypopyon;

AND at least 1 of the following:

- Physician diagnosis of an eye infection;
- Positive antigen test on blood (for example, *Haemophilus influenzae*, *Streptococcus pneumoniae*);
- Organisms cultured from blood.

EENT-EAR: Ear and mastoid

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

Otitis externa shall 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 ($> 38^\circ\text{C}$), pain, redness, or drainage from ear canal;
- Organisms seen on Gram's stain of purulent drainage.

Otitis media shall 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 ($> 38^\circ\text{C}$), pain in the eardrum, inflammation, retraction or decreased mobility of eardrum, or fluid behind eardrum.

Otitis interna shall 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 shall 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 ($> 38^\circ\text{C}$), pain, tenderness, erythema, headache, or facial paralysis;

AND at least 1 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 shall 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 1 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 titre (IgM) or 4-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 shall meet at least 1 of the following criteria:

- Patient has organisms cultured from purulent material obtained from sinus cavity;
- Patient has at least 1 of the following signs or symptoms with no other recognised cause: fever ($> 38^{\circ}\text{C}$), pain or tenderness over the involved sinus, headache, purulent exudate, or nasal obstruction

AND at least 1 of the following:

- Positive transillumination;
- Positive radiographic examination (including CT scan).

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

Upper respiratory tract infections shall meet at least 1 of the following criteria:

- Patient has at least two of the following signs or symptoms with no other recognised cause: fever ($> 38^{\circ}\text{C}$), erythema of pharynx, sore throat, cough, hoarseness, or purulent exudate in throat

AND at least 1 of the following:

- Organisms cultured from the specific site;
- Organisms cultured from blood;
- Positive antigen test on blood or respiratory secretions;
- Diagnostic single antibody titre (IgM) or 4-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.

4.2.8. GI: GASTROINTESTINAL SYSTEM INFECTION

GI-CDI: Clostridioides difficile infection

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

- Diarrhoeal stools or toxic megacolon, AND a positive laboratory assay for *Clostridioides difficile* toxin A and/or B in stools or a toxin-producing *C. difficile* organism detected in stool via culture or other means for example, a positive PCR result;
- Pseudomembranous colitis revealed by lower gastro-intestinal endoscopy;
- Colonic histopathology characteristic of *Clostridioides difficile* infection (with or without diarrhoea) on a specimen obtained during endoscopy, colectomy or autopsy.

GI-GE: Gastroenteritis (excl. CDI)

Gastroenteritis shall 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 ($> 38^{\circ}\text{C}$) and no likely non-infectious cause (for example, diagnostic tests, therapeutic regimen other than antimicrobial agents, acute exacerbation of a chronic condition, or psychological stress);
- Patient has at least 2 of the following signs or symptoms with no other recognised cause: nausea, vomiting, abdominal pain, fever ($> 38^{\circ}\text{C}$), or headache

AND at least 1 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 titre (IgM) or 4-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, shall meet at least 1 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 2 of the following signs or symptoms with no other recognised cause and compatible with infection of the organ or tissue involved: fever ($> 38^{\circ}\text{C}$), nausea, vomiting, abdominal pain, or tenderness

AND at least 1 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 (for example, *Candida* spp. esophagitis or proctitis).

GI-HEP: Hepatitis

Hepatitis shall meet the following criterion:

Patient has at least 2 of the following signs or symptoms with no other recognised cause: fever ($> 38^{\circ}\text{C}$), anorexia, nausea, vomiting, abdominal pain, jaundice, or history of transfusion within the previous 3 months

AND at least 1 of the following:

- Positive antigen or antibody test for hepatitis A, hepatitis B, hepatitis C, or delta hepatitis;
- Abnormal liver function tests (for example, 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 shall 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 ($> 38^{\circ}\text{C}$), nausea, vomiting, abdominal pain, or jaundice

AND at least one of the following:

- Organisms cultured from drainage from surgically placed drain (for example, 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 (for example, 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.

4.2.9. LRI: LOWER RESPIRATORY TRACT INFECTION, OTHER THAN PNEUMONIA

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

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 ($> 38^{\circ}\text{C}$), 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 shall 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.

NEO: Specific neonatal case definitions

NEO-CSEP: Clinical Sepsis

ALL of the three following criteria:

- Supervising physician started appropriate antimicrobial therapy for sepsis for at least 5 days;
- No detection of pathogens in blood culture or not tested;
- No obvious infection at another site.

AND 2 of the following criteria (without other apparent cause):

- Fever ($> 38^{\circ}\text{C}$) or temperature instability (frequent post-set of the incubator) or hypothermia ($< 36,5^{\circ}\text{C}$);
- Tachycardia ($> 200/\text{min}$) or new/increased bradycardia ($< 80/\text{min}$);
- Capillary refilling time (CRT) $> 2\text{ s}$;
- New or increased apnoea (s) ($> 20\text{ s}$);
- Unexplained metabolic acidosis;
- New-onset hyperglycaemia ($> 140\text{ mg/dl}$);
- 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 $> 38^{\circ}\text{C}$ or $< 36,5^{\circ}\text{C}$ 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 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

- At least two of: temperature > 38 °C or < 36,5 °C or temperature instability, tachycardia or bradycardia, apnoea, extended capillary refilling time, metabolic acidosis, hyperglycaemia, other sign of BSI such as apathy
- AND coagulase-negative staphylococci 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 distention, prefeeding residuals, persistent microscopic or gross blood in stools.

4.2.10. 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 signs or symptoms:

- Fever > 38 °C with no other cause;
- Leukopenia (< 4 000 WBC/mm³) or leukocytosis (≥ 12 000 WBC/mm³).

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 tachypnoea;
- Suggestive auscultation (rales or bronchial breath sounds), ronchi, wheezing;
- Worsening gas exchange (for example, O₂ 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 lower respiratory tract (LRT) specimen (PN 1)

- Broncho-alveolar lavage (BAL) with a threshold of $\geq 10^4$ colony-forming units (CFU)/ml 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 $\geq 10^3$ CFU/ml;
- Distal protected aspirate (DPA) with a threshold of $\geq 10^3$ CFU/ml.

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

- Quantitative culture of LRT specimen (for example, 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 examination for viral, bacterial (including atypical bacteria and mycobacteria) or fungal lung infection (for example, influenza virus, *Legionella*, *Mycoplasma*, *Aspergillus*, *Pneumocystis jirovecii* [previously *P. carinii*]):
 - Positive detection of microbial antigen or or genetic material in respiratory secretions, pleural fluid or tissue, e.g. NAAT (including RT-PCR and multiplex PCR), RADT, EIA;
 - Positive direct microscopic examination or positive culture (including shell vial assay) from bronchial secretions or tissue;
 - Seroconversion (for example, *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).

Notes:

- One definitive chest X-ray or CT-scan for the current pneumonia episode may be sufficient in patients with underlying cardiac or pulmonary disease if comparison with previous X-rays is possible.
- PN 1 and PN 2 criteria were validated without previous antimicrobial therapy. However, this does not exclude the diagnosis of PN 1 or PN 2 in case of previous antimicrobial use.

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.

4.2.11. REPR: REPRODUCTIVE TRACT INFECTION

REPR-EMET: Endometritis

Endometritis shall meet at least 1 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 2 of the following signs or symptoms with no other recognised cause: fever ($> 38^{\circ}\text{C}$), 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 infection

Episiotomy infections shall meet at least 1 of the following criteria:

- Post-vaginal delivery patient has purulent drainage from the episiotomy;
- Post-vaginal delivery patient has an episiotomy abscess.

REPR-VCUF: Vaginal cuff infection

Vaginal cuff infections shall meet at least 1 of the following criteria:

- Post-hysterectomy patient has purulent drainage from the vaginal cuff;
- Post-hysterectomy patient has an abscess at the vaginal cuff;
- Post-hysterectomy patient has pathogens cultured from fluid or tissue obtained from the vaginal cuff.

Note reporting instruction

Report vaginal cuff infections as SSI-O if other SSI criteria are met (within 30 days following hysterectomy).

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 shall meet at least 1 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 2 of the following signs or symptoms with no other recognised cause: fever ($> 38^{\circ}\text{C}$), nausea, vomiting, pain, tenderness, or dysuria

AND at least 1 of the following:

- Organisms cultured from blood,
- Physician diagnosis.

Note reporting instructions

- Report endometritis as EMET;
- Report vaginal cuff infections as VCUF.

4.2.12. 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 90 days if implant is in place AND the infection appears to be related to the operation AND infection involves deep soft tissue (for example, 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;
- Organisms isolated from an aseptically obtained culture of fluid or tissue from the deep incision (for example, fascia, muscle);
- 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 ($> 38^{\circ}\text{C}$), 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 radiologic 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 90 days if implant is in place AND the infection appears to be related to the operation AND infection involves any part of the anatomy (for example, 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 radiologic examination;
- Diagnosis of organ/space SSI made by a surgeon or attending physician.

4.2.13. SST: SKIN AND SOFT TISSUE INFECTION

SST-SKIN: Skin infection

Skin infections shall 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 (for example, diphtheroids (*Corynebacterium* spp.), *Bacillus* (not *B. anthracis*) spp., *Propionibacterium* spp., coagulase-negative staphylococci (including *Staphylococcus epidermidis*), viridans group streptococci, *Aerococcus* spp., *Micrococcus* spp.), they shall be a pure culture;
- Organisms cultured from blood;
- Positive antigen test performed on infected tissue or blood;
- Multinucleated giant cells seen on microscopic examination of affected tissue;
- Diagnostic single antibody titre (IgM) or 4-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 fasciitis, infectious gangrene, necrotising cellulitis, infectious myositis, lymphadenitis, or lymphangitis)

Soft tissue infections shall meet at least 1 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 2 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 1 of the following:

- Organisms cultured from blood;
- Positive antigen test performed on blood or urine (for example, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Neisseria meningitidis*, Group B *Streptococcus*, *Candida* spp.);
- Diagnostic single antibody titre (IgM) or 4-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 shall meet the following criterion:

- Patient has at least 2 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 shall meet at least 1 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;
- 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 ($> 38^{\circ}\text{C}$) or hypothermia ($< 36^{\circ}\text{C}$), hypotension, oliguria ($< 20\text{ cc/hr}$), 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 shall 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 ($> 38^{\circ}\text{C}$) and local inflammation of the breast AND physician diagnosis of breast abscess.

4.2.14. *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 (for example, 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 shall be reported;
- Do not report fever of unknown origin (FUO) as DI;
- Report viral exanthems or rash illness as DI.

SYS-CSEP: treated unidentified severe infection

Patient has at least one of the following:

- Clinical signs or symptoms with no other recognised cause;
- Fever ($> 38^{\circ}\text{C}$);
- Hypotension (systolic pressure $< 90\text{ mm/Hg}$);
- Oliguria ($20\text{ cm}^3\text{ (ml)/hr}$).

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).

4.2.15. *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 ($> 38^{\circ}\text{C}$), urgency, frequency, dysuria, or suprapubic tenderness

AND

Patient has a positive urine culture, that is, $\geq 10^5$ 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 ($> 38^{\circ}\text{C}$), 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 $\geq 10^4$ 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 $\geq 10^2$ 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 shall not be reported, but bloodstream infections secondary to asymptomatic bacteriuria shall be reported as BSI with source (origin) S-UTI.

A urinary tract infection is defined as catheter-associated if an indwelling urinary catheter was present (even intermittently) in the 7 days preceding the onset of infection.
