



TESSy - The European Surveillance System

Zika virus disease Reporting Protocol 2019

**in EU/EEA Member States,
and Outermost Regions (OMR)**

Key changes from version 1.4

- Updated data collection schedule for 2019.

Key changes from version 1.3

- Updated data collection schedule for 2018.

Key changes from version 1.2

- Updated data collection schedule for 2017.

Key changes from version 1.1

- Reduced reporting frequency to monthly and added table with dates for reporting;
- Clarified deadline for annual data collection;
- Updated frequency for publication of atlas;
- Addition of variable pregnancy outcome.

Key changes from version 1.0

- Clarified that the first locally-acquired cases in continental Europe should be reported to the Early Warning and Response System (EWRS) and TESSy within 24 hours;
- Clarification on case-based reporting locally acquired cases;
- Updated timing for publication of atlas.

Key changes from draft protocol

- Clarified that reporting of case-based data is preferred, but aggregated reporting possible following comments from countries which preferred case-based data to improve reporting quality;
- Change of terminology from imported to travel-associated and autochthonous to locally-acquired to follow ECDC surveillance atlas terminology;
- Change in name of record type for aggregate reporting of locally-acquired cases to “**ZIKVLOCAGGR**”;
- Changes in format and variables of aggregated reporting to be more consistent with ECDC plan to drop horizontal aggregate record types, to allow for better interpretation of data and to allow for smoother integration in ECDC surveillance atlas;
- Clarified that reporting of geographical variables should be at NUTS 3 level;
- Added reporting deadlines.

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Aim

To support preparedness against and prevention and control of Zika virus infections in Europe through the provision of relevant and timely epidemiological data.

Objectives¹

- Early detection of locally-acquired Zika virus infections in order to trigger appropriate control measures;
- Timely reporting of travel-associated Zika virus infections in Europe, in particular those in receptive areas² in order to trigger appropriate control measures and to inform travel recommendations;
- Support the assessment of the risk of local transmission in the EU through timely publication of maps showing areas affected by Zika virus infection in the EU/EEA;
- Monitor outcome of pregnancies with Zika virus infection.

Finding further information

The Zika Surveillance Protocol is supplemented by the [Technical Annex](#), which contains updated generic information for TESSy data collection.

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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)

¹ An additional objective to detect adverse outcomes of pregnancy related to Zika virus infections will be addressed through a separate system.

² Areas where *Aedes albopictus* or *A. aegypti* are established.

Case definition

Table 1: Case definition for surveillance of Zika virus infection

Definition	
Clinical criteria	A person presenting with a rash
Laboratory criteria	<p><u>Laboratory criteria for a probable case</u> Detection of Zika specific IgM antibodies in a serum sample.</p> <p><u>Laboratory criteria for a confirmed case</u> At least one of the following:</p> <ul style="list-style-type: none"> - Detection of Zika virus nucleic acid in a clinical specimen; - Detection of Zika virus antigen in a clinical specimen; - Isolation of Zika virus from a clinical specimen; - Detection of Zika virus specific IgM antibodies in serum sample(s) <p>AND confirmation by neutralization test;</p> <ul style="list-style-type: none"> - Seroconversion or four-fold increase in the titre of Zika specific antibodies in paired serum samples.
Epidemiological criteria	<p>History of travel to, or residence in an area with documented on-going transmission of Zika virus, within the two-week period prior to the onset of symptoms</p> <p>OR</p> <p>Sexual contact with a person recently exposed to or confirmed with Zika virus infection</p>
Classification	
Probable case	A person meeting the clinical and the epidemiological criteria, and the laboratory criteria for a probable case.
Confirmed case	A person meeting the laboratory criteria for a confirmed case.

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

Reporting of Zika virus infections

Reporting intervals and data format

Member States should report through the EWRS, within 24 hours of confirmation:

- The first locally-acquired case in a receptive area³ in the continental part⁴ of any European Member State;
- Significant events in both receptive and non-receptive areas (e.g. case without epi link to travel-associated case in a non-receptive area).

In addition, all confirmed Zika infection cases in the European continent and in outermost regions (OMR)⁵ should be reported through TESSy on a monthly basis. In case locally-acquired vector-borne cases in each NUTS 3 region in the continental part of any European Member State are detected:

- The first ten cases should be reported in TESSy within 24 hours of confirmation.
- Additional cases should be reported on a weekly basis.

The preferred method for reporting is case-based data (record type: **ZIKV**); it is also possible to report aggregated data (record types: **ZIKVIMPAGGR** and **ZIKVLOCAGGR**). If aggregated reporting is preferred, the following should be reported on a monthly basis:

- Confirmed travel-associated cases (record type: **ZIKVIMPAGGR**). Data to be reported (at national level) include number of travel-associated cases according to residence in receptive areas and by pregnancy status.
- Confirmed locally-acquired cases (record type: **ZIKVLOCAGGR**). Data to be reported include number of locally-acquired cases by NUTS 3 region, mode of transmission and pregnancy status.

Further details are available in [Annex 1: Zika metadata](#).

“Zero cases” should be reported at least once yearly together with the annual EVD data collection until end of May. For countries reporting aggregated data, case-based data for all confirmed cases should be reported through TESSy on an annual basis if available (record type: **ZIKV**). Countries should report all cases diagnosed since 2015 where possible.

An overview of reporting to TESSy is provided in [Annex 2: Overview of reporting to TESSy](#). Note that case-based Zika virus infection data (record type **ZIKV**) may also be reported by clicking on “Manually create a record” in the upload tab in TESSy. This allows reporting of individual records through a web-based form in TESSy. Aggregated data on locally-acquired and travel-associated cases can only be reported by uploading CSV/XML files (record types: **ZIKVLOCAGGR**, **ZIKVIMPAGGR**).

Data sources

A data source profile contains information about the surveillance system in the country from which data are reported. These include the surveillance subject(s) reported, what types of data are available, the case definitions used, etc. The information contained in the profile is linked to each

³ Areas where *Aedes albopictus* or *Ae. aegypti* are established.

⁴ “Continental part” in this document refers to areas in the European continent, including islands in the continent (e.g. Corsica, Cyprus, Ireland, Malta, Sicily, the United Kingdom)

⁵ OMR consist of Guadeloupe, French Guiana, Martinique, Mayotte, Réunion and Saint Martin (France), the Canary Islands (Spain) and the Azores and Madeira (Portugal).

data record that specifies a particular data source. Typically, these profiles are maintained in the TESSy Web application (Data sources tab) by the National Surveillance Focal Points.

Different record types should be reported from different data sources to avoid overwriting of data from overlapping reporting periods. Since a country may need to report three different record types (aggregated travel-associated cases, aggregated locally-acquired cases and case-based data), three separate data sources may need to be set up in TESSy.

Case-based reporting

Data should ideally be reported using the case-based record type **"ZIKV"** on a monthly basis (except for locally-acquired vector-borne cases as explained above). Cases will be classified as locally-acquired or travel-associated based on data reported in the fields "Imported", "PlaceOfInfectionZIKV", "PlaceOfNotificationZIKV" and "PlaceOfResidenceZIKV". Data for geographical variables should be reported at NUTS 3 level.

Cases acquired in the European continent (including those transmitted sexually, even if the partner had previously travelled to an affected area) should be reported with the variable "Imported" = "N".

Aggregated reporting of travel-associated cases in the European continent

For the European continent, travel-associated cases are considered as being cases where infection occurred following exposure outside the continental part of the reporting country during a time compatible with the incubation period of the infection. For example:

- A case likely infected in Brazil and diagnosed in Portugal would be considered to be travel-associated.
- A case likely infected in Martinique and diagnosed in France would be considered to be travel-associated.
- A case likely infected in Malta and diagnosed in Finland would be considered to be travel-associated.

All confirmed travel-associated cases in the continental part of the reporting country should be reported on a monthly basis using the record type **"ZIKVIMPAGGR"**. A breakdown of cases by residence in receptive areas and pregnancy status should be reported.

Aggregated reporting of locally-acquired cases (EU/EEA including OMR)

Confirmed locally-acquired cases (both diagnosed in the European continent and in OMR) should be reported on a monthly basis or more frequently as described above in case of local vector-borne transmission. These cases should be reported using the record type **"ZIKVLOCAGGR"**. The variable "Place of Infection" should be reported at the NUTS 3 level in order to allow for appropriate classification of cases (e.g. OMR vs continental Europe) and to allow adequate assessment of risk and spread. A breakdown of cases by mode of transmission and whether they were pregnant should also be reported. Reporting of these variables is important in order to map "affected areas" in the ECDC online maps, cases in the surveillance atlas and to distinguish cases among pregnant women.

Indicators

The related variables are presented in [Annex 1 Zika metadata](#).

The following standard indicators will be produced for both the European continent and OMR where relevant:

- Number of reported confirmed cases (weekly);
- Number of travel-associated confirmed cases (weekly);
- Number of confirmed locally-acquired, vector-borne cases (weekly);
- Notification rate per 100 000 population (weekly);
- Number of infected pregnant women reported in the European continent (weekly);
- Affected areas at NUTS 3 level.

Reporting deadlines

Cases should be reported according to the schedule in **Table 2**.

Table 2: Deadlines for reporting of Zika virus infection data, 2019

Reminder for reporting	Deadline for reporting	Nominated atlas published	Public atlas published 12:00
Thursday 24/01/2019	Friday 25/01/2019	Monday 28/01/2019	Tuesday 29/01/2019
Wednesday 29/05/2019	Friday 31/05/2019	Tuesday 04/06/2019	Friday 07/06/2019
Thursday 26/09/2019	Friday 27/09/2019	Monday 30/09/2019	Friday 04/10/2019

In case of changes in the reporting schedule these will be communicated via email to the operational contact points (OCP) for Zika and updated on the TESSy website.

The deadline for the annual data collection covering 2018 Zika data is 31 May 2019.

Countries who have either not reported quarterly data or else would like to update aggregated data with case based data should do so by this deadline.

Validation

Table 2 also includes the schedule for publication of the Zika atlas for nominated TESSy users. Should there be any issues with the data, nominated users can contact ECDC (tessy@ecdc.europa.eu) using subject "validation of Zika data – [country]" and upload corrections by the following **Thursday**.

Nominated users will be approached for validation of reported locally-acquired cases and of imported cases infected in countries which did not previously report Zika virus transmission.

Analyses

A selection of results will be presented in the public surveillance atlas which will be refreshed according to the schedule in **Table 2**.

Annex 1: Zika metadata

Aggregated metadata

Two record types are available for reporting of Zika virus infection on a weekly basis:

- **ZIKVLOCAGGR.1** is used for reporting of locally-acquired cases of Zika virus infection (Table 3)
- **ZIKVIMPAGGR.1** is used for reporting of travel-associated cases of Zika virus infection (Table 4)

Table 3: Zika aggregated variables – locally-acquired cases

Field	Description
Subject	Subject of the data reported. Required field. The subject is ZIKV
RecordType	Structure and format of the data (case based reporting or aggregate reporting). Required field. The record type is ZIKVLOCAGGR.
DataSource	The data source (surveillance system) that the record originates from. Required field.
ReportingCountry	The country reporting the record. Required field.
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. The current record type version is ZIKVLOCAGGR.1.
DateUsedForStatistics	The reference date used for standard reports that is compared to the reporting period. The date used for statistics can be any date that the reporting country finds applicable, e.g. date of notification, date of diagnosis or any other date. Required field. Date format must be YYYY-Www.
PlaceOfInfection	The most probable place of infection at NUTS 3 level (5 characters in a code. For example: DE126). Required field.
Transmission	Suspected mode of transmission. Required field. Allowed values: MTCT = mother-to-child transmission SEX = sexual transmission MOSQ = transmission through mosquito bite O = other UNK = unknown
Pregnancy	Pregnancy at the time of infection. Possible values: Y(Yes); N(No); NA(Not Applicable); UNK(Unknown) Required field.
NumberOfCases	Total number of cases during the reported period for the specified record type. Required field.

Table 4: Zika aggregated variables – travel-associated cases

Field	Description
Subject	Subject of the data reported. Required field. The subject is ZIKV
RecordType	Structure and format of the data (case based reporting or aggregate reporting). Required field. The record type is ZIKVIMPAGGR.
DataSource	The data source (surveillance system) that the record originates from. Required field.
ReportingCountry	The country reporting the record. Required field.
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. The current record type version is ZIKVIMPAGGR.1.
DateUsedForStatistics	The reference date used for standard reports that is compared to the reporting period. The date used for statistics can be any date that the reporting country finds applicable, e.g. date of notification, date of diagnosis or any other date. Required field. Date format must be YYYY-Www.
Receptive	Cases resident in receptive areas. Possible values: Y(Yes); N(No); UNK(Unknown) Required field.
PregnancyImported	Pregnancy at the time of infection. Possible values: Y(Yes); N(No); NA(Not Applicable); UNK(Unknown) Required field.
NumberOfCases	Total number of travel-associated cases during the reported period for the specified record type. Required field.

Case-based metadata

The record type version for case-based Zika records is **ZIKV.2**.

Table 5: Zika case-based variables

Field	Description
RecordId	Unique identifier for each record within and across the national surveillance system – MS selected and generated. Required field.
Subject	Subject of the data reported. Required field. The subject is ZIKV.
RecordType	Structure and format of the data (case based reporting or aggregate reporting). Required field. The record type is ZIKV.
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. The current record type version for case-based Zika records is ZIKV.2.
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 more correctly, invalidated). If set to NEW/UPDATE or left empty, the record is entered into the database as a new record.
ReportingCountry	The country reporting the record. Required field.
DataSource	The data source (surveillance system) that the record originates from. Required field.
DateUsedForStatistics	The reference date used for standard reports that is compared to the reporting period. The date used for statistics can be any date that the reporting country finds applicable, e.g. date of notification, date of diagnosis or any other date but should be reported as the week number (format YYYY-Www). Required field.
Gender	Gender of the reported case. Required field.
Age	Age of patient in years as reported in the national system at the time of disease onset. Required field.
AgeMonth	Age of patient in months as reported in the national system for cases < 2 years of age at the time of disease onset.
DateOfOnset	Date of onset of disease. Please report 'NA' (not applicable) for asymptomatic cases. If the date of onset is not known please use 'UNK'. Required field.

Field	Description
Imported	Infection has occurred following exposure outside the continental part of the reporting country during a time compatible with the incubation period of the infection. Required field. Allowed values: Yes No UNK
PlaceOfInfection	The probable place of infection should be provided at the NUTS 3 level. If the probable case of infection is not an EU/EEA country, then use country level. Note this is a repeatable field. Required field.
PlaceONotification	Place of the first notification of the case to a regional authority at NUTS 3 level. Required field.
PlaceOfResidence	Place of residence at NUTS 3 level. Required field.
Pregnancy	Pregnancy at the time of infection. Allowed values: Yes No NA UNK
PregnancyOutcome	Outcome of pregnancy. Report as "UNK" if pregnancy still in progress and "NA" if not pregnant or male case. Pregnancy outcome can be updated at the end of the pregnancy. Repeatable field. Allowed values: LIVE = Healthy live birth STILL = Stillbirth MISC = Miscarriage TOP = Termination of pregnancy MICRO = Microcephaly CNS = Other central nervous system abnormalities O = Other outcome UNK = Unknown NA
Transmission	Suspected mode of transmission. Required field. Allowed values: MTCT = mother-to-child transmission SEX = sexual transmission MOSQ = transmission through mosquito bite O = other UNK = unknown

Annex 2: Overview of 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 is:

1. *Prepare (export and transform) your data.*
2. *Check that your data comply with the metadata.*
3. *Check that your data source profile is up-to-date.*
4. *Submit your file(s) to TESSy.*
5. *Finalise and approve your submission.*

Preparing data

After you have exported the Zika data from your national database, you need to ensure that they are in a format that TESSy can accept. This applies both to the type of file submitted to TESSy (only CSV and XML files can be submitted) and to the format of the data in certain fields.

 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 that are valid as input to TESSy for Zika.

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.

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.

 The [Technical Annex](#) 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 file(s), 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 is important for improving interpretation of data - each surveillance system has different features that need to be taken into account when comparing data at an international level.


If your data source information is out-of-date and you do not have access rights to update it, please request 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 [Technical Annex](#) provides an overview of how you submit files to TESSy, and the [TESSy user documentation](#) provides 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 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 your 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.