TESSy - The European Surveillance System

Mpox (MPX)

Reporting Protocol

Version 5.0, 20 August 2024

Contents

Summary of changes

20 August 2024 (version 5.0)
- Updated to RecordTypeVersion 5.
- Updated categories to include information on subclades within the clade variable.
- Inclusion of HOUSEABROAD and PLANE categories in the ExposureSetting variable.
- Updated categories to include information on subclades within the PreviousMPXclade variable.
- Redefinition of categories for the Sexual Orientation variable to HETERO, MSM, WSW, O, BISEXUAL, NA, UNKNOWN, and relabelling the variable as "Sexual behaviour of the Case" Label: SexualBehaviour

10 March 2023 (version 4.0)
- Added variables PreviousMPX, PreviousMPXDate

23 September 2022 (version 3.2)
- Updated description of variable *OtherGender*.

8 September 2022 (version 3.1)
- Updated case definitions.
- Updated coded value list of *CaseDefinition* variable with category WHO_Aug2022 to collect information on the new case definition by WHO from 25 August 2022.

5 August 2022 (version 3.0)
- Updated to RecordTypeVersion 3.
- Removed variables SmallpoxVaccine and DateLastVaccDose.
- Added variables PrEPHIV, SexWorker, NumberSexPartners, OtherGender, VaccPoxPrev, VaccPoxPrevDate, VaccPoxCurrentStatus, VaccPoxBrand1, VaccPoxBrand2, VaccPoxDate1, VaccPoxDate2, VaccPoxPurpose1, VaccPoxPurpose2, Complications, and ComplicationsOther.
- Updated coded value list of ClinicalSymptoms variable with category PROCT for reporting of proctitis, category DIARR for reporting of diarrhoea, category LYMPHLOCUNK for reporting lymphadenopathy where the location is not known, and category GENITEDEM for reporting of genital soft-tissue oedema/swelling.
- Corrected designation of category SORTHR to SORETHR in the coded value list of ClinicalSymptoms variable.
- Updated coded value list of SpecimenMPX variable with category CSF for reporting of specimen collection of cerebrospinal fluid.
- Added validation rules.

22 June 2022 (version 2.0 revised)
- Added YUNK (yes for unknown reason) to the coded value list for Hospitalisation.

16 June 2022 (version 2.0)
- Updated to RecordTypeVersion 2.
- Changed coded value list for TravelPlaces to include all places worldwide.
- Added RASHLOCUNK (Skin/mucosal lesions where the location is not known) to the coded value list for ClinicalSymptoms variable.

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 for reporting, subject-specific information (e.g. new changes to metadata), and links to further information.
- *Annex* – contains:
    - A history of metadata changes for the subject(s) covered by this Reporting Protocol.
    - The metadata set for the subject(s) 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 in this Reporting Protocol are included in the *TESSy Technical Guidelines & Tools* (see the menu 'Technical Guidelines and Tools' when logged in 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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Introduction

This reporting protocol is intended for reporting national case-based data for surveillance of mpox 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 MPX to the European Surveillance System (TESSy) database hosted at ECDC and access through the *EpiPulse portal*.

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 definition

Probable and confirmed cases should be reported according to the current WHO case definition for mpox **(Annex 2)**. Information on the case definition used should be provided in the variable CaseDefinition. If a national case definition is used this information should also be provided in the variable CaseDefinition.

Aim

To support the timely and complete reporting of key information on mpox epidemiology in 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).

Surveillance Objectives

1. Monitor the intensity and geographical spread of the monkeypox virus in the population in time, place and person;
2. To understand the natural history and epidemiology of the disease including risk factors for infection in order to assess its impact and prepare accordingly
3. To describe the population at highest risk of infection and severe outcomes in order to target preventive or control measures
4. Assess the impact of any control and prevention measures.

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.

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

Please note, if MPXV clade I virus is detected in an mpox case, or if there is an unexpected increase in case numbers, or the emergence of cases in new risk groups, populations, or settings, we kindly request that these be reported immediately through event-based surveillance mechanisms (EpiPulse, EWRS, IHR routes). However, ECDC encourages sharing through the following items from EpiPulse: [*Mpox due to monkeypox virus clade I – Multi-country – 2024* and *Mpox due to clade II - Multi-country (global outbreak) - 2022-2024*].

Data collection schedule

Case data including retrospective updates to cases already in TESSy **should be reported monthly on the first Thursday of each month, by 10:00AM.** Due to potential overlap with holidays, the following dates for monthly data upload for the next five months are as follows:

- 5 September 2024
- 3 October 2024
- 7 November 2024
- 5 December 2024

Please also note that should there be any significant changes in mpox epidemiology in the coming months, the **reporting frequency through TESSy may increase at short notice** to ensure appropriate surveillance according to the epidemiological situation.

If data is shared through event-based surveillance (EpiPulse, EWRS, IHR), subsequently, or concurrently, upload the relevant data to the TESSy database either or immediately or as of the next subsequent data call deadline. Please note that all data are collected jointly with the World Health Organisation – Regional Office for Europe (WHO/Europe) to fulfil Member States reporting requirements to WHO. Duplicate reporting is therefore not required.

Preparing data

Data may be entered directly in TESSy for individual records ('Manually create a record'). For any batch reporting by file upload (CSV or XML format) please note that once the data has been exported from your national database it needs to be in a format that TESSy can accept (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 valid data formats for input to TESSy for a given subject.

To ensure data can be saved correctly in TESSy, please check the data are correctly formatted according to the most recent metadata set.

Changes to the metadata for the subject of this Reporting Protocol are described in:

- *Changes to current metadata* – changes since the last Reporting Protocol.
- *Annex Metadata change history* – all preceding changes.

It is especially important to focus on:

- **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.

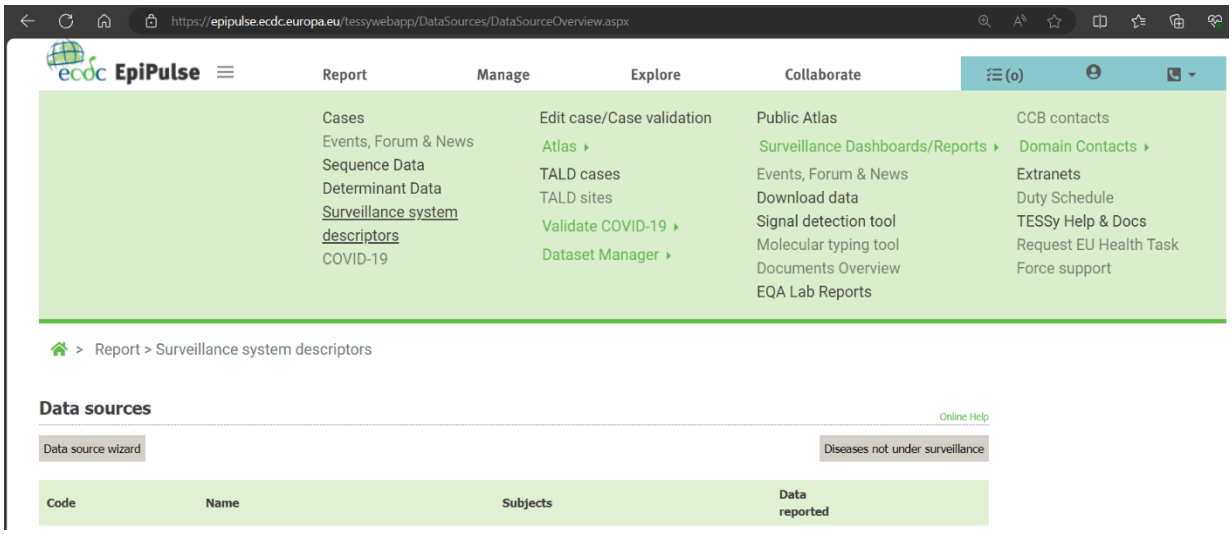
The metadata file contains all the definitions and rules you need to comply with to format your data correctly. The file can be downloaded as an Excel file from the TESSy documents website.

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 an overview of how you work with the metadata file, and the TESSy user documentation provides in-depth details on metadata.

Checking your data source profile

Before submitting file(s), please review your data source(s) in EpiPulse (in the menu, go to 'Report' -> '*Surveillance systems descriptors*') and update the information as necessary.



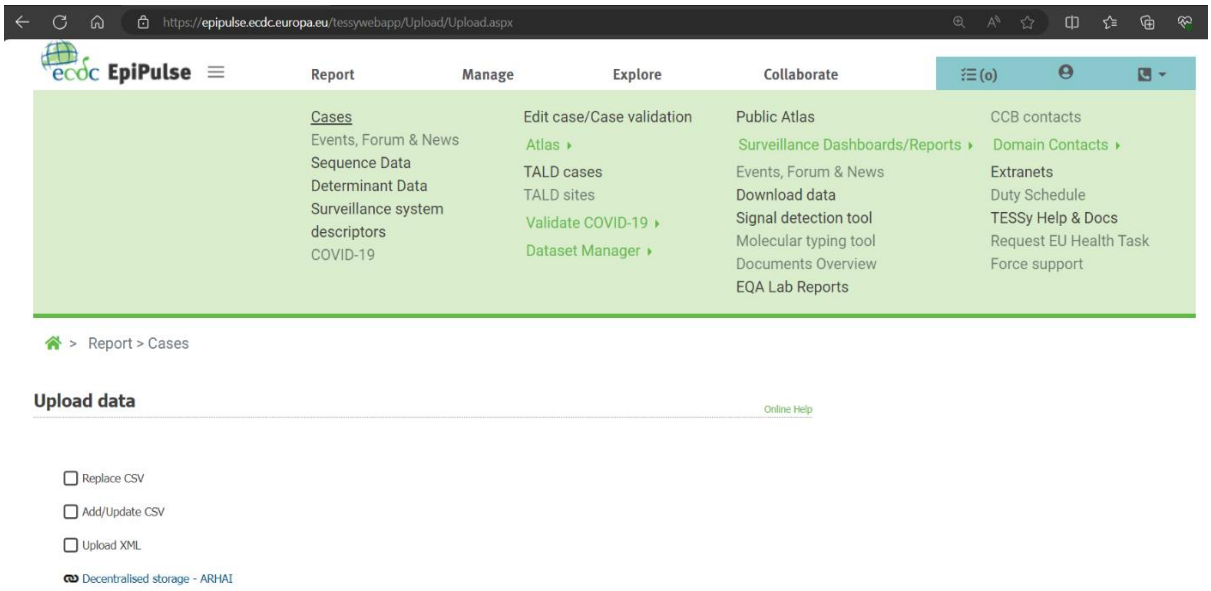
Complete and up-to-date data source information for each subject facilitates surveillance data interpretation - each surveillance system has different features that need to be considered when comparing data at international level.

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 is submitted through the EpiPulse web interface (in the menu, go to Report -> *Cases*).



The *User Guide* provides an overview of how to submit files to TESSy and in-depth descriptions of all the methods for uploading data.

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 check in the **Validation details** webpage has completed. 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)

Changes to mpox (MPX) metadata

RecordType: MPX: RecordType Version 5: Review 2024-08-20

- Updated to RecordTypeVersion 5.
- Updated categories to include information on subclades within the clade variable.
- Inclusion of HOUSEABROAD and PLANE categories in the ExposureSetting variable.
- Updated categories to include information on subclades within the PreviousMPXclade variable.
- Redefinition of categories for the Sexual Orientation variable to HETERO, MSM, WSW, O, BISEXUAL, NA, UNKNOWN, and relabelling the variable as "Sexual behaviour of the Case" Label: SexualBehaviour

Annex 1 – Mpox metadata

Revisions of MPX metadata set

The MPX metadata have been developed in collaboration with WHO.

The TESSy metadata contains all the definitions and rules necessary to format data correctly for every subject (usually a disease). This can be downloaded as an Excel file from the *Technical Guidelines & Tools* section of the 'Documentation and Help' pages.

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 *User Guide* provides an overview of how you work with the metadata file.

Current record type versions

Table 1 shows the record type versions to be used when reporting mpox (Record type: MPX) data to TESSy.

Table 1: MPX record type versions

Record	Type of data	Record type version
MPX	Case-based	5

Common TESSy variables

Record Identifier (mandatory)

Field: RecordId

Coding: Text (max 80 characters)

The record identifier is provided by the Member State. It must be:

- unique within the national MPX reporting system (records with the same ID will be overwritten)
- anonymous.

Record type (mandatory)

Field: RecordType

Coding: MPX

The record type defines the structure and the format of the data reported. The record types are defined by ECDC and are related to the subject. Only valid combinations of subject, record type and data source are accepted.

Record type version

Field: RecordTypeVersion

Coding: 5

The version of the record type defines the current structure of the data reported. The current version of the MPX record type is 5.

This variable is not mandatory as TESSy concludes the record type version from the metadataset indicated by default. However, the variable RecordTypeVersion can override this default.

Subject (mandatory)

Field: Subject

Coding: MPX

The subject describes the disease to be reported.

Data source (mandatory)

Field: DataSource

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 "MPX" is associated with this data source.

Reporting country (mandatory)

Field: ReportingCountry

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

This variable identifies the country reporting the case.

Date used for statistics (mandatory)

Field: DateUsedForStatistics

Coding: yyyy-mm-dd

Date when the case report is notified the first time to the place of notification.

Status (mandatory)

Field: Status

Coding: NEW/UPDATE
DELETE

The field 'Status' is used for updating data; the default is 'New/Update'. By choosing 'Delete' the selected record (or batch of data) will remain in TESSy but be marked as inactive; this data can be used to reconstruct data for a given date in the past.

Epidemiological variables

In alphabetic order by field.

Accession number

Field: AccessionNumber

Coding: TEXT

Sequence identifier for whole genome or whole or partial gene sequence, based on which the sequence read data can be retrieved from external database such as GenBank, ENA or other database.

Age (mandatory)

Field: Age

Coding: Numerical (0-120)
UNK = Unknown

Age of patient in years at the time of disease onset.

Age in months

Field: AgeMonth

Coding: Numerical (0-23)
NA = Not applicable
UNK = Unknown

Age of patient in months at diagnosis for cases <2 years of age at the time of diagnosis.

Animal contact

Field: AnimalContact

Coding: N = No
PET = Household pets excluding rodents
PETRODENTS = Rodent pets
UNK = UNK
WILD = Wild animals excluding rodents
WILDRODENTS = Wild rodents

Animal contact in the 21 days before symptom onset or date of diagnosis.

Antiviral treatment

Field: AntiviralTreatment

Coding: TEC = tecovirimat
BRI = brincidofovir
CID = cidofovir
UNK = Unknown
YUNK = Yes, but name of antiviral treatment not known
N = No antiviral treatment

Information if case has received treatment with antivirals. Note this is a repeatable field.

Brand name of first dose of smallpox/mpox vaccination

Field: VaccPoxBrand1

Coding: SmallpoxVaccine:
ACAM2000 = ACAM2000
APSV = Aventis Pasteur smallpox vaccine)
Imvanex = Imvanex
Imvamune = Imvamune
Jynneos =Jynneos
LC16m8 = LC16m8
O = Other
UNK = Unknown

Brand name of first dose of smallpox/mpox vaccine related to the current mpox event/outbreak.

Brand name of second dose of smallpox/mpox vaccination

Field: VaccPoxBrand2

Coding: SmallpoxVaccine:
ACAM2000 = ACAM2000
APSV = Aventis Pasteur smallpox vaccine)
Imvanex = Imvanex
Imvamune = Imvamune
Jynneos =Jynneos
LC16m8 = LC16m8

O = Other

UNK = Unknown

Brand name of second dose of smallpox/mpox vaccine related to the current mpox event/outbreak.

Case definition used

Field: CaseDefinition

Coding: ECDC = ECDC case definition (prior to 25 August 2022)
NAT = National case definition
UNK = Unknown
WHO = WHO case definition (prior to Interim Guidance from 25 August 2022)
WHO_Aug2022 = WHO case definition (Interim Guidance from 25 August 2022)

Case definition used for classification of the case (see Annex 2 for the current WHO case definitions). Please refer to *Surveillance, case investigation and contact tracing for Monkeypox: Interim guidance* (25 August 2022) for more details on the current WHO mpox case definition.

CD4 cell count

Field: CD4Cells

Coding: Numerical (0-6000)
NA = Not applicable
UNK = Unknown

CD4 count at time of diagnosis of mpox.

Clade of monkeypox virus

Field: Clade

Coding: Ia = Clade Ia,
Ib= Clade Ib
I= Clade I (for cases where clade is known without subclade identification)
IIa= Clade IIa
IIb= Clade IIb
II= Clade II (for cases where clade is known without subclade identification)
UNK= Unknown

Clade of the genomically characterised monkeypox virus. Please reporting using the option that provides the most specific data for the case, ie, sub-clade if information is available or clade, if information on sub-clade is not available).

Classification (mandatory)

Field: Classification

Coding: CONF = Confirmed
PROB = Probable
UNK = Unknown

Case classification according to case definition used.

Clinical symptoms of the case (mandatory)

Field: ClinicalSymptoms

Coding: ASY = Asymptomatic
RASH = Skin/mucosal lesions excluding oral or anogenital areas
GENITAL = Anogenital dermatological skin/mucosal lesions
GENITEDEM = Genital soft-tissue oedema/swelling
RASHLOCUNK = Skin/mucosal lesions where the location is not known
ORAL = Oral dermatological skin/mucosal lesions
FEVER = Fever

MUSC = Muscle pain (myalgia)
SORETHR = Sore throat
FATIGUE = Fatigue (defined as a persistent and overwhelming sense of tiredness, weakness, or lack of energy that is not relieved by rest).
WEAK = Weakness (refers to a reduction in the strength of one or more muscles, leading to difficulty or inability to perform normal physical activities)
CHILLS = Chills or sweats
HEAD = Headache
CONJ = Conjunctivitis
VOMIT = Vomiting/nausea
DIARR = Diarrhoea
COUGH = Cough/respiratory symptoms
LYMPH = Generalised lymphadenopathy
LOCALLYMPH = Localised lymphadenopathy
LYMPHLOCUNK = Lymphadenopathy where the location is not known
PROCT = Anogenital pain and /or bleeding
O = Other symptoms (specify in ClinicalSymptomsOther)
UNK = Unknown

Clinical symptoms including rash/fever/lymphadenopathy at any point during the illness. Note this is a repeatable field.

Clinical symptoms other specified

Field: ClinicalSymptomsOther

Coding: TEXT

Clinical symptoms not captured in the coded values for ClinicalSymptoms variable as indicated by O response for ClinicalSymptoms variable.

Complications

Field: Complications

Coding: NONE = None
ARDS = Acute respiratory distress syndrome
LRTI = Lower respiratory tract infection (e.g. pneumonia)
ENCEPH = Encephalitis
MENINGENCEPH = Meningoencephalitis
MYOCARD = Myocarditis
KERATITIS = Corneal infection
RETROPHARYNXABSC = Retropharyngeal abscess
SEPSIS = Sepsis
STILLBIRTH = Still birth as pregnancy outcome in a case
SSTI = Skin and/or soft-tissue infection due to secondary bacterial infection
OTHBAC = Other secondary bacterial infection
O = Other (please specify separately)
UNK = Unknown

Complications related to the current mpox event. Note this is a repeatable field and more than one option can be chosen.

Complications (Other)

Field: ComplicationsMPXOther

Coding: TEXT

Complications not captured in the coded values for Complications variable as indicated by O response for Complications variable.

Concurrent STI

Field: ConcurrentSTI

Coding: CHLAM = Chlamydia
HERP = Genital herpes
LGV = LGV
MYCO = Mycoplasma genitalium
N = No concurrent STI
SYPH = Infectious syphilis
TRICH = Trichomonas vaginalis
WARTS = Genital warts
GONO = Gonorrhoea
UNK = Unknown

Concurrent STI at time of diagnosis. Note this is a repeatable field.

Date of death

Field: DateOfDeath

Coding: *yyyy-mm-dd*
UNK = Unknown

Date for date of death. If not applicable, please use 'UNK'.

Date of diagnosis

Field: DateOfDiagnosis

Coding: yyyy-mm-dd
UNK = Unknown

First date of clinical or laboratory diagnosis. In case the DateofOnset is missing this timestamp is used.

Date of onset of symptoms (mandatory)

Field: DateOfOnset

Coding: *yyyy-mm-dd*
UNK = Unknown

Date of onset of symptoms. Not applicable in asymptomatic cases. If not applicable, please use 'UNK'.

Date of first dose smallpox/mpox vaccination

Field: VaccPoxDate1

Coding: *yyyy-mm-dd*
yyyy-Www
UNK= Unknown

Date of first smallpox/mpox vaccination dose related to current mpox event/outbreak.

Date of second dose smallpox/mpox vaccination

Field: VaccPoxDate2

Coding: *yyyy-mm-dd*
yyyy-Www
UNK= Unknown

Date of second smallpox/mpox vaccination dose related to current mpox event/outbreak.

Date of previous smallpox vaccination

Field: VaccPoxPrevDate

Coding: *yyyy-mm-dd*
yyyy-Www
yyyy-mm
yyyy
UNK= Unknown

Date of last vaccination for smallpox vaccine unrelated to the current mpox event/outbreak.

Epidemiological link

Field: EpiLinked

Coding: N = No
UNK = Unknown
Y = Yes

Epidemiological link to a confirmed or probable case.

Exposure setting

Field: ExposureSetting

Coding: HOUSE = Household
HOUSEABROAD: Household in a country other than the reporting country
WORK = Workplace
SCHOOL = School/nursery
HEALTH = Healthcare (including laboratory exposure and transfussion)
PARTY = Sexual contact at night club/private party/sauna or similar setting
BAR = Bar/restaurant or other small event where there was no sexual contact
LARGE = Large event with no sexual contact (e.g., festival or sports event)
LARGECONTACT = Large event with sexual contact (e.g. PRIDE, ship).
O = Other location (specify in ExposureSettingDetails)
PLANE: Airplane
UNK= Unknown

Location of exposure in the 21 days before symptom onset or date of diagnosis. Note this is a repeatable field.

Exposure setting details

Field: ExposureSettingDetails

Coding: TEXT

Details on place of exposure if ExposureSetting "O" or any organised event.

Gender (mandatory)

Field: Gender

Coding: F = Female
M = Male
O = Other
UNK = Unknown/Missing

Gender of the reported case.

Gender (Other)

Field: OtherGender

Coding: TEXT

Please indicate if the case is transgender, regardless of the coded value for *Gender*.

Genomic characterisation

Field: GenomicCharacterisation

Coding: N = No
UNK = Unknown
Y = Yes

Information if genomic characterisation has been carried out.

Health care worker

Field: HealthCareWorker

Coding: N = No
UNK = Unknown
Y = Yes

Information on whether the case is a healthcare worker.

HIV status

Field: HIVStatus

Coding: POS = Positive
NEG = Negative
UNK = Unknown

HIV status of the case.

Hospitalisation

Field: Hospitalisation

Coding: N = No
UNK = Unknown
YISOL = yes for isolation purposes
YTREAT = yes due to clinical need
YUNK= yes for unknown reason

Information if case was admitted to hospital.

Immunocompromised

Field: ImmunoCompromised

Coding: N = No
UNK = Unknown
YD = Yes, due to disease
YM = Yes, due to medication
YRU = Yes, reason unknown

Information if a case is immunocompromised (if there is immunocompromise related to HIV infection, it should be coded as yes due to disease).

Intensive care

Field: IntensiveCare

Coding: N = No
UNK = Unknown
Y = Yes

Information if case was admitted to an intensive care unit or high dependency unit (unit with capabilities for more intensive observation, treatment and nursing care than can be provided on a regular ward).

Laboratory method

Field: LabMethod

Coding: MPXPCR = Positive monkeypoxvirus-specific PCR
ORTHOPOXPCR = Positive orthopoxvirus PCR
SEQ = Sequencing
ISOV = Isolation of virus
EM = Virus detection by electron microscopy
SERO = Serology
UNK = Unknown

Laboratory method used to diagnose the case. Note this is a repeatable field.

Number of sexual partners

Field: NumberSexPartners

Coding: 0 = No active sexual partner
1 = One sexual partner
2 = Two to four sexual partners
5 = Five to nine sexual partners
10 = Ten or more sexual partners
UNK = Unknown

Information on the number of sexual partners (sequential or concurrent) of a case in the past 3 months from the diagnosis of mpox.

Outcome of the case (mandatory)

Field: Outcome

Coding: A = Alive
D = Died
UNK = Unknown

Information on whether the case is alive (still ill, recovered, cured) or deceased. The death should be due to the reported disease.

Place of notification

Field: PlaceOfNotification

Coding: NUTS_GAUL
UNK = Unknown

The place of notification should be provided by regions (up to NUTS3 level). Select the most detailed NUTS level possible. If the place of notification is not an EU/EEA country, then use GAUL nomenclature.

Pregnant

Field: Pregnant

Coding: PREG = Pregnancy, trimester is unknown
PREG1 = Pregnancy, 1st trim, the 1st trim is from week 1 to the end of week 12
PREG2 = Pregnancy, 2nd trim, the 2nd trim is from week 13 to the end of week 26
PREG3 = Pregnancy, 3rd trim, the 3rd trim is from week 27 to the end of the pregnancy
PREGPOST = Post-partum (<6 weeks)
N = No
UNK = Unknown
NA = Not applicable

Information if case is pregnant.

Pre-exposure prophylaxis for HIV

Field: PrEPHIV

Coding: N = No

UNK = Unknown
Y = Yes

Information if the case used pre-exposure prophylaxis for HIV any time in the past year from diagnosis of mpox.

Previous mpox infection

Field: PreviousMPX

Coding: N = No
UNK = Unknown
Y = Yes

Information if case has been previously diagnosed with mpox.

Previous mpox clade infection

Field: PreviousMPXclade

Coding: Ia = Clade Ia,
Ib= Clade Ib
I= Clade I (without subclade identification)
IIa= Clade IIa
IIb= Clade IIb
II= Clade II (without subclade identification)
UNK= Unknown

Clade of the genomically characterised monkeypox virus in a previous infection. Please reporting using the option that provides the most specific data for the case, ie, sub-clade if information is available or clade, if information on sub-clade is not available).

Previous mpox infection date

Field: PreviousMPXDate

Coding: *yyyy-mm-dd*
yyyy-Www
yyyy-mm
yyyy
UNK= Unknown

Date of previous mpox diagnosis. If date of diagnosis is unknown, date of symptom onset or date of notification of previous mpox infection can be used.

Previous smallpox vaccination

Field: VaccPoxPrev

Coding: N = No
UNK = Unknown
Y = Yes

Information if case has been previously vaccinated with a smallpox vaccine unrelated to the current mpox event/outbreak.

Purpose for first dose smallpox/mpox vaccination

Field: VaccPoxPurpose1

Coding: PREEXP = Vaccinated for pre-exposure prophylaxis for current event
POSTEXP = Vaccinated for post-exposure prophylaxis for current event
O = Other
UNK = Unknown

Information on the strategy context for vaccination with first smallpox/mpox vaccination dose related to current mpox event/outbreak.

Purpose for second dose smallpox/mpox vaccination

Field: VaccPoxPurpose 2

Coding: PREEXP = Vaccinated for pre-exposure prophylaxis for current event
POSTEXP = Vaccinated for post-exposure prophylaxis for current event
O = Other
UNK = Unknown

Information on the strategy context for vaccination with second smallpox/mpox vaccination dose related to current mpox event/outbreak.

Sexual behaviour of the case

Field: SexualBehaviour

Coding: HETERO = Heterosexual, sex with members of the opposite sex
MSM = Men who have sex with men
WSW = Women who have sex with women
BISEXUAL = Bisexual
NA = No applicable
O = Other
UNK = Unknown or undetermined

This variable captures sexual behaviour over the past 30 days..

SexWorker

Field: SexWorker

Coding: N = No
UNK = Unknown
Y = Yes

Information if case is a sex worker (defined as exchanged sex for money or goods) in the past 3 months from diagnosis of mpox.

Specimen type

Field: SpecimenMPX

Coding: CRUST = lesion crust
CSF = Cerebrospinal fluid
SWAB = lesion swab
OROPH = Oropharyngeal swab
SER = Serum
SEM = Semen
URINE = Urine
RECTAL = Rectal swab
GENITAL = Genital swab
O = Other specimen (specify in SpecimenOther)
UNK = Unknown

Type of specimen used for diagnosis. Note this is a repeatable field.

Specimen other specified

Field: SpecimenMPXOther

Coding: TEXT

Specimen not captured in the coded values for Specimen variable as indicated by O response for Specimen variable.

Transmission mode (mandatory)

Field: TransmissionMPX

Coding: ANIMAL = Animal to human transmission
HAI = Healthcare-associated
LAB = Transmission in a laboratory due to occupational exposure
MTCT = Transmission from mother to child during pregnancy or at birth
O = Other transmission (specify in TransmissionMPXOther)
FOMITE = Contact with contaminated material (e.g bedding, clothing, objects)
PTP = Person-to-person (**excluding:** mother-to-child during pregnancy or at birth, healthcare-associated or sexual transmission)
SEX = Sexual transmission
TRANSFU = Transfusion recipient
UNK = Unknown

Most likely mode of transmission. Note this is a repeatable field.

Transmission mode other specified

Field: TransmissionMPXOther

Coding: TEXT

Transmission mode not captured in the coded values for TransmissionMPX variable as indicated by O (Other) response for TransmissionMPX variable.

Travel

Field: Travel

Coding: N = No travel
UNK = Unknown
Y = Yes

Case travelled outside country of residence in the three weeks before onset of symptoms or date of diagnosis.

Travel places

Field: TravelPlaces

Coding: NUTS_GAUL
UNK = Unknown

Regions (up to NUTS3 level) visited in the three weeks before onset of symptoms. Select the most detailed NUTS level possible. If the region visited is not in an EU/EEA country, then use GAUL nomenclature. Note this is a repeatable field.

Vaccination status relative to current mpox event/outbreak

Field: VaccPoxCurrentStatus

Coding: VaccStatusMpx:
NOTVACC = 0 dose unvaccinated
1DOSE = 1 dose
2DOSE = 2 doses
3DOSE = 3 doses
DOSEUNK = Vaccinated with unknown number of doses
UNK = Unknown vaccination status

Information on whether the case was recently vaccinated against smallpox/mpox and number of vaccine doses received, in relation/response to the current mpox event/outbreak.

Annex 2 – Case definitions

Please refer to *Surveillance, case investigation and contact tracing for Monkeypox: Interim guidance* for more details on the current WHO mpox case definition.

Note that suspected cases should not be reported in TESSy.

The previously used ECDC interim case definitions for mpox are available in the Monkeypox Reporting Protocol versions 1.0 to 3.0.

Patients who fulfil the criteria for suspected or probable cases should be tested with a monkeypox virus specific PCR assay or an orthopoxvirus specific PCR assay which is then confirmed through sequencing. If negative, these records should be removed from TESSy.

WHO outbreak case definition for mpox

As of March 2024

Suspected case:

i) A person who is a contact of a probable or confirmed mpox case in the 21 days before the onset of signs or symptoms, and who presents with any of the following: acute onset of fever (>38.5°C), headache, myalgia (muscle pain/body aches), back pain, profound weakness, or fatigue.

OR

ii) A person presenting with an unexplained acute skin rash, mucosal lesions or lymphadenopathy (swollen lymph nodes). The skin rash may include single or multiple lesions in the ano-genital region or elsewhere on the body. Mucosal lesions may include single or multiple oral, conjunctival, urethral, penile, vaginal, or ano-rectal lesions. Ano-rectal lesions can also manifest as ano-rectal inflammation (proctitis), pain and/or bleeding.

AND

for which the following common causes of acute rash or skin lesions do not fully explain the clinical picture: varicella zoster, herpes zoster, measles, herpes simplex, bacterial skin infections, disseminated gonococcus infection, primary or secondary syphilis, chancroid, lymphogranuloma venereum, granuloma inguinale, molluscum contagiosum, allergic reaction (e.g., to plants); and any other locally relevant common causes of papular or vesicular rash.

Probable case:

A person presenting with an unexplained acute skin rash, mucosal lesions or lymphadenopathy (swollen lymph nodes). The skin rash may include single or multiple lesions in the ano-genital region or elsewhere on the body. Mucosal lesions may include single or multiple oral, conjunctival, urethral, penile, vaginal, or ano-rectal lesions. Ano-rectal lesions can also manifest as ano-rectal inflammation (proctitis), pain and/or bleeding.

AND

One or more of the following:

- has an epidemiological link[a] to a probable or confirmed case of mpox in the 21 days before symptom onset
- has had multiple and/or casual sexual partners in the 21 days before symptom onset
- has a positive test result for orthopoxviral infection (e.g., OPXV-specific PCR without MPXV-specific PCR or sequencing) [b]

Confirmed case:

A person with laboratory confirmed MPXV infection by detection of unique sequences of viral DNA by real-time polymerase chain reaction (PCR)[c] and/or sequencing.

Discarded case:

A suspected or probable case for which laboratory testing of lesion fluid, skin specimens or crusts by PCR and/or sequencing is negative for MPXV[c] . Conversely, a retrospectively detected probable case for

which lesion testing can no longer be adequately performed (i.e., after the crusts fall off) and no other specimen is found PCR-positive, would remain classified as a probable case. A suspected or probable case should not be discarded based on a negative result from an oropharyngeal, anal or rectal swab or from a blood test alone.

[a] The person has been exposed to a probable or confirmed monkeypox case. A contact is defined as a person who has been exposed to a person with suspected (clinically compatible), probable or confirmed mpox during the infectious period and who has one or more of the following exposures: • direct skin-to-skin,skin-to-mucosal or mouth-to-mucosal physical contact (such as touching, hugging, kissing, intimate oral or other sexual contact) • contact with contaminated materials such as clothing or bedding, including material dislodged from bedding or surfaces during handling of laundry or cleaning of contaminated rooms • prolonged face-to-face respiratory exposure in close proximity (inhalation of respiratory droplets and possibly short-range aerosols) • respiratory (i.e., possible inhalation) or mucosal (e.g., eyes, nose, mouth) exposure to lesion material (e.g., scabs/crusts) from a person with mpox • The above also apply for health workers potentially exposed in the absence of proper use of appropriate personal protective equipment (PPE).

[b] PCR on a blood specimen may be unreliable and should also not be used alone as a first line diagnostic test. If blood PCR is negative and was the only test done, this is not sufficient to discard a case that otherwise meets the definition of a suspected or probable case. This applies regardless of whether the blood PCR was for OPXV or MPXV-specific.

[c] Confirmation of MPXV infection should consider clinical and epidemiological information. Positive detection using an OPXV PCR assay followed by confirmation of MPXV via PCR and/or sequencing or detection using MPXV PCR assay indicates confirmation of MPXV infection. Positive detection using OPXV PCR assay alone can be considered strongly indicative of MPXV in countries where other OPXVs (such as buffalopox or other OPXV) have not been found. Currently, the WHO mpox case definition considers an OPXV-positive case as a probable case. Countries with no significant co-circulation of OPXVs other than MPXV may adapt testing strategies according to available resources and, in conjunction with the clinical and epidemiological information available, consider OPXV PCR positive cases as confirmed mpox. Vigilance for the remote possibility of a smallpox emergence or other potentially pathogenic OPXV must always be maintained.