EU case definitions for respiratory viruses

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Background

- Commission Implementing Decision (EU) 2018/945 lists 59 diseases and related special health issues under EU/EEA surveillance as well as their case definitions
- Reviewing/revising the list of notifiable disease is one of the strategic actions in the EU/EEA long-term surveillance framework 2021-2027
- A panel of NFPs for Surveillance and ECDC surveillance experts conducted the prioritisation of diseases for EU/EEA surveillance in August and September 2022
- The proposal has been endorsed by the Advisory Forum and will inform the implementing act of the new cross-border health threat regulation[1]

1) L_2022314EN.01002601.xml (europa.eu) 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

Proposal for respiratory viral infections - surveillance objectives and types of surveillance

ILI, ARI, SARI

Influenza

COVID-19

RSV infection

Zoonotic influenza in humans

Indicator-based surveillance objectives:

- Monitor trends by time, place and person
- Early event detection
- Monitor PH programmes (all except zoonotic influenza)

Reporting: Weekly

Temporal granularity: Day (case-based), week (aggregate)

Geographic granularity: NUTS1 (countries, regions)

Event-based surveillance (all except ILI, ARI and SARI); Influenza[a], COVID-19[b]

[a] Detection of new reassortant of seasonal influenza virus

[b] New variant of concern

Case definitions proposed

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

2018	2025 proposal (changes in red)
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.	**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.

Case definitions proposed (2)

2018	2025 proposal (changes in red)
Influenza-like illness (ILI) Sudden onset of symptoms AND at least one of the following four systemic symptoms: — Fever or feverishness — Malaise — Headache — Myalgia AND — At least one of the following three respiratory symptoms: — Cough — Sore throat — Shortness of breath	**Influenza-like illness (ILI)** An acute respiratory infection (ARI) with at least one of the following four systemic symptoms: — Measured fever or feverishness — Malaise — Headache — Myalgia

Case definitions proposed (3)

2018	2025 proposal (changes in red)
-	**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.

Case definitions proposed (4)

2018	2025 proposal (changes in red)
Influenza - Laboratory Criteria At least one the following four: — Isolation of influenza virus from a clinical specimen — Detection of influenza virus nucleic acid in a clinical specimen — Identification of influenza virus antigen by DFA test in a clinical specimen — Influenza specific antibody response Sub typing of the influenza isolate should be performed, if possible	**INFLUENZA IN HUMANS, SEASONAL** 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 (1) — Isolation of influenza virus from a clinical specimen
Influenza - Epidemiological Criteria An epidemiological link by human to human transmission Case Classification A. Possible case Any person meeting the clinical criteria (ILI or ARI) A. Probable case Any person meeting the clinical criteria (ILI or ARI) with an epidemiological link A. Confirmed case Any person meeting the clinical (ILI or ARI) and the laboratory criteria	**Influenza - 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

(1) Antigen tests used in healthcare and other settings where testing can be performed by trained/professional staff, e.g. pharmacies

Case definitions proposed (5)

2018	2025 proposal (changes in red)
NA	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 (1) — 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

(1) Antigen tests used in healthcare and other settings where testing can be performed by trained/professional staff, e.g. pharmacies

Case definitions proposed (6)

2018	2025 proposal (changes in red)
NA	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(1) — 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

(1) Antigen tests used in healthcare and other settings where testing can be performed by trained/professional staff, e.g. pharmacies

Next steps

Final decision of Comitology committee expected in 2025

Case definitions make it Member State obligation to report data on the listed diseases

Give ECDC mandate to collect surveillance data in these topics

Case definitions define only the topics and how a case is defined - More on reporting can be found and clarified in the reporting protocol

Network discussions on topics like reinfections are important in order to agree on definitions at regional level even if such might not be captured in the case definition

Questions?

Legal process for EU-level surveillance of infectious diseases

- The EC establishes and **updates the list of infectious diseases** and relevant health issues such as anti-microbial resistance to ensure their coverage by the epidemiological surveillance network (Decision No 1082/2013/EU).
- The EC also **sets the case definitions** concerning each infectious disease that Member States use for surveillance and reporting to ECDC, thus ensuring the comparability and compatibility of the collected data at Union level.
- 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
- ECDC to implement surveillance
- Proposal for changing implementing decision for influenza and ORV

INFLUENZA A/H5N1

Clinical Criteria

Any person with one of the following two:

— Fever AND signs and symptoms of acute respiratory infection;
— Death from an unexplained acute respiratory illness.

Laboratory Criteria

At least one of the following three:

— Isolation of influenza A/H5N1 from a clinical specimen;
— Detection of influenza A/H5 nucleic acid in a clinical specimen;
— Influenza A/H5 specific antibody response (four-fold or greater rise or single high titre).

Epidemiological Criteria

At least one of the following four:

— Human to human transmission by having been in close contact (within 1 metre) to a person reported as probable or confirmed case;

INFLUENZA IN HUMANS, ZOONOTIC

Clinical Criteria

At least one of the following:

— ARI
— ILI
— SARI
— Conjunctivitis
— Neurological presentation (e.g. encephalitis)
— Atypical presentations

Laboratory Criteria

At least one of the following

— Isolation of zoonotic influenza virus from a clinical specimen
— Detection of zoonotic influenza virus nucleic acid in a clinical specimen
— Specific antibody response (four-fold or greater rise or single high titre)

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 influenza-infected animal
— Having been in an environment (e.g. home, farm, market, work) with suspected influenza-infected animals

Proposal for respiratory viral infections - surveillance objectives and types of surveillance

	Surveillance objectives			Indicator-based surveillance				Event-based surveillance
Disease	Monitor trends by time, place and person	Early event detection	Monitor PH programmes		Reporting frequency	Temporal granularity (day, week, month)	Geographic granularity (NUTS level)	
Respiratory viral infections								
ILI, ARI, SARI	X	X	X	X	Weekly	Day (case-based), week (aggregate)	NUTS1	
Influenza	X	X	X	X	Weekly	Day (case-based), week (aggregate)	NUTS1	X[a]
COVID-19	X	X	X	X	Weekly	Day (case-based), week (aggregate)	NUTS1	X[b]
RSV infection	X	X	X	X	Weekly	Day (case-based), week (aggregate)	NUTS1	X
Zoonotic influenza in humans	X	X		X	Weekly	Day (case-based), week (aggregate)	NUTS1	X

[a] Detection of new reassortant seasonal influenza virus

[b] New variant of concern