TESSy - The European Surveillance System

Hepatitis of unknown origin

Reporting Protocol 2022

Version 3.0

2 June 2022

Contents

Change log

Summary of changes in this reporting protocol

V3.0 (2 June 2022)

1. Added variables *DateOfDischarge*; *MetagenomicsLabID*; *AdenoAssociatedVirusResultPCR*; *AdenoAssociatedVirusSpecimen*; *AdenoAssociatedVirusType*; *AdenoAssociatedVirusCtValue*; *AdenoAssociatedVirusSpecimenDate*

V2.1 (6 May 2022)

1. Added variables *Hospitalisation*; *AdenoUrineResult*; *AdenoUrineDate*; *AdenoUnknownSpecimenResult*; *AdenoUnknownSpecimenDate*; *AdenoCtValue*; *AdenoCtValueSpecimenDate*; *AdenotypeSpecimen*; *AdenoSeqDone*; *ADVSequence*; *OtherTypingResult*; *RhinoResult*; *hMPVResult*; *BrucellaResult*; *BartonellaResult*; *BorreliaResult*; *StoolBacterialPCRResult*; *AdditionalInfo*
2. Added "DISC" (discarded case) to coded value list for variable *Classification*
3. Added "IgM, IgG, IgMIgG" to coded value list for variable *SARSCoV2Serology*
4. Added "OTHCOR" to coded value list for variable *PrevInfectionDetails*
5. Added "SEPSIS" to coded value list for variable *Complications*
6. Added "ADENO", "ROTA", "ASTRO" to coded value list for variable *StoolViralPCRResult*

V2.0 (29 April 2022)

1. Note added to case definition
2. Added "Epi-linked" to and removed "Confirmed" from coded value list for variable *Classification*
3. Variable *ClinicalPresentation* renamed to *PreviousClinicalPresentation*
4. Variable *ClinicalPresentationOther* renamed to *PreviousClinicalPresentationOther*
5. Variable *Adenotype* renamed to *AdenovType* and defined as text
6. Added "Other" to coded value list for variable *Complications*. Variable configured as repeatable
7. Added "WAITTRANS" (waiting for transplant) to coded value list of variable *Transplant* and removed from variable *Outcome*
8. Added variables *PlaceofResidence*; *PrevInfection*; *PrevInfectionDetails*; *PrevInfectionDetailsOther*; *ComplicationsOther*; *PeakBilirubin*; *PeakINR;* *DateOfPrevSARSCoV2*; *SARSCoV2VaccLastDate*; *SARSCoV2VaccLastBrand*; *AdenoStoolDate*; *AdenoRespDate*; *AdenoWholeBloodDate*; *AdenoSerumDate*; *AdenoOtherDate*; *SARSCoV2PCRDate*
9. Variable *PeakASP* removed

V1.0 (25 April 2022)

Introduction

This reporting protocol is intended for reporting national case-based data for surveillance of hepatitis of unknown origin from all the countries and areas of the WHO European Region, including the 27 countries of the European Union (EU) and the additional three countries of the European Economic Area (EEA), to the European level.

Data are submitted through the case-based record type NOVHEP to the European Surveillance System (TESSy) database hosted at ECDC.

Data can be reported to TESSy either manually, for entry of single cases, or through metadata-standardised csv or xml files for multiple cases (please see technical annex).

Case data should be entered manually into TESSy as soon as possible, and retrospective updates should be submitted through metadata-standardised csv or xml files at least **every Wednesday by 10:00** (including updates to cases diagnosed/reported from Monday to Sunday during the previous week).

This reporting protocol is supplemented by a technical annex, which contains updated generic information for data submission.

Case Definition

Cases of hepatitis of unknown origin should be reported to TESSy if they meet any of the following criteria:

- **Confirmed**: N/A
- **Probable**: A person presenting with an acute hepatitis (non-hepatitis viruses A, B, C, D and E*) with aspartate transaminase (AST) or alanine transaminase (ALT) over 500 IU/L, who is 16 years old or younger, since 1 October 2021.
- **Epi-linked**: A person presenting with an acute hepatitis (non-hepatitis viruses A, B, C, D and E*) of any age who is a close contact of a probable case since 1 October 2021.
- **Discarded**: A subject previously classified as case, that following further investigations did not meet the case definition criteria.

*Cases of hepatitis with known aetiology such those due to specific infectious diseases, drug toxicity, metabolic hereditary, or autoimmune disorders should not be reported under this protocol.

Surveillance Objectives

1. To understand the magnitude and spread of this novel public health threat in the WHO European region to inform a proportionate response
2. To generate hypotheses about disease aetiology in order to guide investigations and initial preventive or control measures
3. To describe the population at highest risk of infection and severe outcomes in order to target preventive or control measures
4. To understand the natural history of disease in order to assess its impact and prepare accordingly

Key variables

Although the current version of the reporting protocol includes a significant number of variables, Member States are strongly encouraged to report data as soon as possible (please see section Data collection schedule), even if incomplete or provisional, so Surveillance Objective 1 can be fulfilled. In

case there is the need to discard a case, its classification can be updated so it is removed from analysis.

The variables that are currently considered key include:

- *Age* (mandatory)
- *Classification* (mandatory: Probable, Epi-linked, Discarded)
- *DateOfOnset* (date of onset of first symptoms of disease)
- *DateOfHospitalisation* (date of hospitalisation)
- *AdmittedICUHDU* (whether admitted to intensive care unit or high-dependency unit.)
- *Transplant* (whether case received or is waiting for liver transplant)
- *Outcome* (mandatory: recovered, deceased, still on medical treatment)
- Variables related to adenovirus and SARS-CoV-2 testing and results (please see section Laboratory findings)

How to use this document

This reporting protocol provides information for data managers in reporting countries in two main sections:

- *Reporting to TESSy* – contains guidelines on how to prepare data for submission to TESSy, deadlines and links to further information.
- *Annex - Hepatitis of unknown origin metadata* – the metadata set for the subject covered by this reporting protocol.

Finding further information

Paragraphs denoted by the information icon tell where you can find further information.

Updated links to all the schedules, documentation and training materials mentioned are included in *TESSy Technical Guidelines & Tools* (see the menu 'Technical Guidelines and Tools' when logged in to TESSy), including:

- Metadata sets and history
- Tutorials for data transformation using respectively Excel and Access
- TESSy user documentation
- *CSV* and *XML* transport protocols.

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Reporting to TESSy

This section provides both an overview of the TESSy reporting process and tips on where you can find useful information.

The overall process includes:

1. Familiarising yourself with the data collection deadlines
2. Preparing (exporting and transforming) your data
3. Checking that your data comply with the metadata
4. Checking that your data source profile is up-to-date
5. Submitting your data to TESSy
6. Finalising and approving your submission.

Data collection schedule

Case data should be entered manually into TESSy as soon as possible, and retrospective updates should be submitted through metadata-standardised csv or xml files at least every Wednesday by 10:00 (including retrospective updates to cases diagnosed/reported from Monday to Sunday during the previous week).

The following reporting routine is suggested:

1. Report a first timely dataset with the core set of variables (please see section Key variables)
2. Update cases with additional testing results or new case classification, not available at the time of initial report (please see section Submitting your data, "replace" options)

Preparing data

Data relating to new cases should be entered directly in TESSy for individual records ('Manually create a record'). For any retrospective updates by file upload (CSV or XML format), please note that the data need to be in a format that TESSy accepts (see "checking metadata").

Tutorials covering how you can transform your data to the correct TESSy format using Excel or Access are available on the *TESSy documents website*. Information on the file formats is available in the *CSV Transport Protocol* and *XML Transport Protocol*.

Checking metadata

The TESSy metadata define the fields and data formats valid for a given subject. They are updated in agreement with disease and surveillance networks when public health information needs change.

It is especially important to focus on the following areas.

- **Field formats**

  Many fields require that data are formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.

- **Coded values**

  Some fields only permit the use of specific values (coded values). For example, **M**, **F**, **UNK**, or **Other** are the coded values for *Gender* and any other value in a *Gender* field will be rejected.

- **Repeatable fields**

  For variables where multiple items of the coded value list apply, the field should be repeated as needed to include only one item per field. If not applicable, use N/A.

The metadata file contains all the definitions and rules you need to comply with to format your data correctly. The file can be downloaded as an Excel file from the TESSy documents website.

By filtering the fields in the file by subject, you can see the fields required for your subject and the rules applying to these fields.

The *Tessy User Guide* provides instructions on how you work with the metadata file.

Checking your data source profile

Before submitting your data, please review the profile for your data source(s) in TESSy (go to **Data Sources**), and update the information, if necessary.

Complete and up-to-date data source information for each subject facilitates surveillance data interpretation - each surveillance system has different features that need to be considered when comparing data at international level.

If your data source information is outdated and you do not have access rights to update it, please ask your National Focal Point for Surveillance or National Coordinator to do so.

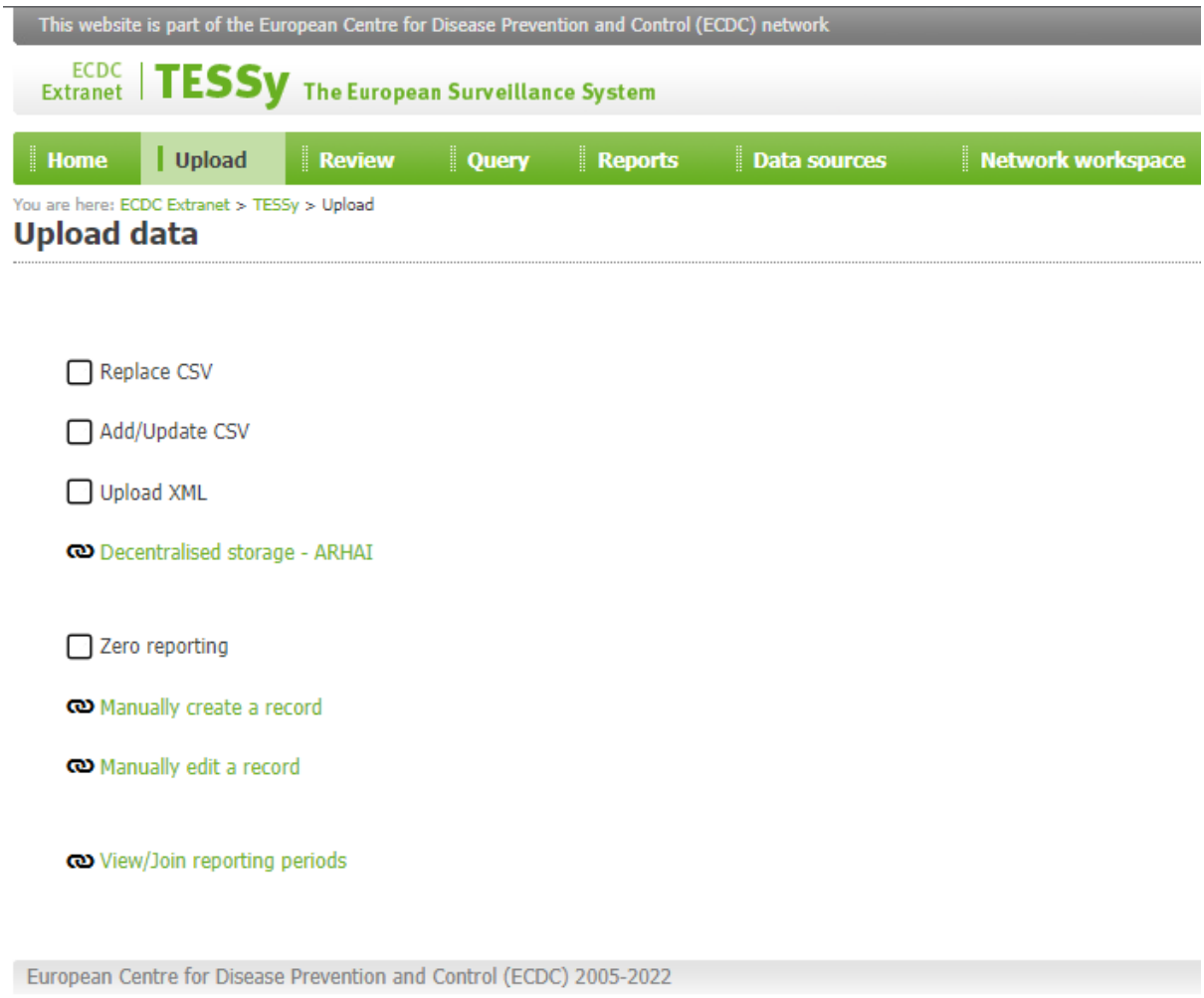
In-depth information on the data source variables is available in the TESSy user documentation.

Submitting your data

Data are submitted through the TESSy web interface (go to **Upload**).

The *Tessy User Guide* provides instructions on how to submit files to TESSy, and the TESSy user documentation provides in-depth descriptions of all the upload methods.

The screenshot below shows the different options available for NOVHEP data submissions, including manual submissions (individual records), zero reporting and CSV/XML uploads.



Finalising your submission

The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process.

The result of your upload – i.e. rejected or validated – is displayed immediately after the conclusion of the check in the **Validation details** webpage. Please review the result carefully:

- If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that you need to correct.
- If your file has been validated, there might be warnings and remarks relating to possible data quality issues or to potential overwriting of existing records that you should consider.

When you file has been validated and you are satisfied that all corrections have been made, please ensure prompt approval – unapproved uploads can block the approval of other uploads.

The TESSy user documentation provides information on reviewing validation results and adjusting reporting periods to avoid overwriting existing records.

General training and guidance on reporting is available on the *TESSy website*.

TESSy HelpDesk

Email: *TESSy@ecdc.europa.eu*

Telephone number: **+46-(0)8-5860 1601**

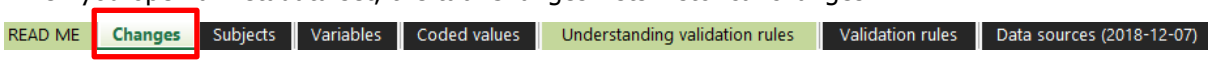
Availability: 9:00 – 16:00 Stockholm time, Monday to Friday (except ECDC holidays)

Annex - Hepatitis of unknown origin metadata

Revisions of metadata set

The most recent metadata set is available from the TESSy website under the "Technical Guidelines & Tools" tab (as shown below).

When you open a metadata set, the tab 'Changes' lists historical changes.



Current record type versions

Table 1 shows the record type versions to be used when reporting hepatitis of unknown origin surveillance data to TESSy.

Table 1: Current record type version for hepatitis of unknown origin

Record Type	Type of data	Record type version
NOVHEP	Case-based	3
NOVHEP	Case-based	2 - deactivated
NOVHEP	Case-based	1 - deactivated

Changes to hepatitis of unknown origin surveillance metadata

Record type NOVHEP Version 3 – 2 June 2022

New variables: *DateOfDischarge*; *MetagenomicsLabID*; *AdenoAssociatedVirusResultPCR*; *AdenoAssociatedVirusSpecimen*; *AdenoAssociatedVirusType*; *AdenoAssociatedVirusCtValue*; *AdenoAssociatedVirusSpecimenDate*

Record type NOVHEP Version 2 – 29 April 2022

New variables: *PlaceofResidence*; *PrevInfection*; *PrevInfectionDetails*; *PrevInfectionDetailsOther*; *ComplicationsOther*; *DateOfPrevSARSCoV2*; *SARSCoV2VaccLastDate*; *SARSCoV2VaccLastBrand*; *AdenoStoolDate*; *AdenoRespDate*; *AdenoWholeBloodDate*; *AdenoSerumDate*; *AdenoOtherDate*; *SARSCoV2PCRDate; Hospitalisation; AdenoUrineResult; AdenoUrineDate; AdenoUnknownSpecimenResult*; *AdenoUnknownSpecimenDate*; *AdenoCtValue*; *AdenoCtValueSpecimenDate*; *AdenotypeSpecimen*; *AdenoSeqDone*; *ADVSequence*; *OtherTypingResult*; *RhinoResult*; *hMPVResult*; *BrucellaResult*; *BartonellaResult*; *BorreliaResult*; *StoolBacterialPCRResult*; *AdditionalInfo*

Changes in coded value lists: Please refer to Change log

INACTIVATED variables (from NOVHEP v1):

ClinicalPresentation - renamed to PreviousClinicalPresentation

ClinicalPresentationOther - renamed to PreviousClinicalPresentationOther

Adenotype – renamed to AdenovType

PeakASP – removed

Record type NOVHEP Version 1 – 22 April 2022

NOVHEP metadata

The NOVHEP metadata, **record type version 3,** is used for reporting case-based data on hepatitis of unknown origin.

In the descriptions of the variables, the following conventions are used:

VariableName	Literal name of a variable. This never contains spaces. Case is only used to improve readability.
Coding	Code as accepted by the system.
Description of code	Description of the meaning of a possible values for a specific variable.

Example: The gender of a case is described in the variable **Gender**, that can have the possible values ***M*** for 'Male', ***F*** for 'Female', ***O*** for 'Other' and ***Unk*** for 'Unknown'.

Common TESSy Variables

RecordID (mandatory)

Unique case identifier (used in the country)

Coding: Text (max 80 characters)

Please note that ID must be unique if they are derived from the same national reporting system; records with the same ID will be overwritten.

RecordType (mandatory)

Structure and format of the data (case based reporting or aggregate reporting).

Coding: NOVHEP'

RecordTypeVersion

Indicates the version of the Record type used in the reported batch. If no RecordTypeVersion is provided in the batch, it is set automatically with current version of the Record type. RecordTypeVersion is required when no metadata set is provided at upload or when a RecordTypeVersion, other than the current one, needs to be used.

Coding: NUM

Subject (mandatory)

Subject of the data reported.

Coding: NOVHEP = Novel hepatitis

DataSource (mandatory)

The data source (surveillance system) that the record originates from.

Coding: To be assigned by each country to an existing data source, or to a newly created one.

The data source specifies the surveillance system from which the data originates and is generated and revised/updated by the national focal point in each Member State. The descriptions of the surveillance systems submitted to TESSy (*section Data Sources*) will be used to assist with data interpretation. Make sure that the subject "NOVHEP" is associated with this data source.

ReportingCountry (mandatory)

The country reporting the case(s).

Coding: International organization for standardization (ISO) 3166-1-alpha-2, (two-letter code)

(*See the coded values list*)

This variable identifies the country reporting the case.

DateUsedForStatistics (mandatory)

The date used for statistics is date of reporting to national health authority.

Coding: yyyy-mm-dd

Status

Status of reporting NEW/UPDATE or DELETE (inactivate). Default if left out: NEW/UPDATE. If set to DELETE, the record with the given recordId will be deleted from the TESSy database (or better stated, invalidated.) If set to NEW/UPDATE or left empty, the record is newly entered into the database.

Coding: [Statuses]:

DELETE = Delete a previously reported record

NEW/UPDATE = Report a new or update a previously reported record (default)

Demographic variables

Age (mandatory)

Age of patient in years as reported in the national system at the time of disease onset.

Coding: NUM

AgeMonths

Age of patient in months as reported in the national system for cases < 2 years of age at the time of disease onset.

Coding: NUM

Gender

Gender of the reported case.

Coding: Sex:

F = Female

M = Male

O = Other (e.g. transsexual)

Unk = Unknown

PlaceofResidence

Place of residence of patient at the time of disease onset. Select the most detailed NUTS (EU/EEA) or GAUL (nonEU/EEA) level possible.

Coding: NUTS_GAUL

(*See the coded values list*)

Case classification

Classification (mandatory)

Case classification according to agreed case definition.

Coding: ClassificationNOVHEP

PROB = Probable

EPILINK = Epi-linked case

DISC = Discarded case

Clinical findings and outcomes

PreviousClinicalPresentation (Repeatable)

Clinical symptoms and signs in the four weeks preceding the onset of hepatitis.

Coding: PrecedingSymptomsNOVHEP:

CONJ = Conjunctivitis

DIARR = Diarrhoea

FEVER = History of fever / chills

HEAD = Headache

NONE = None

O = Other, please specify

RESP = Respiratory symptoms

RASH = Rash

SORETHR = Sore throat

UNK = Unknown

VOMIT = Nausea / vomiting

PreviousClinicalPresentationOther

Other clinical symptoms and signs in the four weeks preceding the onset of hepatitis.

Coding: TEXT

PrevInfection

Patient had a confirmed acute infectious disease in the four weeks preceding the onset of hepatitis.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

If yes, please specify in PrevInfectionDetails.

PrevInfectionDetails (repeatable)

Specify pathogen responsible for previous known acute infectious disease in the four weeks preceding the onset of hepatitis.

Coding: ADENO = Adenovirus

ASTRO = Astrovirus

BOCA = Bocavirus

CAMP = Campylobacter

CMV = CMV

COX = Coxsackie

EBV = EBV

ESCCOL = E. coli

ENVI = Enterovirus

HSV1 = HSV1

HHV6 = HHV6

HHV7 = HHV7

METAPNEU = Metapneumovirus

INFL = Influenza

LEGI = Legionella

LEPT = Leptospira

NOROV = Norovirus

O = Other, please specify

OTHCOR = Other coronavirus (non SARS-CoV-2)

PARAINFL = Parainfluenza

PARVOV = Parvovirus

ROTAV = Rotavirus

RSV = RSV

SALM = Salmonella

SAPO = Sapovirus

SHIG = Shigella

YERS = Yersinia

UNK = Unknown

PrevInfectionDetailsOther

If other previous known acute infectious disease in the four weeks preceding the onset of hepatitis not included in PrevInfectionDetails, please specify.

Coding: TEXT

ClinicalSymptoms (Repeatable)

Clinical symptoms and signs since onset of hepatitis.

Coding: ClinicalSymptomsNOVHEP:

ANO = Anorexia / poor feeding

CONJ = Conjunctivitis

DARKU = Dark urine

DIARR = Diarrhoea

FEVER = Fever

HEAD = Headache

HEPATOME = Hepatomegaly

IRR = Irritability / confusion

JAUNDICE = Jaundiced

O = Other, please specify

PAINABDO = Pain – abdominal

RESP = Respiratory symptoms

RASH = Rash

SORETHR = Sore throat

STOBLO = Bloody stool

STOPAL = Pale stool

UNK = Unknown

VOMIT = Nausea / vomiting

WEAK = General weakness

ClinicalSymptomsOther

Other reported clinical symptoms anytime during illness, not found in the list of possible values.

Coding: TEXT

Complications (repeatable)

Complications at any time.

Coding: ALF = Acute Liver Failure

BMF = Bone Marrow Failure

RF = Renal Failure

HAEM = Haemorrhage

HEPENCEPH = Hepatic encephalopathy

COMA = coma

SEPSIS = Sepsis/Multi-organ failure

O = other

ComplicationsOther

Other reported complications, not found in the list of possible values. Please separate using a semi-colon (;) if multiple.

Coding: TEXT

DateOfOnset

Date of onset of first symptoms of disease.

Coding: yyyy-mm-dd

Hospitalisation

Whether the case was admitted to hospital.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

DateOfHospitalisation

Date of Hospitalisation. If multiple hospitalisations, please indicate the first related to hepatitis.

Coding: yyyy-mm-dd

DateOfDischarge

Date of discharge from hospital. If multiple hospitalisations, please use the end date of the most recent hospitalisation related to hepatitis.

Coding: yyyy-mm-dd

AdmittedICUHDU

Whether admitted to intensive care unit or high-dependency unit.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

AdmittedTransUnit

Whether case was admitted to transplant unit.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

Transplant

Whether case received liver transplant.

Coding:

N = No

Unk = Unknown

WAITTRANS = Waiting for transplant

Y = Yes

HistologyBiop

Liver histology results either from biopsy, removed organ or post mortem – please indicate including any immunohistochemistry for adenovirus or other infectious agents.

Coding: TEXT

Ideally, results should be reported in English.

Outcome (mandatory)

Information on the outcome of the case.

Coding: OutcomeNOVHEP:

ALIVE = Alive, recovered, cured

DIEDHEP = Died due to severe acute hepatitis

DIEDOTHER = Death not related to severe acute hepatitis

DIEDUNK = Cause of death unknown

STILLTREATMENT = Still on medical treatment (not recovered)

UNK = Unknown outcome

DateOfDeath

Date of death (exact date only).

Coding: yyyy-mm-dd

Precondition (mandatory) (repeatable)

Patient's underlying condition or conditions.

Coding: PreconditionsNOVHEP:

ASPL = Asplenia

ASTH = Asthma

AUTOIMMUNE = Autoimmune disease

CANC = Cancer, malignancy

CARDIACDIS = Cardiac disorder, excluding hypertension

DIAB = Diabetes

ENDO = Endocrine disease

GASTRO = Gastrointestinal tract disease

GENET = Genetic disorder

HIV = HIV/other immune deficiency

HYPERT = Hypertension

KIDNEY = Kidney-related condition, renal disease

IMMUN = immunosuppressed

LIVER = Liver-related condition, liver disease

LUNG = Chronic lung disease, excluding asthma

METAB = Metabolic disorder

NEUROMUS = Neuromuscular disorder, chronic neurological

NONE = None

O = Other precondition, please specify

OBES = Obesity

PREG = Pregnant

TB = Tuberculosis

UNK = Unknown precondition

PreconditionOther

Details of underlying conditions, if precondition is coded as 'other', but is known. Please separate using a semi-colon (;) if multiple.

Coding: TEXT

Previous SARS-CoV-2 infection or vaccination

PrevSARSCoV2

Patient had a confirmed infection with SARS-CoV-2.

Coding: Unk = Unknown

Y = Yes

DateOfPrevSARSCoV2

Date of previous SARS-CoV-2 infection.

Coding: yyyy-mm-dd (preferred)

yyyy-Www

UNK= Unknown

If no exact date available, please provide an estimate.

SARSCoV2VaccStatus

Indicates if the case is vaccinated against SARS-Cov-2 and number of vaccine doses received.

Coding: VaccStatusCOVID:

1DOSE = 1 dose

2DOSE = 2 doses

3DOSE = 3 doses

4DOSE = 4 doses

DOSEUNK = Vaccinated with unknown number of doses

NOTVACC = 0 doses - unvaccinated

UNK = Unknown vaccination status

SARSCoV2Vacc**LastDate**

Date of last dose of COVID-19 vaccine (if vaccinated)

Coding: yyyy-mm-dd (preferred)

yyyy-Www

UNK= Unknown

Date on which the case received last dose of vaccine (preferably exact date, formatted as yyyy-mm-dd). If no exact date available, please provide an estimate.

SARSCoV2Vacc**LastBrand**

Brand of the COVID-19 vaccine administered for last dose

Coding: AZ = AstraZeneca - AZD1222

BECNBG = Beijing CNBG - Inactivated

BHACOV = Bharat - Covaxin

CHU = Chumakov - Covi-Vac

COM = Pfizer BioNTech - Comirnaty

CVAC = Curevac-CVnCOV

HAYAT-VAC = Hayat-VAX

JANSS = Janssen - Ad26.COV 2.5

MOD = Moderna - mRNA-1273

NVX = Novavax - Covovax

NVXD = Novavax - Nuvaxovid
QAZVAQ = QazCovid-In
SGSK = Sanofi GSK - Subunit
SIICOV = SII - Covishield
SIN = Coronavac – Sinovac
SPU = Gamaleya - Sputnik V
SPUL = Gamaleya - Sputnik-Light
SRCVB = SRCVB - EpiVacCorona
UNK = Unknown
WUCNBG = Wuhan CNBG - Inactivated
ZFUZ = Sino-Uzbek - ZF-UZ-VAC

Type of vaccine received for first dose of vaccination course (product name/brand). Product names should be in line with the latest *ECDC NCOVVACC reporting protocol*.

Laboratory findings

PeakALT

Peak level of Alanine transaminase (ALT) in IU/L.

Coding: NUM

PeakAST

Peak level of Aspartate transaminase (AST) in IU/L

Coding: NUM

PeakBilirubin

Peak level of Bilirubin in mg/dl

Coding: FLOAT

PeakINR

Peak level of INR

Coding: FLOAT

AdenoStoolResult

Result of adenovirus test on stool specimen.

Coding: LaboratoryResultNOVHEP:
N = Negative
NT = Not tested
P = Positive
IN = Indeterminate / equivocal
UNK = Tested, but result unknown
DK = Don’t know if tested

AdenoStoolDate

Date of adenovirus test on stool specimen. In case of multiple specimens, indicate first date (if all negative) or date of first positive result.

Coding: yyyy-mm-dd

UNK= Unknown

AdenoUrineResult

Result of adenovirus test on urine specimen.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

AdenoUrineDate

Date of adenovirus test on urine specimen. In case of multiple specimens, indicate first date (if all negative) or date of first positive result.

Coding: yyyy-mm-dd

UNK= Unknown

AdenoRespResult

Result of adenovirus test on respiratory specimen.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

AdenoRespDate

Date of adenovirus test on respiratory specimen. In case of multiple specimens, indicate first date (if all negative) or first date of positive result.

Coding: yyyy-mm-dd

UNK= Unknown

AdenoWholeBloodResult

Result of adenovirus test on whole blood specimen.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

AdenoWholeBloodDate

Date of adenovirus test on whole blood specimen. In case of multiple specimens, indicate first date (if all negative) or first date of positive result.

Coding: yyyy-mm-dd

UNK= Unknown

AdenoSerumResult

Result of adenovirus test on serum specimen.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

AdenoSerumDate

Date of adenovirus test on serum specimen. In case of multiple specimens, indicate first date (if all negative) or first date of positive result.

Coding: yyyy-mm-dd (preferred)

UNK= Unknown

AdenoOtherResult

Result of adenovirus test on other specimen (not stool, respiratory, blood, plasma).

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

AdenoOtherDate

Date of adenovirus test on another specimen (not stool, respiratory, blood, plasma). In case of multiple specimens, indicate first date (if all negative) or first date of positive result.

Coding: yyyy-mm-dd

UNK= Unknown

AdenoUnknownSpecimenResult

Result of adenovirus test where type of specimen is unknown.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

AdenoUnknownSpecimenDate

Date of adenovirus test where type of specimen is unknown. In case of multiple specimens, indicate first date (if all negative) or first date of positive result.

Coding: yyyy-mm-dd

UNK= Unknown

AdenoCtValue

Ct (cycle threshold) value of adenovirus in blood or serum. If multiple results, indicate the lowest value.

Coding: NUM

AdenoCtValueSpecimenDate

Date of adenovirus sample on which the lowest Ct (cycle threshold) value was measured.

Coding: yyyy-mm-dd (preferred)

UNK= Unknown

AdenotypeDone

Whether adenovirus typing was done.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

AdenotypeSpecimen

Type of specimen on which adenovirus typing was done.

Coding: SpecimenNOVHEP:

BLOOD = Blood

SERUM = Serum

RESP = Respiratory

STOOL = Stool

O = Other

URINE = URINE

Unk = Unknown

AdenovType

Result of adenovirus typing.

Coding: TEXT

AdenoSeqDone

Whether adenovirus sequencing was done.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

ADVSequence (repeatable)

Consensus sequence of ADV DNA sequencing.

Coding: TEXT

OtherTypingResult (repeatable)

Result of other typing – please specify pathogen.

Coding: TEXT

MetagenomicsLabID

In case there were metagenomics results submitted to Epipulse, please provide Lab ID in this field (unique in the country, including a prefix for country of origin)

Coding: TEXT

AdenoAssociatedVirusResultPCR

Result of PCR test for adeno-associated virus

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

AdenoAssociatedVirusSpecimen

Type of specimen on which adeno-associated virus typing was done.

Coding: SpecimenNOVHEP:

BLOOD = Blood

SERUM = Serum

RESP = Respiratory

STOOL = Stool

O = Other

URINE = URINE

Unk = Unknown

AdenoAssociatedVirusType

Adeno-associated virus type or types identified

Coding: TEXT

AdenoAssociatedVirusCtValue

Ct (cycle threshold) value of adeno-associated virus. If multiple results, indicate the lowest value.

Coding: NUM

AdenoAssociatedVirusSpecimenDate

Date of adeno-associated virus sample. on which the lowest Ct (cycle threshold) value was measured.

Coding: yyyy-mm-dd (preferred)

UNK= Unknown

SARSCoV2PCR

Result of PCR for SARS-CoV-2 (after onset of hepatitis).

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

SARSCoV2PCRDate

Date of SARS-CoV-2 PCR test (after onset of hepatitis). In case of multiple specimens, indicate first date (if all negative) or first date of positive result.

Coding: yyyy-mm-dd (preferred)

UNK= Unknown

SARSCoV2Serology

Serology result for past SARS-CoV-2 infection during this episode of illness.

Coding: SARSCoV2Serology:

N = Negative

NT = Not tested

P = Positive unspecified

IgM = IgM detected

IgG = IgG detected

IgMIgG = IgM and IgG detected

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

CMVResult

Whether CMV test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

EBVResult

Whether EBV test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

EnterovBloodResult

Whether enterovirus test (PCR on blood) was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

EnterovThroatResult

Whether enterovirus test was done (PCR throat swab) during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

HSV1Result

Whether HSV-1 test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

LeptoResult

Whether Leptospirosis test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

HHV6Result

Whether HHV6 test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

HHV7Result

Whether HHV7 test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

RSVResult

Whether RSV test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

INFLResult

Whether influenza test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

RhinoResult

Whether Rhinovirus test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

hMPVResult

Whether human metapneumovirus test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

VaricellaResult

Whether Varicella PCR test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

ParvovirusResult

Whether parvovirus test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

HIVResult

Whether HIV test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

LegionellaResult

Whether legionella test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

MycoplasmaResult

Whether mycoplasma test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

HPeVResult

Whether human parechoviruses (HPev) test was done during this episode of illness and what result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

ParainfluenzaResult

Whether human parainfluenza test was done during this episode of illness and what result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

ASOTResult

Whether ASOT (antistreptolysin O titer) test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

BocavirusResult

Whether Bocavirus test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

BrucellaResult

Whether Brucella test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

BartonellaResult

Whether Bartonella test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

BorreliaResult

Whether Borrelia test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:

N = Negative

NT = Not tested

P = Positive

IN = Indeterminate / equivocal

UNK = Tested, but result unknown

DK = Don't know if tested

StoolViralPCRResult

Whether viral stool PCR was done during this episode of illness and what the result was.

Coding: StoolViralPCRNOVHEP:

N = Negative

NT = Not tested

ADENO = Adenovirus detected

SAPO = Sapovirus detected

NORO = Norovirus detected

ENTERO = Enterovirus detected

ROTA = Rotavirus detected

ASTRO = Astrovirus detectedO = Other

UNK = Tested, but result unknown

StoolBacterialPCRResult

Whether bacterial stool PCR was done during this episode of illness and what the result was.

Coding: TEXT

StoolVirCultDone

Whether viral stool culture was done during this episode of illness.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

StoolVirCultResult

Result of viral stool culture during this episode of illness.

Coding: TEXT

StoolBacCultDone

Whether bacterial stool culture was done during this episode of illness.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

StoolBacCultResult

Result of bacterial stool culture during this episode of illness.

Coding: TEXT

ThroatBacCultDone

Whether throat bacterial culture done during this episode of illness.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

ThroatBacCultResult

Result of throat bacterial culture during this episode of illness.

Coding: TEXT

ToxResult

Result of toxicology screen during this episode of illness.

Coding: TEXT

AdditionalInfo

Any other relevant laboratory or clinical information not included in any other variable.

Coding: TEXT

Epidemiological links and travel history

JAUNDICEFAM

Family member with history of jaundice within 2 months prior to symptom onset in the case.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

SARSCoV2FAM

Family member had SARS-CoV-2 infection within 2 months prior to symptom onset in the case.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

EpiLink

Epidemiological link to other case.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

EpiLinkCaseID

Unique case identifier (*RecordID* used in the country) of other case to which there is an epidemiological link.

Coding: TEXT

Travel

Whether the case has travelled to another country or region in the 30 days prior to symptom onset.

Coding: YesNoUnk:

N = No

Unk = Unknown

Y = Yes

Regular domestic travels (such as daily commutes) should not be considered for this purpose.

TravelLocation

Location of travel in the 30 days prior to symptom onset.

Coding: TEXT