



TESSy - The European Surveillance System

Influenza Reporting Protocol 2018

Seasonal influenza

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Introduction

Since 2014, influenza surveillance in Europe has been jointly coordinated by the WHO Regional Office for Europe and ECDC.

Surveillance data from the 53 countries of the WHO European Region, which include the 28 countries of the European Union (EU) and the additional three countries of the European Economic Area (EEA), are submitted to a joint ECDC/WHO database hosted in the European Surveillance System (TESSy).

The purpose of this protocol is to provide instructions for the weekly reporting of influenza surveillance data during the influenza season (week 40 to week 20 of the following year) and the interseason. The protocol covers the contents of reporting these data to TESSy, including the case definitions, the population under surveillance and the timing of reporting.

ECDC's Reporting Protocols are part of the ECDC Surveillance Protocol, which is currently under preparation.

The Reporting Protocols are supplemented by the [TESSy Technical Annex](#), which contains updated generic information for each data collection.

How to use this document

This Reporting Protocol provides the following information:

- [Reporting to TESSy](#) – contains guidelines on how to prepare data for submission to TESSy, deadlines for data submission, subject-specific information, and links to further information.
- [Annex](#) – contains information on the influenza record types.

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 [Technical Annex](#), including:

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

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. [Familiarise yourself with the data collection deadlines.](#)
2. [Prepare \(export and transform\) your data.](#)
3. [Check that your data comply with the metadata.](#)
4. [Check that your data source profile is up-to-date.](#)
5. [Submit your file\(s\) to TESSy.](#)
6. [Finalise and approve your submission.](#)

Checking the data collection schedule

 An updated link to the current data collections schedule is provided in the [Technical Annex](#).

Preparing data

After data are exported from a national database, the data submitter needs to ensure that the data 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 a given subject.

As the requirements to the data that are shared among TESSy users change, the data changes needed to support the new requirements are identified and agreed upon between the National Surveillance Contact Points, the Network Coordination Groups and ECDC's and WHO's Disease Experts, and then implemented as changes to the TESSy metadata.

In order to ensure that your data can be saved correctly in TESSy, you therefore need to check that your 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 1 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.

The metadata file contains all the definitions and rules you need to comply with to format your data correctly for every subject (usually a disease). 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 [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 noncompliance 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 for the approval of other uploads.

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

TESSy HelpDesk

Email: TESSy@ecdc.europa.eu

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

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

Annex: Influenza metadata

This section describes the influenza metadata set.

Influenza record types

The influenza record types are:

- [INFLANTIVIR](#) - Influenza antiviral susceptibility strain-based, weekly
- [INFLCLINAGGR](#) - Influenza clinical data (ILI/ARI) aggregate, weekly
- [INFLSARI](#) - Severe acute respiratory infections (SARI) case-based, weekly
- [INFLSARIDENOM](#) - Severe acute respiratory infections (SARI) denominator, weekly
- [INFLSARIAGGR](#) - Severe acute respiratory infections (SARI) aggregate, weekly
- [INFLVIRWAGGR](#) - Virological data aggregate, weekly

Current record type versions

Table 1 shows the record type versions to be used when reporting influenza surveillance data to TESSy during the 2018-2019 season.

Table 1. Influenza record version types for 2018-2019 season data

| Record | Record type version |
|---------------|---------------------|
| INFLANTIVIR | INFLANTIVIR.6 |
| INFLCLINAGGR | INFLCLINAGGR.4 |
| INFLSARI | INFLSARI.4 |
| INFLSARIDENOM | INFLSARIDENOM.2 |
| INFLSARIAGGR | INFLSARIAGGR.1 |
| INFLVIRWAGGR | INFLVIRWAGGR.9 |

Influenza antiviral susceptibility strain-based (INFLANTIVIR)

The objectives of antiviral susceptibility surveillance of seasonal influenza viruses are:

- To provide timely data on the antiviral susceptibility of influenza viruses and related amino acid substitutions, also enabling comparisons with previous seasons;
- To monitor the distribution of influenza viruses associated with antiviral drug resistance;
- To identify treatment courses associated with antiviral drug resistance;
- To inform treatment guidelines.

Case definition

The influenza case definition is specified in the EU Commission Decision 2012/506/EU of 8 August 2012.

Specimens for antiviral susceptibility analysis are selected from the positive specimens detected from sentinel and non-sentinel sources. The specimens should be selected representing different subtypes

and according to age groups, geographic location and severity. Specimens both from untreated patients and from patients that receive antiviral treatment should be included.

Virus strain-based data should be reported weekly during the influenza season (week 40 to week 20 of the following year) and interseason (weeks 21-39). The metadata includes information on virus, demographics, source of specimen, hospitalisation, underlying conditions, vaccination status and treatment (see the TESSy metadata). The reporting of antiviral susceptibility data to TESSy includes also the strain-based reporting of the genetic clade and antigenic group to which the virus belongs.

The antiviral susceptibility data can originate from two different sources; from testing in the own laboratory/country or from testing of viruses that have been submitted to the WHO Collaborating Centre (WHOCC), London, UK. Countries are asked to upload both data as soon as results are available. For both datasets a different DataSource variable should be used when uploading the data. For country data the DataSource has been defined by the country itself. The DataSource for WHOCC data is pre-set by ECDC and has the structure NN-CNRL_Influenza, where NN is the 2-letter ISO code for the country.

Influenza clinical data (ILI/ARI) weekly aggregate (INFLCLINAGGR)

The objectives of weekly epidemiologic surveillance of seasonal influenza infections (influenza-like illnesses (ILI) and acute respiratory infections (ARI)) in primary care facilities during weeks 40 and 20 are:

- To estimate the intensity of ILI/ARI rates in the community;
- To compare this intensity to previous seasons and to other countries with similar denominators and case definitions;
- To identify most affected age groups.

Case definition

Any person with at least one of the following clinical forms:

Influenza-like illness (ILI)

Sudden onset of symptoms

AND

at least one of the following four systemic symptoms: fever or feverishness, malaise, headache, myalgia

AND

at least one of the following three respiratory symptoms: cough, sore throat, shortness of breath.

Acute respiratory infection (ARI)

Sudden onset of symptoms

AND

at least one of the following four respiratory symptoms: cough, sore throat, shortness of breath, coryza

AND a clinician's judgement that the illness is due to an infection.

ILI is clinically more specific for influenza-infection than ARI, which encompasses all infections of the upper respiratory tract. Some countries report both clinical data.

The covered population is variable, making comparisons between countries difficult or impossible: in some countries, sentinel general practitioners have a determined list of patients or an averaged number of weekly patients, and in these countries the denominators can be calculated for 100.000 inhabitants. Some countries calculate the number of cases by physician or by the number of consultation for ILI or ARI. In countries with discrepant definitions, only trends over time may be used.

The sentinel physicians report the weekly aggregated number of ILI and /or ARI numbers by four age groups (0-4, 5-14, 15-64, ≥ 65 years old, unknown and total) with a denominator for each age group.

In addition to clinical indicators, qualitative indicators are also reported:

- Intensity
- Geographic spread
- Trend
- Dominant type
- Impact

Intensity

The intensity indicator is a measure of influenza activity within individual Member States.

- Baseline or below epidemic threshold: ILI or ARI rates that are very low and at levels usually seen throughout the inter-epidemic period.
- Low: ILI or ARI rates that are relatively low compared to rates from historical data but higher than the baseline. Influenza virus detections have been reported.
- Medium: ILI or ARI rates that are similar to rates usually observed, based on historical data. Influenza virus detections have been reported.
- High intensity: ILI or ARI rates that are higher than rates usually observed, based on historical data. Influenza virus detections have been reported.
- Very high: ILI/ARI rates that are much higher than rates usually observed, based on historical data. Influenza virus detections have been reported.

Intensity level can be defined using two approaches:

a) Qualitative indicator based on a national expert evaluation of intensity. For Member States that report intensity as a qualitative indicator using an expert evaluation of intensity, they can do so by reviewing the weekly ILI or ARI rates and comparing them to rates in previous seasons. It is recommended to take influenza virus detections into account as well.

b) Semi-quantitative indicator using historical data (e.g. MEM, WHO or other methods). For Member States that report intensity as a semi-quantitative indicator, they can do so by a predefined method. It is recommended to take influenza virus detections into account as well as syndromic data.

Geographic spread

Geographic spread is a measure for the geographic distribution of reported detections of influenza viruses in specimens from sentinel or non-sentinel sources.

- No activity: No influenza viruses detected (other than detections from cases with recent known history of travel).
- Sporadic: Influenza viruses sporadically detected.
- Local(ised): Circulation of influenza viruses limited to one administrative unit in the MS (or reporting site).
- Regional: Circulation of influenza viruses appearing in multiple but less than 50% of the administrative units of the MS (or reporting sites)*.
- Widespread: Circulation of influenza viruses appearing in 50% or more of the administrative units of the Member State (or reporting sites).

*Regional activity is generally not used for Member States with a small population (<5 M) and covering a small geographic area.

Trend

Trend indicator is a measure of changes in ILI and/or ARI rates and lab-confirmed influenza cases in comparison to the previous week or weeks.

- Increasing: ILI and/or ARI consultation rates are substantially higher compared to the previous week(s) and influenza viruses must have been detected in specimens from sentinel and/or non-sentinel sources ^{a,b}.
- Stable: ILI and/or ARI consultation rates are similar compared to the previous week(s). Influenza viruses must have been detected in specimens from sentinel and/or non-sentinel sources ^b.
- Decreasing: ILI and/or ARI consultation rates are substantially lower compared to the previous week(s). Influenza viruses must have been detected in specimens from sentinel and/or non-sentinel sources ^{a,b}.

^a Multiple prior weeks should be used to assign increasing or decreasing trend when intensity is "No activity or below epidemic threshold" and in the absence of such evidence default to stable;

^b Sentinel data are preferred but if these are not available non-sentinel data may be used.

Dominant type

Dominant virus reports on the dominant influenza virus type and/or subtype/lineage in the MS.

- The dominant influenza virus type, subtype or lineage is reported when 10 or more influenza-positive results per week (or weeks) are available, with the type (A or B) defined as a minimum return. The threshold for dominance is set at 60% and the threshold for co-dominance is set between 40% and 60%. The report of subtypes or lineage also requires a minimum of 10 positive viruses sub-typed or ascribed to a lineage.
- We advise Member States to base their dominant type on sentinel data, where possible. These are generally from sentinel primary care facilities and best represent the circulation of influenza in the community. Where a Member State does not have data from sentinel sources, data from non-sentinel sources can be used to determine the dominant influenza type.

Impact

Impact is a measure of resultant hospitalization of the epidemic within individual Member States.

- Baseline: influenza related hospitalizations (SARI or laboratory confirmed hospitalizations, as counts, percentage positivity or rates) at levels usually seen throughout the inter-epidemic period.
- Low: influenza related hospitalizations (SARI or laboratory confirmed hospitalizations, as counts, percentage positivity or rates) that are relatively low compared to rates from historical data but higher than the baseline.
- Medium: influenza related hospitalizations (SARI or laboratory confirmed hospitalizations, as counts, percentage positivity or rates) that are similar to rates usually observed, based on historical data.
- High: influenza related hospitalizations (SARI or laboratory confirmed hospitalizations, as counts, percentage positivity or rates) that are higher than rates usually observed, based on historical data.
- Very high: influenza related hospitalizations (SARI or laboratory-confirmed hospitalizations, as counts, percentage positivity or rates) that are much higher than rates usually observed, based on historical data.

Severe acute respiratory infections (SARI) case-based (INFLSARI)

The objectives of hospital surveillance of seasonal influenza are:

- To provide timely data on the severity and burden of more severe influenza, also enabling comparisons with previous seasons;
- To monitor the distribution of influenza viruses associated with severe clinical presentations;
- To identify underlying conditions associated with severe influenza;
- To detect what factors and interventions seem to protect against severe disease.

Case-based data should be reported weekly during the influenza season (week 40 to week 20 of the following year). The metadata includes information on demographics, type of hospitalisation, underlying conditions, vaccination status and treatment (see TESSy metadata).

Case definition

Both laboratory-confirmed influenza requiring hospitalisation and severe acute respiratory infection (SARI) can be reported.

Laboratory-confirmed hospitalised influenza case

A severe influenza case is defined as a person with laboratory-confirmed influenza infection requiring overnight hospitalisation. According to the EU case definition, a laboratory-confirmed influenza infection is a person meeting the clinical definition of ILI or ARI and at least one of the following laboratory criteria for case confirmation:

- Isolation of influenza virus from a clinical specimen;
- Detection of influenza virus nucleic acid in a clinical specimen;
- Identification of influenza virus antigen by direct fluorescence antibody test in a clinical specimen;
- Influenza-specific antibody response.

An emergency room consultation without hospitalisation is not considered an admission.

Severe acute respiratory infection (SARI)

An acute respiratory illness with onset during the previous 7 days requiring overnight hospitalization that includes:

- History of fever or measured fever of $\geq 38^{\circ}\text{C}$, AND
- Cough, AND
- Shortness of breath or difficulty breathing.

This also includes any health care-acquired influenza infections.

Population under surveillance

Countries select sentinel acute care hospitals that are willing to participate and have the capacity to do so. In certain Member States, all hospitals may participate, if feasible. In these sentinel sites, all laboratory-confirmed hospitalised influenza or SARI cases are reported. The data are then transferred to the national public health authority in charge of influenza surveillance from where the nominated influenza contact point reports them to ECDC.

Sentinel sites have to be carefully selected, taking into account the balance between urban/rural areas, broad geographical coverage in a country, priorities in the national plan for hospital preparedness, etc. The denominator (hospital catchment population) should be defined (see [Virological weekly data \(INFLVIRWAGGR\)](#)).

Severe acute respiratory infections (SARI) weekly denominator (INFLSARIDENOM)

Several options may be used to determine the proportion of the population covered by the selected sentinel hospitals:

1. If the information on the hospitals' catchment population is available, it should be provided directly.
2. If the information on hospitals' catchment population is not available, it should be estimated. Two approaches to calculating denominators are provided below.
 - a) Estimate based on the number of patient discharges from the previous year: proportion of patients discharged from the selected hospitals divided by the total number of patients discharged from all hospitals in the Member State.
 - b) Estimate based on the number of beds: in an urban area, the catchment population can be estimated by taking into account the population of the city, the number of hospitals in the city and the number of beds in a hospital. Coefficients should be attributed to each hospital in the city depending on their activity estimated by the number of beds. For example, in a city with 3 hospitals, if hospital A has 50 beds, the coefficient to be applied will be 0.5, if hospital B has 125 beds, the coefficient will be 1.25 and if hospital C has 75 beds, the coefficient will be 0.75, so:

Catchment population = City population*coefficient (based on the number of beds)/Number of hospitals in the city.

In this approach, the estimation of population coverage of hospitals should first be done for each hospital and estimates from hospitals should be summed up, so that the estimates apply to the full surveillance system.

Severe acute respiratory infections (SARI) aggregate (INFLSARIAGGR)

For countries unable to report case-based data for severe influenza, this record type allows the reporting of aggregate data (total and by age group) for:

- Sentinel SARI hospitalisations (numerator);
- Sentinel SARI hospitalisation deaths (numerator);
- Sentinel hospitalisations admissions (denominator);
- Sentinel hospitalisations population (denominator);
- Sentinel SARI specimens tested (denominator);
- Sentinel SARI specimens tested positive for influenza viruses (numerator)

Virological weekly data (INFLVIRWAGGR)

The objectives for virological surveillance are:

- To collect and provide timely information on the distribution of types, subtypes, lineages and clades among circulating influenza viruses over the influenza season.
- Early warning upon emergence of new subtypes.
- To assess the start of the influenza season.
- To monitor the intensity and geographic progression of influenza throughout the season
- Inform public health preparedness in Europe, especially in countries not yet affected by widespread influenza epidemics, and trigger operational plans (e.g. use of antivirals and personal protective measures).
- To inform WHO vaccine composition meeting.

Aggregated virological data should be reported weekly during the influenza season (week 40 to week 20 of the following year). The metadata includes information on virus detection by (sub-)type from sentinel and non-sentinel sources, number virus (sub-)types isolated by sentinel and non-sentinel sources and characterisation of viruses by genetic and antigenic methods. In addition to influenza, respiratory syncytial virus (RSV) detections can also be reported from sentinel and non-sentinel sources (see TESSy metadata).

The characterisation data of viruses should preferably be reported via the strain-based reporting in the INFLANTIVIR record type (see [Influenza antiviral susceptibility strain-based \(INFLANTIVIR\)](#)). The aggregate reporting for characterisation data should only be used if the country does not have resources for strain-based reporting.

The virological data are entered in the week that the swab was taken (by week of sampling).

One virus detection corresponds to the detection of influenza in one patient, regardless of the number of specimens taken from that patient, or which technique(s) were used to detect the virus.

Case definition

The influenza case definition is specified in the EU Commission Decision 2012/506/EU of 8 August 2012.

Population under surveillance

Virological surveillance can be either sentinel or non-sentinel. Surveillance is considered sentinel when virological testing is performed in the same population in which clinical cases are recorded and reported taking a country-wide representative collection scheme into account. The virological surveillance of laboratory-confirmed influenza and RSV in Europe uses the same primary healthcare sentinel network model as the syndromic surveillance of ILI/ARI. The catchment population of the sentinel physicians forms the main population under surveillance. Patients with ILI/ARI (or a subset of these patients) seen by a sentinel physician are swabbed according to a defined sampling protocol. The virological surveillance system also captures non-sentinel detections of influenza virus, but the non-sentinel population under surveillance is not defined in all Member States. Virological data from non-sentinel sources can be from patients presenting at outpatient or inpatient health care facilities, outbreak investigations and as part of enhanced surveillance, for example as performed by countries during the early stages of the pandemic.