TESSy - The European Surveillance System

Monkeypox (MPX)

Reporting Protocol

Version 3.0, 5 August 2022

Contents

Summary of changes

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 monkeypox 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.

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 including retrospective updates to cases already in TESSy should be reported at least twice weekly, Tuesdays by 10:00AM and Fridays by 10:00AM.

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

First cases should be reported to WHO/ECDC through IHR/EWRS mechanisms. Any additional cases should be reported to TESSy only. 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.

Case definition

Probable and confirmed cases should be reported according to the current ECDC or WHO case definitions for monkeypox **(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 monkeypox epidemiology in the 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.

Data collection schedule

Case data including retrospective updates to cases already in TESSy should be reported at least twice weekly, Tuesdays by 10:00AM and Fridays by 10:00AM.

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 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**). Previously reported data can be found through the review tab (see below).

The *Tessy User Guide* provides an overview of how you submit files to TESSy and in-depth descriptions of all the upload methods.

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 Monkeypox (MPX) metadata

RecordType: MPOX: RecordType Version 3: Update 2022-08-05

Removed variable SmallpoxVaccine, in order to specifically collect information on smallpox vaccination unrelated to the current monkeypox event in new variable VaccPoxPrev.

Removed variable DateLastVaccDose, in order to specifically collect information on date of previous smallpox vaccination unrelated to the current monkeypox event in new variable VaccPoxPrevDate.

Added variable VaccPoxPrev to collect information on previous smallpox vaccination, where the reason for vaccination was unrelated to the current monkeypox event/outbreak.

Added variable VaccPoxPrevDate to collect information on date of previous smallpox vaccination, where the reason for vaccination was unrelated to the current monkeypox event/outbreak.

Added variable VaccPoxCurrentStatus to collect information on whether a case was recently vaccinated against smallpox/monkeypox and number of vaccine doses received, in relation/response to the current monkeypox event/outbreak.

Added variable VaccPoxBrand1 to collect information on the brand of the first dose of smallpox/monkeypox vaccine related to the current monkeypox event/outbreak.

Added variable VaccPoxBrand2 to collect information on the brand of the second dose of smallpox/monkeypox vaccine related to the current monkeypox event/outbreak.

Added variable VaccPoxDate1 to collect information on the date of the first dose of smallpox/monkeypox vaccine related to the current monkeypox event/outbreak.

Added variable VaccPoxDate2 to collect information on the date of the second dose of smallpox/monkeypox vaccine related to the current monkeypox event/outbreak.

Added variable VaccPoxPurpose1 to collect information on the strategy context of the first dose of smallpox/monkeypox vaccine related to the current monkeypox event/outbreak.

Added variable VaccPoxPurpose2 to collect information on the strategy context of the second dose of smallpox/monkeypox vaccine related to the current monkeypox event/outbreak.

Added variable PrEPHIV to collect information on the use by a monkeypox case of pre-exposure prophylaxis for HIV any time in the past year from diagnosis of monkeypox.

Added variable SexWorker to collect information on whether a case is a sex worker (defined as exchanged sex for money or goods) in the past 3 months from diagnosis of monkeypox.

Added variable NumberSexPartners to collect information on the number of sexual partners (sequential or concurrent) of a case in the past 3 months from the diagnosis of monkeypox.

Added variable OtherGender to collect information on gender otherwise not captured in the prespecified coded values for Gender variable.

Added variable Complications to collect information on complications related to the current monkeypox event/outbreak.

Added variable ComplicationsOther to collect information on complications otherwise not captured in the prespecified coded values for Complications variable.

Updated coded value list of ClinicalSymptoms variable with category PROCT to collect information on possible clinical presentations with proctitis (anorectal pain and/or bleeding), category DIARR to collect information on diarrhoea, category LYMPHLOCUNK to collect information on lymphadenopathy where the location is not known, and category GENITEDEM to collect information on genital soft-tissue oedema/swelling.

Updated coded value list of SpecimenMPX variable with category CSF to collect information on specimen collection from cerebrospinal fluid.

Added validation rules.

Annex 1 – Monkeypox metadata

Revisions of MPX metadata set

The MPX metadata have been developed in collaboration with WHO. The most recent metadata set is available from the TESSy website under technical guidelines and tools tab (as shown below).

Current record type versions

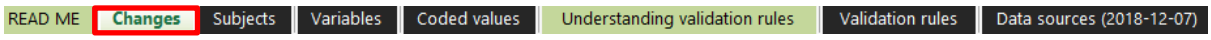
Table 1 shows the record type versions to be used when reporting monkeypox (Record type: MPX) data to TESSy.

Table 1: MPX record type versions

Record	Type of data	Record type version
MPX	Case-based	3

MPX metadata change history

When you open a metadata set, the Excel file has a tab 'Changes', recording historical changes.



MPX metadata recordtype version 3

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: 3

The version of the record type defines the current structure of the data reported. The current version of the MPX record type is 3.

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/monkeypox 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/monkeypox vaccine related to the current monkeypox event/outbreak.

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

Case definition used

Field: CaseDefinition

Coding: ECDC = ECDC case definition
NAT = National case definition
UNK = Unknown
WHO = WHO case definition

Case definition used for classification of the case (see Annex 2 for the ECDC and WHO case definitions).

CD4 cell count

Field: CD4Cells

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

CD4 count at time of diagnosis of monkeypox.

Clade of monkeypox virus

Field: Clade

Coding: WA = West African clade
CB = Congo Basin clade
UNK = Unknown

Clade of the genomically characterised monkeypox virus.

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
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 monkeypox 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/monkeypox vaccination

Field: VaccMpxDate1

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

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

Date of second dose smallpox/monkeypox vaccination

Field: VaccMpxDate2

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

Date of second smallpox/monkeypox vaccination dose related to current monkeypox 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 monkeypox 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
WORK = Workplace
SCHOOL = School/nursery
HEALTH = Healthcare (including laboratory exposure)
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
O = Other location (specify in ExposureSettingDetails)
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

Gender not captured in the coded values for Gender variable as indicated by O (Other) response (e.g transgender man, or transgender woman).

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 monkeypox.

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 monkeypox.

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 monkeypox event/outbreak.

Purpose for first dose smallpox/monkeypox 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/monkeypox vaccination dose related to current monkeypox event/outbreak.

Purpose for second dose smallpox/monkeypox 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/monkeypox vaccination dose related to current monkeypox event/outbreak.

Sexual orientation of the case

Field: SexualOrientation

Coding: HETERO = Heterosexual contact
MSM = MSM/homosexual or bisexual male
LESBIAN = Women who have sex with women
BISEXUAL = Bisexual
O = Other
UNK = Unknown or undetermined

Information on sexual orientation of the case.

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 monkeypox.

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, 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 monkeypox 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/monkeypox and number of vaccine doses received, in relation/response to the current monkeypox event/outbreak.

Annex 2 – Case definitions

ECDC interim case definition for monkeypox

The case definition currently does not define possible cases.

The following **interim case definition** is proposed:

Confirmed case

A person with a laboratory-confirmed monkeypox infection (1) monkeypox virus specific PCR assay positive result or (2) orthopoxvirus specific PCR assay positive result which is then confirmed by nucleotide sequence determination of the detected virus as MPXV) with symptom onset since 1st March 2022

Probable case

(1) A person with an unexplained rash* on any part of their body

AND one or more other symptom(s) of monkeypox infection** with symptom onset since 1 March 2022

AND one of the following:

- has a positive laboratory test result on orthopoxvirus infection (e.g. orthopoxvirus specific positive PCR without sequencing, electron microscopy, serology);
- has an epidemiological link to a confirmed or probable case of monkeypox in the 21 days before symptom onset;
- reports travel to MPX endemic countries in the 21 days before symptom onset;
- is a person (of any sexual orientation) who had multiple or anonymous sexual partners in the 21 days before symptom onset;
- is a man who has sex with men.

OR

(2) A person with an unexplained generalised or localised maculopapular or vesiculopustular rash with centrifugal spread, with lesions showing umbilication or scabbing, lymphadenopathy and one or more other MPX-compatible symptoms**.

* Since EU/EEA countries are just starting to identify cases and if testing capacity is sufficient, the above more sensitive case definition can be used. In countries with limited testing capacity for orthopoxviruses, the following description can be added to characterise the rash: 'unexplained localised or generalised maculopapular or vesiculopustular rash potentially with umbilication or scabbing'.

**Fever (usually high >38.5°C), headache, back ache, fatigue, lymphadenopathy (localised or generalised).

Patients who fulfil the criteria for 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 patients should be excluded.

WHO suggested outbreak case definition for monkeypox

As of 24 June 2022

Suspected case:

A person of any age presenting since 1 January 2022 with an unexplained acute rash or one or more acute skin lesions

AND:

One or more of the following signs or symptoms:

- Headache
- Acute onset of fever (>38.5oC),
- Lymphadenopathy (swollen lymph nodes)
- Myalgia (muscle pain/body aches)
- Back pain

- Asthenia (profound weakness)

AND

For which the following common causes of acute rash do not explain the clinical picture: varicella zoster, herpes zoster, measles, Zika, dengue, chikungunya, 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.

N.B. It is not necessary to obtain negative laboratory results for listed common causes of rash illness in order to classify a case as suspected.

Probable case:

A person meeting the case definition for a suspected case

AND

One or more of the following:

- has an epidemiological link [prolonged[1] face-to-face exposure in close proximity, including health workers without appropriate PPE (gloves, gown, eye protection and respirator); direct physical contact with skin or skin lesions, including sexual contact; or contact with contaminated materials such as clothing, bedding or utensils] to a probable or confirmed case of monkeypox in the 21 days before symptom onset
- has had multiple or anonymous sexual partners in the 21 days before symptom onset
- has detectable levels of anti-orthopoxvirus (OPXV) IgM antibody[2] (during the period of 4 to 56 days after rash onset); or a four-fold rise in IgG antibody titre based on acute (up to day 5-7) and convalescent (day 21 onwards) samples; in the absence of a recent smallpox/monkeypox vaccination or other known exposure to OPXV
- has a positive test result for orthopoxviral infection (e.g. OPXV-specific PCR without MPXV-specific PCR or sequencing)[3]

Confirmed case:

Laboratory confirmed monkeypox virus by detection of unique sequences of viral DNA by real-time polymerase chain reaction (PCR)[3] 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[3].

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.

1. Evidence is currently lacking as to the duration of exposure necessary for infection by the respiratory route, including how it relates to the severity of the index case's disease. Characterization of this parameter is one of the goals of the case investigation form described below
2. Serology can be used for retrospective case classification for a probable case in specific circumstances such as when diagnostic testing through PCR of skin lesion specimens has not been possible, or in the context of research with standardized data collection. The primary diagnostic test for monkeypox diagnosis is PCR of skin lesion material or other specimen such as an oral or nasopharyngeal swab as appropriate. Serology should not be used as a first line diagnostic test.
3. 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 for probable case. This applies regardless of whether the blood PCR was for OPXV or MPXV specific.