EpiPulse Cases

Invasive Bacterial Diseases (IBD) Reporting Protocol 2024

Invasive *H. influenzae* Disease, Invasive Meningococcal disease, *Neisseria Meningitidis* Isolate, Invasive Pneumococcal Disease

Surveillance data for 2023

Contents

Introduction

This reporting protocol describes the reporting of 2024 measles and rubella cases to **EpiPulse Cases**, which is replacing TESSy.

Please note:

- Since February 2023, the reporting of diphtheria is described in a separate reporting protocol: Diphtheria, Reporting Protocol 2023, Version 1.0.
- The Vaccine Preventable Diseases (VPD) reporting protocol 2024 describes reporting of: pertussis, mumps, poliomyelitis and tetanus.
- The Invasive Bacteria Diseases (IBD) reporting protocol 2024 describes reporting of: invasive H. influenzae disease, invasive meningococcal disease, Neisseria Meningitidis isolates, and invasive pneumococcal disease.

Reporting protocols are data collection guidelines for the data managers of reporting countries and the protocol design is intended to improve user-friendliness by:

- introducing a uniform structure to make it easier for data managers to find data collection information across different subjects;
- removing information which is not relevant for data managers.

Similarly, the surveillance protocol will contain some of the generic information previously contained in the reporting protocols.

Since the data managers in reporting countries often have multiple roles, subject-specific material is sometimes distributed together with a reporting protocol. To maintain the uniform structure, this type of material is now included in Annex 2.

How to use this document

This reporting protocol provides information for the data managers of reporting countries in three main sections:

- Reporting to EpiPulse Cases which contains guidelines on how to prepare data for submission to EpiPulse Cases, deadlines, subject-specific information (e.g. new changes to metadata), and links to further information.
- Annex 1 which contains:
  - the metadata set for the subject(s) covered by this reporting protocol.
  - a list of metadata changes for the subject(s) covered by this reporting protocol.
- Annex 2 which contains subject-specific material relevant for distribution with the reporting protocol.

Finding further information

Updated links to all the schedules, documentation and training materials mentioned in this reporting protocol are included in the Documentation and Help pages, including links to:

- EpiPulse Cases Metadata
- TESSy Metadata sets and change history
- EpiPulse Cases Machine to Machine Technical Documentation
- Tutorials for data transformation using respectively Excel and Access

Copyright

Reporting to EpiPulse Cases

In September 2024 EpiPulse Cases is expected to go live. We have built it as a replacement for TESSy, with the aim of improving the process of reporting, reviewing, and updating surveillance data.

Only Vaccine-Preventable Diseases will be reported to EpiPulse Cases in 2024, all other diseases will continue to be reported to TESSy for now.

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

The overall process is as follows:

- Familiarise yourself with the data collection deadlines.
- Prepare (export and transform) your data.
- Check that your data complies with the EpiPulse Cases metadata.
- Check that your data sources are up to date.
- Submit your file(s) to EpiPulse Cases.
- Finalise and approve your submission.

Checking the data collection schedule

A link to the current data collections schedule can be found in the Communication section of the 'Documentation and Help' pages.

Preparing data

After you have exported the data from your national database, you need to ensure that the data are in a format that EpiPulse Cases can accept. EpiPulse Cases accepts only CSV and XML files, optionally ZIP-compressed. The EpiPulse Cases metadata has been developed from the TESSy Metadata, with the aim to make only the minimal number of changes necessary, and to hopefully provide a better experience when reporting your datasets to ECDC.

Specific guidelines for measles and rubella data collection and preparation for EpiPulse Cases are provided in Annex 1 and Annex 2.

Checking metadata

The metadata defines the fields and data formats that are valid as input to EpiPulse Cases for a given subject. The EpiPulse Cases metadata includes a section that compares and highlights the changes between TESSy and EpiPulse Cases, to facilitate the transition.

As the requirements for data to be shared among ECDC Stakeholders can change, the data format 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 Disease Experts. These changes are then implemented to the EpiPulse Cases metadata.

Changes to the metadata for the subject of this reporting protocol are described in Annex 1.

It is especially important to focus on:

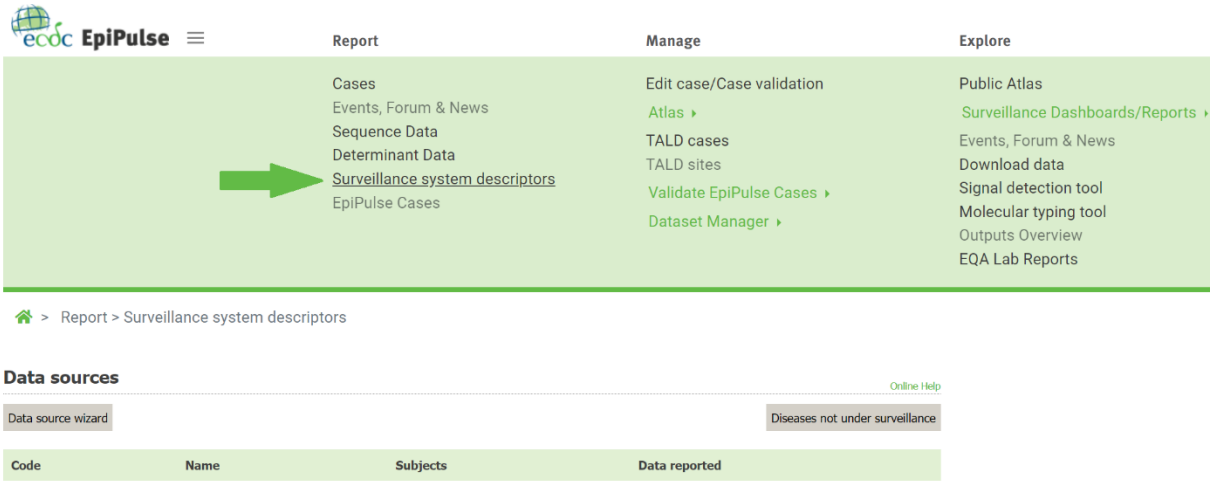
- **Field formats**
  Many fields require the data to be formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.
- **Reference Values (the equivalent of TESSy Coded Values)**
  Some fields only permit the use of specific values (reference values). For example, **M**, **F** or **OTH** are the coded values for 'Gender' and any other value in a 'Gender' field will be rejected. Please note that **UNK** is no longer a valid code, you may leave the field empty instead.

The EpiPulse Cases metadata Excel file contains all the definitions and rules necessary to format data correctly. The READ ME sheet of the Excel document explains how to work with the metadata. It can be downloaded from the Technical Guidelines & Tools section of the 'TESSy Help & Docs' pages.

Filtering the fields in the file by subject will enable you to see the fields required for your subject and the rules that apply to these fields.

Checking your Surveillance System Descriptors

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.



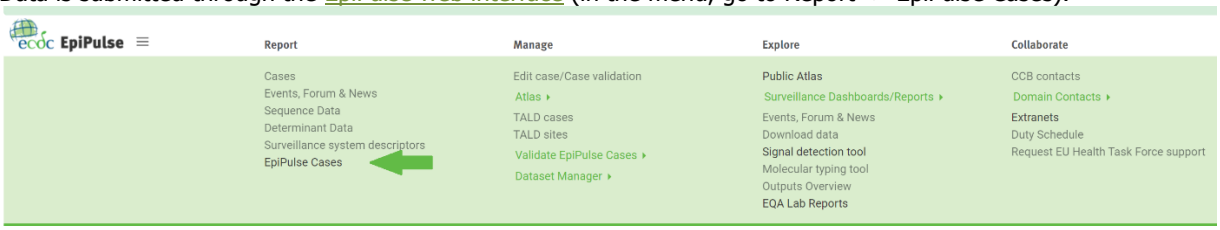
Complete and up-to-date data source information for each subject is important for improving the interpretation of data - each surveillance system has different features that need to be taken into account when comparing data European level.

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

Information on data sources is available in the TESSy User Guide, as this functionality is still only available through TESSy.

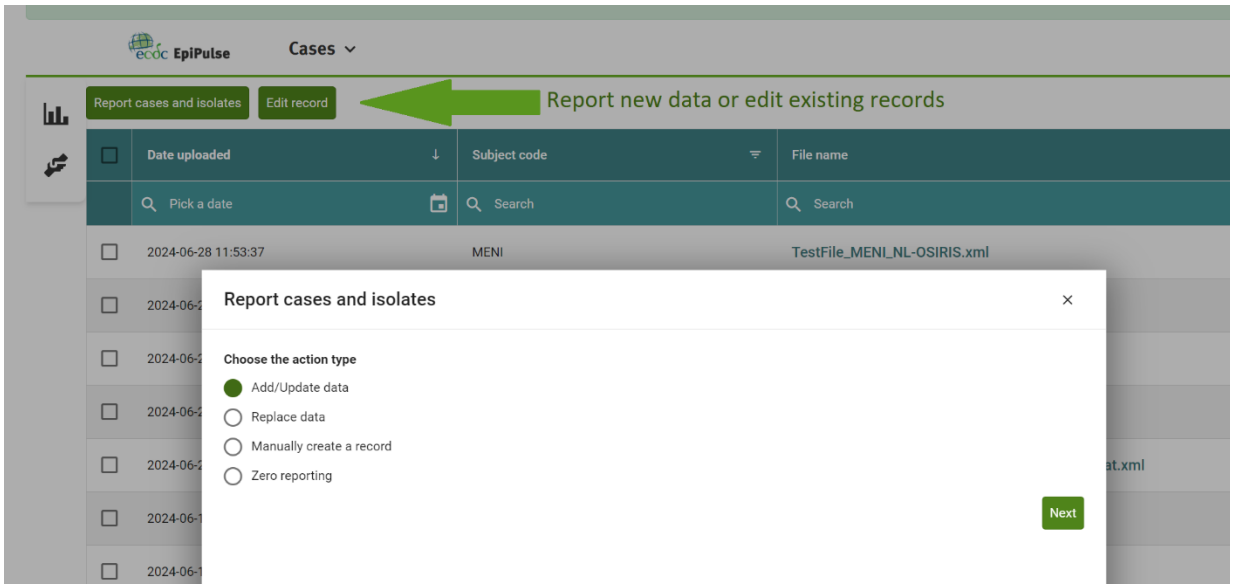
Uploading your data

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

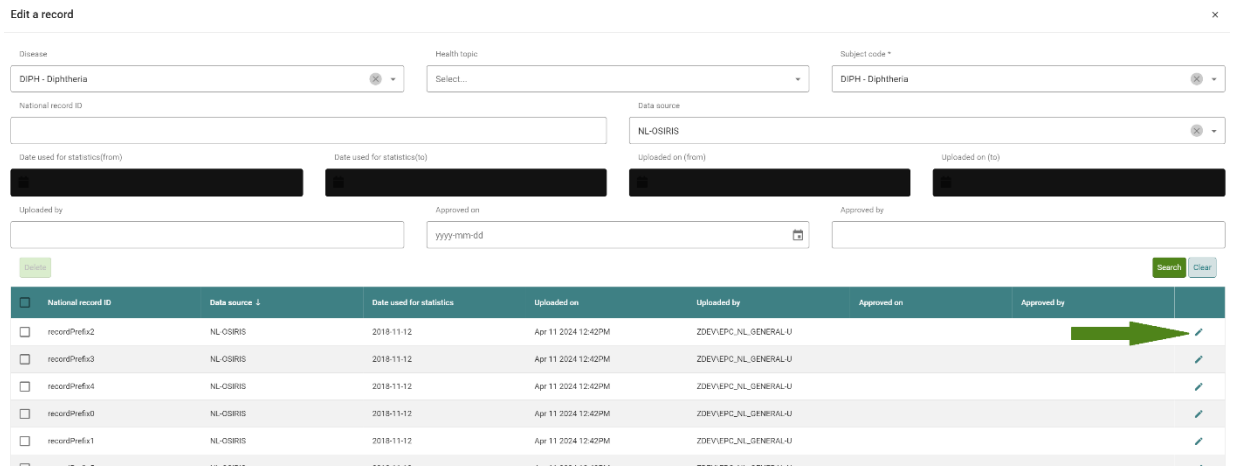


The visual interface for reporting new data and editing existing records has remained very similar to that of TESSy. For those of you that are also responsible for reporting diseases outside of the Vaccine Preventable Diseases group, you will continue to use TESSy (under EpiPulse) in parallel with the new EpiPulse Cases, until all disease groups will have been migrated to the new tool.

Similar to TESSy, you can Add/Update or Replace data with new uploads, using either CSV or XML files. You can also manually create records for some diseases, and report zero cases where appropriate.



The functionality for manually editing existing records is also a familiar experience. Search for the record you wish to edit, and modify the existing information as needed.



Finalising your submission

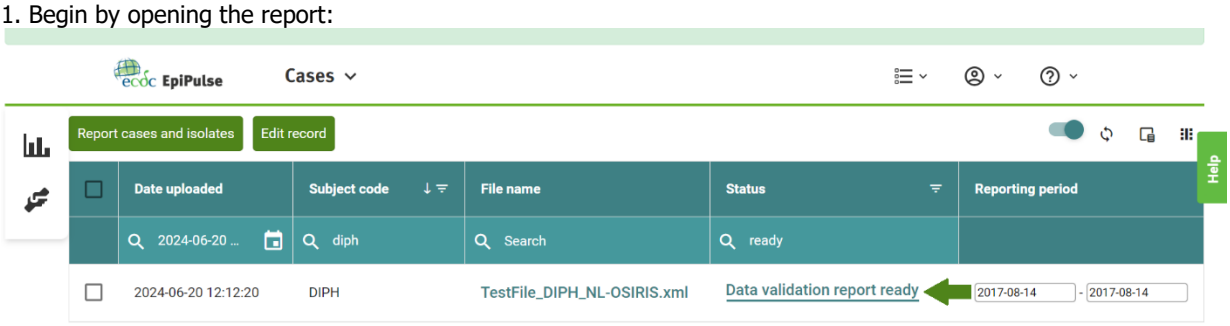
The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process. In EpiPulse Cases this process is called "Technical Validation", and it is the only step where your upload can be rejected, for severe data quality issues, such as the file format not being readable by the system, or (one of the few) mandatory variables having missing values.

If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that needs correcting.

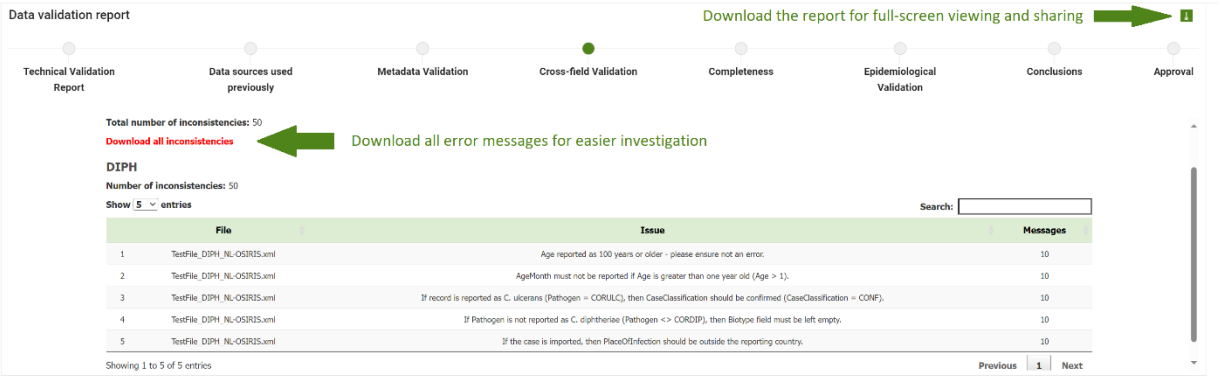
The significant new feature in EpiPulse Cases is the Data Validation Report, which puts your data in the context of the already existing information for the same disease, and provides you with a detailed overview of the new data in the file you have just uploaded, as well as the resulting overall epidemiological situation painted by the existing (past) data together with the newly uploaded file(s). This means much more timely feedback on your uploads, including details on data quality, as well as outputs (graphs, charts, and tables) on some of epidemiological indicators. The Data Validation reports will evolve and grow based on your feedback in collaboration with our Disease Experts. These reports will provide a new and better way of understanding and updating the information collected at European level, and will hopefully increase the quality and timeliness of the data, while reducing workloads.

Below you can find a few screenshots of the Data Validation Report.

1. Begin by opening the report:



2. View the report in a window, download the list of eventual validation messages, or download the report



3. Check data completeness; both for the new upload, and in the context of historical data

Completeness

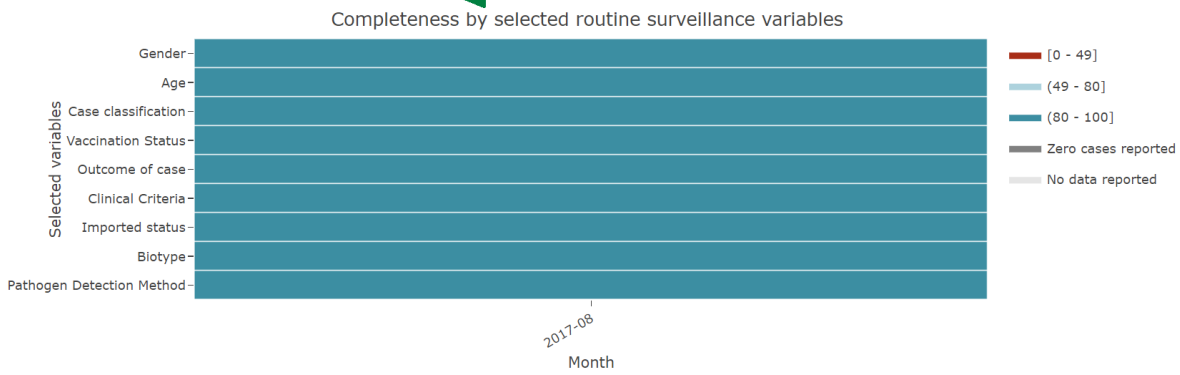
Diphtheria

Period of analysis: 2016-08 to 2018-08 (data from 2016-08-01 to 2018-08-31)

Number of records included: 27

Number of records excluded (incompatible date resolution): 0

New and historical data combined | New data submitted



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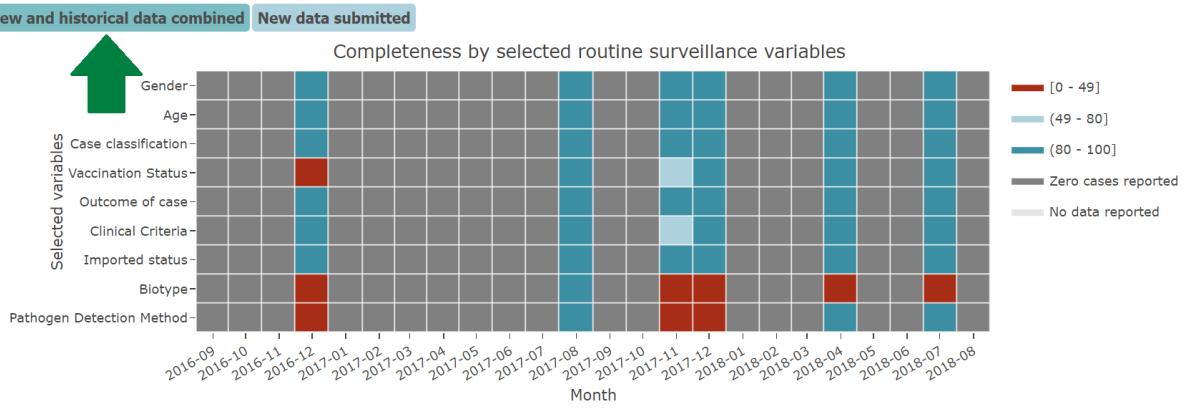
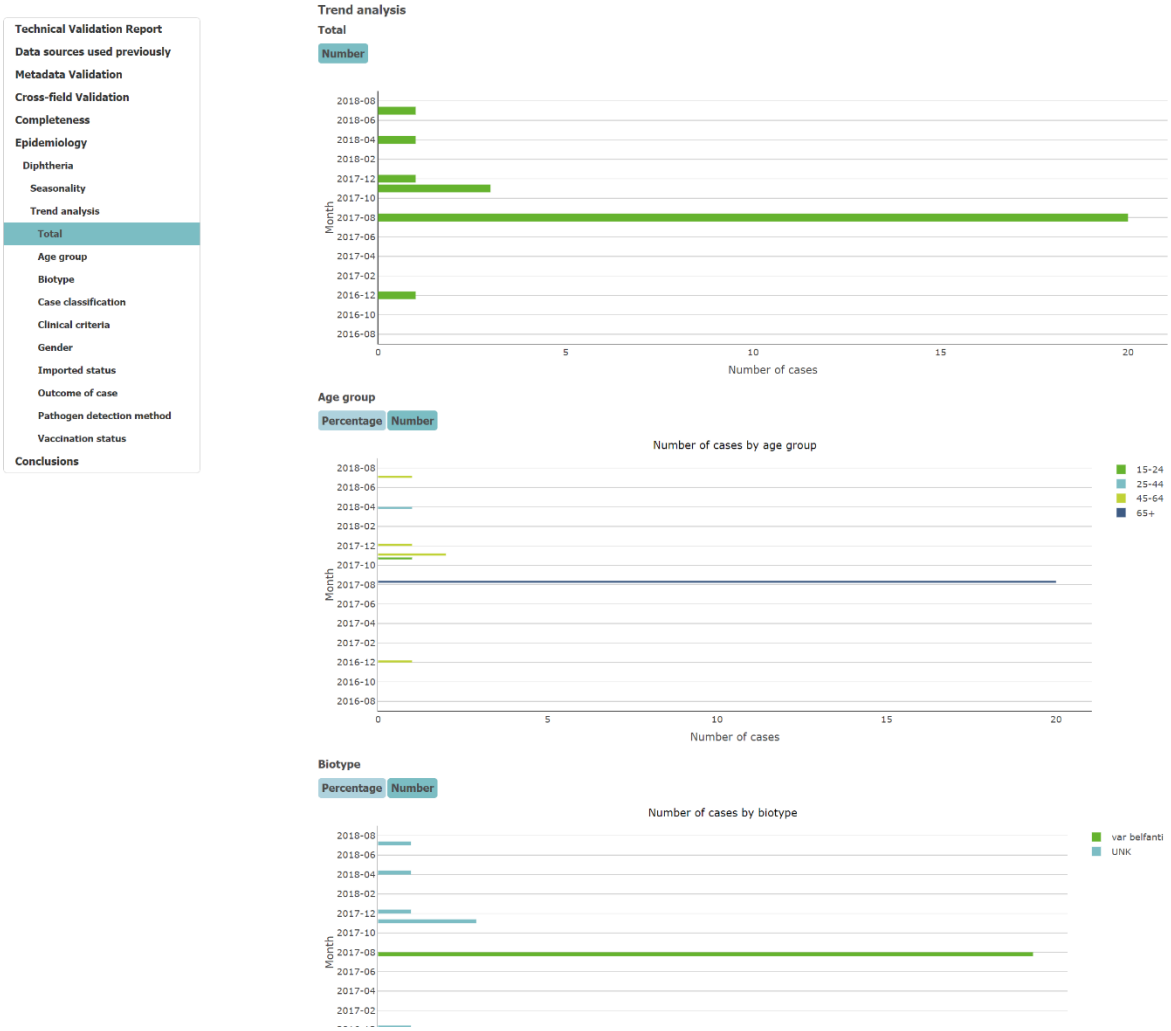
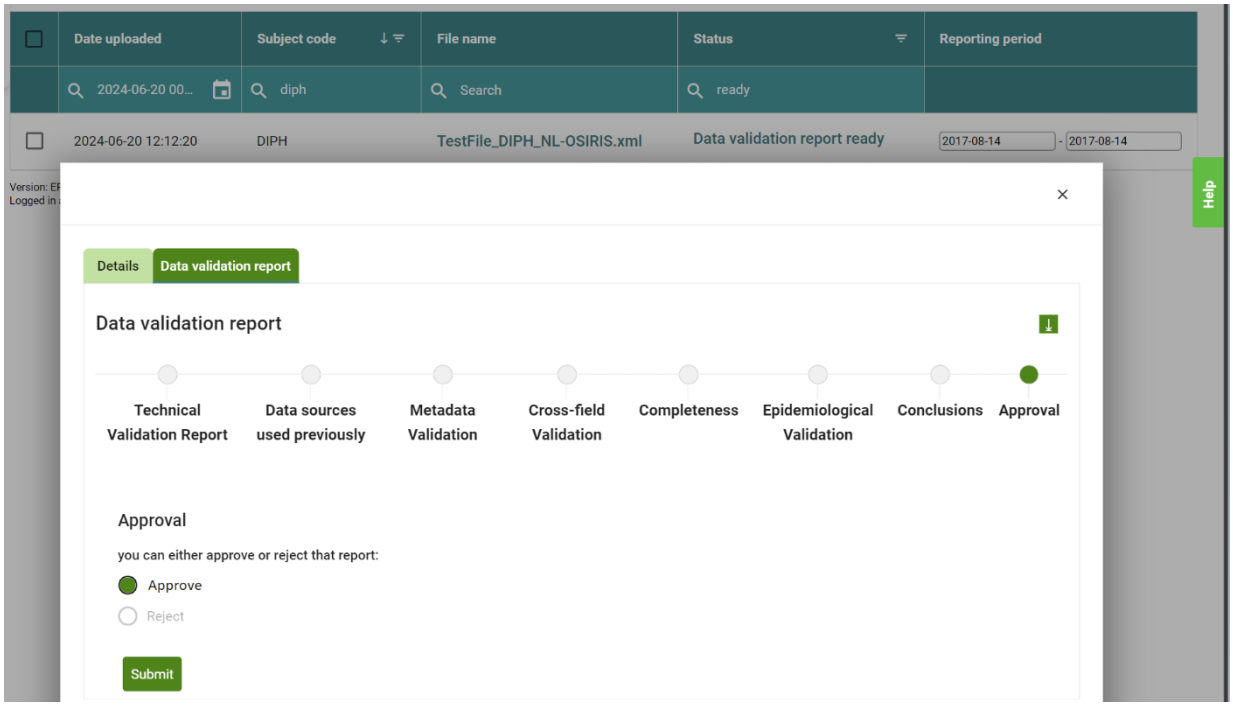


4. The downloaded report can be opened full screen for easier viewing and navigation. This is a preview of the currently developed epidemiological indicators/stratifications.



5. After reviewing the information in the Data Validation Report you can choose to approve or reject it.



If you choose to reject it, no data will be saved in the EpiPulse Cases system, but your file will remain visible should you wish to re-download it, or resubmit it for a new Data Validation at a later date or after further checks. Please check the Epi Validation Report carefully, there might be warnings and remarks relating to possible data quality issues or 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 or rejection. Unapproved uploads can block the approval of other related uploads.

EpiPulse Cases Helpdesk

Email: EpiPulseCases@ecdc.europa.eu

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

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

Annex 1. IBD metadata

This section describes:

- *The IBD metadata set*
- *Changes to the IBD metadata*

IBD metadata set

Current subject codes

Table 1 shows the subject codes (formerly 'record types') to be used when reporting 2023 VPD surveillance data to Epipulse Cases (EPC). Cases should be reported according to the relevant EU Case Definition[1].

We strongly encourage **case-based reporting**. If case-based data are not available, aggregated data may be reported.

Table 1: IBD subject codes

Disease	Case-based subject code	Aggregated subject code
Invasive Haemophilus influenzae disease	HAEINF	HAEINFAGGR
Invasive meningococcal disease	MENI	MENIAGGR
Invasive pneumococcal disease	PNEU	PNEUAGGR
Neisseria Meningitidis Isolates (Molecular surveillance)	MENIISO	n/a

Comment: An aggregated format called "AGGR" was previously available. From 2024, with the move from TESSy reporting to Epipulse Cases, aggregated subject codes HAEINFAGGR, MENIAGGR and PNEUAGGR have been launched. An aggregated subject code is not available for MENIISO.

Case-based reporting

The metadata set has variables that are common across all the Invasive Bacterial Diseases (IBD): invasive *H. influenzae* disease (HAEINF), invasive meningococcal disease (MENI), invasive pneumococcal disease (PNEU), which are summarised in Table 2. Disease-specific variables (in addition to the common variables) are subsequently summarised in Table 3 (HAEINF), Table 4 (MENI) and Table 5 (PNEU). Case-based variables for the *Neisseria meningitidis* Isolates (MENIISO) dataset are summarised in Table 6.

[1] EU case definitions (europa.eu)

Table 2: Case-based metadata common across IBD data (subject codes: HAEINF, MENI, PNEU)

Variable	Description	Coded value list
Age	Age of patient in years as reported in the national system at the time of disease onset.	
AgeMonth	Age of patient in months as reported in the national system for cases < 2 years of age at the time of disease onset.	
CaseClassification [2]	Case classification according to EU case definition.	CONF = Confirmed POSS = Possible PROB = Probable
DataSource	The data source (surveillance system) that the record originates from. The DataSource value must be a special reference value from EpiPulse Cases metadata.	Consult the reference values in mdDataSource dataset
DateOfDiagnosis	First date of clinical or lab diagnosis. In case the DateOfOnset is missing this date is used for analysis.	
DateOfLastVaccination	Date of administration of the last vaccination dose - indicates the date when the last dose of vaccine was given before disease onset (if exact date is not known, then provide month or year).	
DateOfNotification	Date when the case report is first notified to public health authorities.	
DateOfOnset [3]	Date of onset of disease. Leave empty for asymptomatic cases.	
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.	
Disease	The code of the disease that is being reported.	HAEINF = Haemophilus infection MENI = Invasive meningococcal disease PNEU = Invasive pneumococcal disease
Gender	Gender of the reported case.	F = Female M = Male OTH = Other
NationalRecordId	Unique identifier for each record within and across the specified surveillance system (data source) – selected and generated by the country reporting the record.	
Outcome	Information on whether the case is alive or deceased. The death should be due to the reported disease.	A = Alive D = Died
PlaceOfNotification	Place of the first notification of the case to a regional authority. Select the most detailed NUTS level possible.	Consult the reference values in mdLocation dataset
PlaceOfResidence	Place of residence of patient at the time of disease onset. Select the most detailed NUTS level possible.	Consult the reference values in mdLocation dataset
ReportingCountry	The country reporting the record.	Consult the reference values in mdLocation dataset
Status	The Status value is used to provide the functionality for a record within EpiPulse Cases database. Default value: NEW/UPDATE. If set to DELETE, the record with the specified NationalRecordId is deleted (invalidated) from EpiPulse Cases database, if it exists. If set to NEW/UPDATE, the record is inserted into the database: If	DELETE = Delete a previously reported record. NEW/UPDATE = Update a previously reported record (default).

[2] For both PNEU and HAEINF: only confirmed cases should be reported according to the EU Case Definition. For MENI: confirmed, probable and possible cases can be reported according to the EU Case Definition.

[3] Only reported for HAEINF and MENI - not included in PNEU dataset.

	the same NationalRecordId already exists for the same data source and subject code, then the current submitted record updates (replace) the existing one.	
SubjectCode	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).	HAEINF = Haemophilus infection MENI = Meningococcal disease PNEU = Pneumococcal infection

Table 3: Case-based metadata – additional HAEINF-specific variables

Variable	Description	Coded value list
ClinicalCriteria	Clinical presentation of the disease.	CELL = Cellulitis EPIG = Epiglottitis MENI = Meningitis/Meningeal/ Meningoencephalitic MENISEPTI = Meningitis and septicaemia OSE = Osteomyelitits/septic arthritis OTH = Other PNEU = Pneumonia SEPTI = Septicaemia
MainPathogenDetectionMethod	Pathogen detection method used on the primary laboratory specimen with a positive result for case confirmation and further characterisation of the disease. More than one method can be reported.	ANTIGEN = Antigen detection CULT = Culture GENOSEQ = Genotyping/Sequencing IMMUNO = Immunodiagnostic tests NUCLACID = Detection of nucleic acid OTH = Other
SecondPathogenDetectionMethod	Pathogen detection method used on the second type of laboratory specimen with a positive result (if taken) for diagnosis or further characterisation of the disease. More than one method can be reported.	ANTIGEN = Antigen detection CULT = Culture GENOSEQ = Genotyping/Sequencing IMMUNO = Immunodiagnostic tests NUCLACID = Detection of nucleic acid OTH = Other
Serotype	Serotype of the pathogen which is the cause of the reported disease.	HAEINF_A = H. influenzae type a HAEINF_B = H. influenzae type b HAEINF_C = H. influenzae type c HAEINF_D = H. influenzae type d HAEINF_E = H. influenzae type e HAEINF_F = H. influenzae type f HAEINF_NONCAPS = H. influenzae non-capsulated strain HAEINF_NOT_B = H. influenzae non-b strain HAEINF_UNK = H. influenzae type unknown
VaccinationStatus	Indicates if the case is vaccinated against serotype b and number of vaccine doses received.	10DOSE = 10 doses 1DOSE = 1 dose

		2DOSE = 2 doses 3DOSE = 3 doses 4DOSE = 4 doses 5DOSE = 5 doses 6DOSE = 6 doses 7DOSE = 7 doses 8DOSE = 8 doses 9DOSE = 9 doses NOTVACC = Not vaccinated UNKDOSE = Vaccinated, dose unknown

Table 4: Case-based metadata – additional MENI-specific variables

Variable	Description	Coded value list
ClinicalCriteria	Clinical presentation of the disease according to the EU case definition.	MENI = Meningitis/Meningeal/ Meningoencephalitic MENISEPTI = Meningitis and septicaemia OTH = Other PNEU = Pneumonia SEPTI = Septicaemia
Imported	Infection has occurred following exposure outside the reporting country during a time compatible with the incubation period of the infection.	0 = No 1 = Yes
IsolateId	Unique identifier for each isolate within the data source/laboratory system related to the case. In option1 in the Reporting Protocol, this variable corresponds to the EMERT II identifier.	
MainPathogen DetectionMethod	Pathogen detection method used on the primary laboratory specimen with a positive result for case confirmation and further characterisation of the disease. More than one method can be reported.	ANTIGEN = Antigen detection CULT = Culture GENOSEQ = Genotyping/Sequencing MICRO = Microscopy NUCLACID = Detection of nucleic acid OTH = Other
MICSign_CIP	This field can indicate if a value of the MICValueAST_CIP test is "less than" (<); "equal to or less than" (<=); "equal to" (=); "equal to or greater than"(>=); or "greater than" (>) the value indicated in the following field.	< = Less than <= = Less than or equal = = Equal > = Greater than >= = Greater than or equal
MICSign_CTX_CFX	This field can indicate if a value of the MICValueAST_CTX_CFX test is "less than"(<); "equal to or less than"(<=); "equal to"(=); "equal to or greater than"(>=); or "greater than"(>) the value indicated in the following field.	< = Less than <= = Less than or equal = = Equal > = Greater than >= = Greater than or equal

MICSign_PEN	This field can indicate if a value of the MICValueAST_PEN test is "less than" (<); "equal to or less than" (<=); "equal to" (=); "equal to or greater than"(>=); or "greater than" (>) the value indicated in the following field.	< = Less than <= = Less than or equal = = Equal > = Greater than >= = Greater than or equal
MICSign_RIF	This field can indicate if a value of the MICValueAST_RIF test is "less than" (<); "equal to or less than" (<=); "equal to" (=); "equal to or greater than"(>=); or "greater than" (>) the value indicated in the following field.	< = Less than <= = Less than or equal = = Equal > = Greater than >= = Greater than or equal
MICValueAST_CIP	MIC (Value in mg/l). Use '.' as decimal delimiter, e.g. 0.25.	
MICValueAST_CTX_CFX	MIC (Value in mg/l). Use '.' as decimal delimiter, e.g. 0.25.	
MICValueAST_PEN	MIC (Value in mg/l). Use '.' as decimal delimiter, e.g. 0.25.	
MICValueAST_RIF	MIC (Value in mg/l). Use '.' as decimal delimiter, e.g. 0.25.	
PlaceOfInfection	If Imported = 1 (TRUE): The probable place of infection should be provided at the country level. One entry for each country visited during the incubation period of the disease. Note this is a repeatable field.	Consult the reference values in mdLocation dataset
ReportedEMERTII	Describe if the isolate related to the case was reported to EMERT II.	0 = No 1 = Yes
ResultFetVR	Serotype Gene FetA VR variable region. Values from http://neisseria.org/nm/typing/tessy/.	Consult the reference values for SubjectCode = MENI and Variable = ResultFetVR
ResultMLST	Multilocus Sequence Typing clonal complex of strain. Values from http://neisseria.org/nm/typing/tessy/.	Consult the reference values for SubjectCode = MENI and Variable = ResultMLST
ResultPorA1	Serotype Gene PorA variable region 1. Values from http://neisseria.org/nm/typing/tessy/.	Consult the reference values for SubjectCode = MENI and Variable = ResultPorA1
ResultPorA2	Serotype Gene PorA variable region 2. Values from http://neisseria.org/nm/typing/tessy/.	Consult the reference values for SubjectCode = MENI and Variable = ResultPorA2
SecondPathogen DetectionMethod	Pathogen detection method used on the second type of laboratory specimen with a positive result (if taken) for diagnosis or further characterisation of the disease. More than one method can be reported.	ANTIGEN = Antigen detection CULT = Culture GENOSEQ = Genotyping/Sequencing MICRO = Microscopy NUCLACID = Detection of nucleic acid OTH = Other
Serogroup	Serogroup will not be known if clinical diagnosis only used to identify disease.	NEIMENI_29E = N. meningitidis serogroup 29E NEIMENI_A = N. meningitidis serogroup A NEIMENI_B = N. meningitidis serogroup B NEIMENI_C = N. meningitidis serogroup C NEIMENI_NGA = N. meningitidis not groupable NEIMENI_OTH = N. meningitidis other serogroup NEIMENI_W = N. meningitidis serogroup W NEIMENI_X = N. meningitidis serogroup X NEIMENI_Y = N. meningitidis serogroup Y

		NEIMENI_Z = N. meningitidis serogroup Z NEIMENI_Z/29E = N. meningitidis serogroup Z/29E
SIR_CIP	Susceptibility to Ciprofloxacin as the final interpretation based on one or more test results.	I = Intermediate R = Resistant S = Susceptible
SIR_CTX_CFX	Susceptibility to Cefotaxime or Ceftriaxone as the final interpretation based on one or more test results.	I = Intermediate R = Resistant S = Susceptible
SIR_PEN	Susceptibility to Penicillin as the final interpretation based on one or more test results.	I = Intermediate R = Resistant S = Susceptible
SIR_RIF	Susceptibility to Rifampicin as the final interpretation based on one or more test results.	I = Intermediate R = Resistant S = Susceptible
VaccinationStatus	Indicates if the case is vaccinated against the serogroup of meningococcus that was the cause of infection and number of vaccine doses received.	1DOSE = 1 dose 2DOSE = 2 doses 3DOSE = 3 doses 4DOSE = 4 doses NOTVACC = Not vaccinated UNKDOSE = Vaccinated, dose unknown

Table 5: Case-based metadata – additional PNEU-specific variables

Variable	Description	Coded value list
ASTMethod	Test method(s) used for MIC determination.	AGARDIL = Agar dilution AUTOM = Automated instrument method BROTHDIL = Broth microdilution GRAD = Antimicrobial gradient (E-test, etc) OTH = Other
BrandPCV1	Type of PCV at first dose.	PCV10 = Pneumococcal conjugate vaccine 10 PCV13 = Pneumococcal conjugate vaccine 13 PCV15 = Pneumococcal conjugate vaccine 15 PCV20 = Pneumococcal conjugate vaccine 20 PCV7 = Pneumococcal conjugate vaccine 7
BrandPCV2	Type of PCV at second dose.	PCV10 = Pneumococcal conjugate vaccine 10 PCV13 = Pneumococcal conjugate vaccine 13 PCV15 = Pneumococcal conjugate vaccine 15 PCV20 = Pneumococcal conjugate vaccine 20 PCV7 = Pneumococcal conjugate vaccine 7

BrandPCV3	Type of PCV at third dose.	PCV10 = Pneumococcal conjugate vaccine 10 PCV13 = Pneumococcal conjugate vaccine 13 PCV15 = Pneumococcal conjugate vaccine 15 PCV20 = Pneumococcal conjugate vaccine 20 PCV7 = Pneumococcal conjugate vaccine 7
BrandPCV4	Type of PCV at fourth dose.	PCV10 = Pneumococcal conjugate vaccine 10 PCV13 = Pneumococcal conjugate vaccine 13 PCV15 = Pneumococcal conjugate vaccine 15 PCV20 = Pneumococcal conjugate vaccine 20 PCV7 = Pneumococcal conjugate vaccine 7
ClinicalCriteria	Clinical presentation of the disease.	BACTERPNEUMO = Bacteraemic pneumonia MENI = Meningitis/Meningeal/Meningoencephalitic MENISEPTI = Meningitis and septicaemia OTH = Other SEPTI = Septicaemia
DatePCV1	Date of first dose of PCV.	
DatePCV2	Date of second dose of PCV.	
DatePCV3	Date of third dose of PCV.	
DatePCV4	Date of fourth dose of PCV.	
DatePPV	Date of PPV.	
DosePCV1	First dose of vaccination with a PCV.	0 = No 1 = Yes
DosePCV2	Second dose of vaccination with a PCV.	0 = No 1 = Yes
DosePCV3	Third dose of vaccination with a PCV.	0 = No 1 = Yes
DosePCV4	Fourth dose of vaccination with a PCV.	0 = No 1 = Yes
DosePPV	Vaccinated with PPV.	0 = No 1 = Yes
MICSign_CTX_CFX	This field can indicate if a value of the MICValueAST_CTX_CFX test is "less than"(<); "equal to or less than"(<=); "equal to"(=); "equal to or greater than"(>=); or "greater than"(>) the value indicated in the following field.	< = Less than <= = Less than or equal = = Equal > = Greater than >= = Greater than or equal
MICSign_ERY	This field can indicate if a value of the MICValueAST_ERY test is "less than" (<); "equal to or less than" (<=); "equal to" (=); "equal to or greater than"(>=); or "greater than" (>) the value indicated in the following field.	< = Less than <= = Less than or equal = = Equal > = Greater than >= = Greater than or equal

MICSign_PEN	This field can indicate if a value of the MICValueAST_PEN test is "less than" (<); "equal to or less than" (<=); "equal to" (=); "equal to or greater than"(>=); or "greater than" (>) the value indicated in the following field.	< = Less than <= = Less than or equal = = Equal > = Greater than >= = Greater than or equal
MICValueAST_CTX_CFX	MIC (Value in mg/l). Use '.' as decimal delimiter, e.g. 0.25.	
MICValueAST_ERY	MIC (Value in mg/l). Use '.' as decimal delimiter, e.g. 0.25.	
MICValueAST_PEN	MIC (Value in mg/l). Use '.' as decimal delimiter, e.g. 0.25.	
NRLData	If 1 (TRUE) - data is based on data from National Reference laboratory, if 0 (FALSE) - data is based on clinical and non-reference-laboratory data.	0 = No 1 = Yes
PathogenDetectionMethod	Pathogen detection method used for serotyping. More than one method can be reported.	COAGG = Coagglutination GDIFF = Gel diffusion MPCR = Multiplex PCR OTH = Other PTEST = Pneumotest QUE = Quellung SLAGG = Slide agglutination
PCVDoses	Total number of PCV doses received by case prior to onset.	
PPVDoses	Total number of PPV doses received by case prior to onset.	
Serotype	Serotype of the pathogen which is the cause of the reported disease.	Consult the reference values for SubjectCode = PNEU and Variable = Serotype
SIR_CTX_CFX	Susceptibility to Cefotaxime or Ceftriaxone as the final interpretation based on one or more test results.	I = Intermediate R = Resistant S = Susceptible
SIR_ERY	Susceptibility to Erythromicin as the final interpretation based on one or more test results.	I = Intermediate R = Resistant S = Susceptible
SIR_PEN	Susceptibility to Penicillin as the final interpretation based on one or more test results.	I = Intermediate R = Resistant S = Susceptible
VaccinationStatus	Indicates if the case is vaccinated and number of vaccine doses received.	10DOSE = 10 doses 1DOSE = 1 dose 2DOSE = 2 doses 3DOSE = 3 doses 4DOSE = 4 doses 5DOSE = 5 doses 6DOSE = 6 doses 7DOSE = 7 doses 8DOSE = 8 doses 9DOSE = 9 doses NOTVACC = Not vaccinated UNKDOSE = Vaccinated, dose unknown

Vaccine	Type of pneumococcal vaccine; if the last vaccine given in the series was different from the vaccine with which the series was initiated, indicate the last vaccine in the series.	PCV10 = Pneumococcal conjugate vaccine 10 PCV13 = Pneumococcal conjugate vaccine 13 PCV15 = Pneumococcal conjugate vaccine 15 PCV20 = Pneumococcal conjugate vaccine 20 PCV3 = Pneumococcal conjugate vaccine - third dose PCV7 = Pneumococcal conjugate vaccine 7 PPV23 = Pneumococcal polysaccharide vaccine

Table 6: Case-based metadata – MENIISO-specific variables

Variable	Description	Coded value list
CaseId	Unique identifier for each case within the data source / surveillance system related to the isolate, so that isolate records can be linked to case records. This should match the corresponding NationalRecordId of MENI case-based data in option 2, as per Reporting Protocol.	
DataSource	The data source (laboratory) that the record originates from.	Consult the reference values in mdDataSource dataset
DateOfReceiptReferenceLab	Date of receipt in reference laboratory or typing laboratory with reference function.	
DateOfReceiptSourceLab	Date of receipt in source laboratory, i.e. the laboratory the sample was first sent to.	
DateOfSampling	Date the sample from which the isolate was derived, was taken.	
DateUsedForStatistics	The most epidemiologically relevant date for the isolate. Equal to the date of sampling if available. If not, equal to the date of receipt in the source lab, and if that is not available, the date of receipt in the reference lab.	
Disease	The code of the disease that is being reported.	MENI = Invasive meningococcal disease
HealthTopic	The code of the health topic that is being reported.	ISO = Isolate data
ItemCode	Item code.	
NationalRecordId	Unique identifier for each record within and across the specified surveillance system (data source) – selected and generated by the country reporting the record.	
ReportingCountry	The country reporting the record.	Consult the reference values in mdLocation dataset
Status	The Status value is used to provide the functionality for a record within EpiPulse Cases database. Default value: NEW/UPDATE. If set to DELETE, the record with the specified NationalRecordId is deleted (invalidated) from EpiPulse Cases database, if it exists. If set to NEW/UPDATE, the record is inserted into the database: If the same NationalRecordId already exists for the same data source and subject code, then the current submitted record updates (replace) the existing one.	DELETE = Delete a previously reported record. NEW/UPDATE = Update a previously reported record (default).
SubjectCode	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).	MENIISO = Neisseria meningitidis isolate
WgsAccession	European Nucleotide Archive (ENA) run identifier, based on which the sequence read data can be retrieved / Sequence Read Archive (SRA) run identifier, based on which the sequence read data can be retrieved. Starts with ERR or SRR, i.e. not the sample or experiment which ERS/ERX or SRS/SRX.	

WgsAssembler	The assembler used for sequencing, optionally including parameter settings.	MAP_TO_LOCI1 = Mapping to individual loci, variant 1 for IonTorrent SKESA = SKESA assembler SPADES = SPAdes without read mapping and consensus calling SPADES_READMAP = SPAdes either including or followed by read mapping and consensus calling VELVET = Velvet without read mapping and consensus calling VELVET_READMAP = Velvet using k-mer optimisation, and followed by read mapping and consensus calling
WgsAssembly	The assembled genome, as a gzipped FASTA file. The file contents are subsequently converted into a Base64-encoded string for inclusion into either the XML or CSV data for the isolate.	
WgsProtocol	Protocol used for sequencing, limited to the sequencing technology used (today Illumina or IonTorrent) and the read length.	HISEQ_2X100 = Illumina HiSeq 2x100 IONTORRENT = IonTorrent MINISEQ_2X150 = Illumina MiniSeq 2x150 MISEQ_2X150 = Illumina MiSeq 2x150 MISEQ_2X250 = Illumina MiSeq 2x250 MISEQ_2X300 = Illumina MiSeq 2x300 NEXTSEQ_2X150 = Illumina NextSeq 2x150 PAIRED_END_ILLUMINA = Illumina HiSeq, MiSeq, NextSeq or MiniSeq
WgsRawReads	The raw reads obtained from the sequencer stored as FASTQ files. Each FASTQ file is a text file which represents sequence readouts for a sample.	

Aggregated reporting

Please refer to Table 7 to see the format for aggregated reporting of IBD data. If only a few variables can be reported, it is recommended to give the following priority for reporting: AgeGroup, Classification, VaccStatus, Gender.

Table 7: Aggregate metadata for reporting of IBD data (record type: AGGR)

Variable	Description	Coded value list
AgeGroup	Age group of the reported record.	0 = <1 year 01-04 = 1-4 years 05-09 = 5-9 years 10-14 = 10-14 years 15-19 = 15-19 years 20-24 = 20-24 years 25-29 = 25-29 years 30-34 = 30-34 years 35-39 = 35-39 years 40-44 = 40-44 years

		45-49 = 45-49 years 50-54 = 50-54 years 55-59 = 55-59 years 60-64 = 60-64 years 65+ = 65 and over
CaseClassification [4]	Case classification according to EU case definition.	CONF = Confirmed POSS = Possible PROB = Probable
DataSource	The data source (surveillance system) that the record originates from. The DataSource value must be a special reference value from EpiPulse Cases metadata.	Consult the reference values in mdDataSource dataset
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.	
Disease	The code of the disease that is being reported.	HAEINF = Haemophilus infection MENI = Invasive meningococcal disease PNEU = Invasive pneumococcal disease
Gender	Gender of the reported record.	F = Female M = Male OTH = Other
NumberOfCases	Total number of cases during the reported period for the specified disease.	
ReportingCountry	The country reporting the record.	Consult the reference values in mdLocation dataset
SubjectCode	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).	HAEINFAGGR = Haemophilus infection aggregated MENIAGGR = Meningococcal disease aggregated PNEUAGGR = Pneumococcal infection aggregated
VaccinationStatus	Indicates if the case is vaccinated and number of vaccine doses received.	1DOSE = 1 dose 2DOSE = 2 doses 3DOSE = 3 doses 4DOSE = 4 doses NOTVACC = Not vaccinated UNKDOSE = Vaccinated, dose unknown

[4] For PNEU and HAEINF, only confirmed cases should be reported according to the EU Case Definition. For MENI, confirmed, probable and possible cases can be reported.

Changes to the IBD metadata

Metadata changes prior to 2014 can be found on the TESSy documents website. Changes from 2014 onwards have been summarised in Table 8 below.

Table 8: Summary of implemented changes in case-based and aggregated subject codes (formerly 'record types') for IBD from 2014 to current

Year of change	Subject	Variables	Description
2024	HAEINF MENI PNEU MENIISO HAEINFAGGR MENIAGGR PNEUAGGR	ALL	Reporting moved from TESSy to the Epipulse Cases platform. This transition has led to changes in some variable names and categorical values (see below).
		RecordTypeVersion	Remove variable
	MENI	ECDCIsolateID	Remove variable
	PNEU	DosePCV1; DatePCV1; BrandPCV1; DosePCV2; DatePCV2; BrandPCV2; DosePCV3; DatePCV3; BrandPCV3; DosePCV4; DatePCV4; BrandPCV4; PCVDoses; DosePPV; DatePPV; PPVDoses	ADD variables: DosePCV1: First dose of vaccination with a PCV DatePCV1: Date of first dose of PCV BrandPCV1: Type of PCV at first dose DosePCV2: Second dose of vaccination with a PCV DatePCV2: Date of second dose of PCV BrandPCV2: Type of PCV at second dose DosePCV3: Third dose of vaccination with a PCV DatePCV3: Date of third dose of PCV BrandPCV3: Type of PCV at third dose DosePCV4: Fourth dose of vaccination with a PCV DatePCV4: Date of fourth dose of PCV BrandPCV4: Type of PCV at fourth dose PCVDoses: Total number of PCV doses received prior to onset DosePPV: Vaccinated with PPV DatePPV: Date of PPV PPVDoses: Total number of PPV doses received prior to onset
	HAEINFAGGR MENIAGGR PNEUAGGR	VaccinationStatus	ADD Variable
	HAEINF MENI PNEU	Classification → CaseClassification; ClinicalPresentation → ClinicalCriteria ; DateLastVaccDose → DateOfLastVaccination; RecordId → NationalRecordId; RecordType → SubjectCode; Subject → Disease; VaccStatus → VaccinationStatus	Variable names changed from (TESSy) → to (Epipulse Cases): Classification → CaseClassification; ClinicalPresentation → ClinicalCriteria; DateLastVaccDose → DateOfLastVaccination; RecordId → NationalRecordId; RecordType → SubjectCode; Subject → Disease; VaccStatus → VaccinationStatus
	HAEINF MENI	TestMethod1 → MainPathogenDetectionMethod; TestMethod2 → SecondPathogenDetectionMethod	Variable names changed from (TESSy) → to (Epipulse Cases): TestMethod1 → MainPathogenDetectionMethod; TestMethod2 → SecondPathogenDetectionMethod
	MENI	ResultMICSign_CTX_CFX → MICSign_CTX_CFX;	Variable names changed from (TESSy) → to (Epipulse Cases):

	PNEU	ResultMICSign_PEN → MICSign_PEN; ResultMICValueCTX_CFX → MICValueAST_CTX_CFX; ResultMICValuePEN → MICValueAST_PEN	ResultMICSign_CTX_CFX → MICSign_CTX_CFX; ResultMICSign_PEN → MICSign_PEN; ResultMICValueCTX_CFX → MICValueAST_CTX_CFX; ResultMICValuePEN → MICValueAST_PEN
	MENI	ProbableCountryOfInfection → PlaceOfInfection; ResultMICSign_CIP → MICSign_CIP; ResultMICSign_RIF → MICSign_RIF; ResultMICValueCIP → MICValueAST_CIP; ResultMICValueRIF → MICValueAST_RIF	Variable names changed from (TESSy) → to (Epipulse Cases): ProbableCountryOfInfection → PlaceOfInfection; ResultMICSign_CIP → MICSign_CIP; ResultMICSign_RIF → MICSign_RIF; ResultMICValueCIP → MICValueAST_CIP; ResultMICValueRIF → MICValueAST_RIF
	PNEU	ResultMICSign_ERY → MICSign_ERY ResultMICValueERY → MICValueAST_ERY TestMethodMIC → ASTMethod; VaccType → Vaccine	Variable names changed from (TESSy) → to (Epipulse Cases): ResultMICSign_ERY → MICSign_ERY ResultMICValueERY → MICValueAST_ERY TestMethodMIC → ASTMethod; VaccType → Vaccine
	HAEINFAGGR MENIAGGR PNEUAGGR	AgeClass → AgeGroup; Classification → CaseClassification; RecordType → SubjectCode; Subject → Disease;	Variable names changed from (TESSy) → to (Epipulse Cases): AgeClass → AgeGroup; Classification → CaseClassification; RecordType → SubjectCode; Subject → Disease;
	HAEINF MENI PNEU	CaseClassification	Discontinued "UNK" categorical value
		ClinicalCriteria	Discontinued "UNK" and "NUS" categorical values, and "O" remapped to "OTH"
		Status	Remapping of "NEW/UPDATE" to "ADD/UPDATE"
	HAEINF MENI	MainPathogenDetectionMethod; SecondPathogenDetectionMethod	Discontinued "UNK" and "NA" categorical values, and "O" remapped to "OTH"
		Outcome	Discontinued "UNK" and "NUS" categorical values
	HAEINF PNEU	VaccinationStatus	Discontinued "UNK" categorical value and "DOSEUNK" remapped to "UNKDOSE"
	MENI PNEU	SIR_CTX_CFX; SIR_PEN	Discontinued "UNK" categorical value
	HAEINF	Serotype	Discontinued "NUS" categorical values and remapping of: "A" to "HAEINF_A" "B" to "HAEINF_B" "C" to "HAEINF_C" "D" to "HAEINF_D" "E" to "HAEINF_E" "F" to "HAEINF_F" "UNK" to "HAEINF_UNK" "non-b" to "HAEINF_NOT_B" "non-caps" to "HAEINF_NONCAPS"
	MENI	Imported; ReportedEMERTII	Discontinued "UNK" categorical value and variable changed from coded value to Boolean (0 = No ; 1 = Yes)
		ResultFetVR; ResultPorA1; ResultPorA2	Discontinued "UNK" and "NUS" categorical values
		ResultMLST; SIR_CIP; SIR_RIF	Discontinued "UNK" categorical value
		VaccinationStatus	Discontinued "UNK", "5DOSE", "6DOSE", "7DOSE", "8DOSE", "9DOSE", "10DOSE" categorical values and "DOSEUNK" remapped to "UNKDOSE"

		Serogroup	Discontinued "UNK" and "NUS" categorical values and remapping of: "29E" to "NEIMENI_29E" "A" to "NEIMENI_A" "B" to "NEIMENI_B" "C" to "NEIMENI_C" "NGA" to "NEIMENI_NGA" "O" to "NEIMENI_OTH" "W" to "NEIMENI_W" "X" to "NEIMENI_X" "Y" to "NEIMENI_Y" "Z" to "NEIMENI_Z" "Z/29E" to "NEIMENI_Z/29E"
		ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	Update coded values (once a year or upon request) from the following list: http://neisseria.org/nm/typing/tessy/
	PNEU	ASTMethod	Discontinued "UNK" categorical value and "O" remapped to "OTH"
		NRLData	Variable changed from coded value to Boolean (0 = No ; 1 = Yes)
		Outcome; SIR_ERY	Discontinued "UNK" categorical value
		PathogenDetectionMethod	Discontinued "UNK" and "NA" categorical values, and "O" remapped to "OTH"
		Vaccine	Discontinued "UNK" and "NA" categorical values
		Serotype	Discontinued "NT" and "O" categorical values and remapping of: "1" to "STRPNE_1" "10" to "STRPNE_10" "10A" to "STRPNE_10A" "10B" to "STRPNE_10B" "10C" to "STRPNE_10C" "10F" to "STRPNE_10F" "11" to "STRPNE_11" "11A" to "STRPNE_11A" "11B" to "STRPNE_11B" "11C" to "STRPNE_11C" "11D" to "STRPNE_11D" "11E" to "STRPNE_11E" "11F" to "STRPNE_11F" "12" to "STRPNE_12" "12A" to "STRPNE_12A" "12B" to "STRPNE_12B" "12F" to "STRPNE_12F" "13" to "STRPNE_13" "14" to "STRPNE_14" "15" to "STRPNE_15" "15A" to "STRPNE_15A" "15B" to "STRPNE_15B" "15B/C" to "STRPNE_15B/C" "15C" to "STRPNE_15C" "15F" to "STRPNE_15F" "16" to "STRPNE_16" "16A" to "STRPNE_16A" "16F" to "STRPNE_16F" "17" to "STRPNE_17" "17A" to "STRPNE_17A" "28" to "STRPNE_28" "28A" to "STRPNE_28A" "28F" to "STRPNE_28F" "29" to "STRPNE_29" "3" to "STRPNE_3" "31" to "STRPNE_31" "32" to "STRPNE_32" "32A" to "STRPNE_32A" "32F" to "STRPNE_32F" "33" to "STRPNE_33" "33A" to "STRPNE_33A" "33B" to "STRPNE_33B" "33C" to "STRPNE_33C" "33D" to "STRPNE_33D" "33F" to "STRPNE_33F" "34" to "STRPNE_34" "35" to "STRPNE_35" "35A" to "STRPNE_35A" "35B" to "STRPNE_35B" "35C" to "STRPNE_35C" "35F" to "STRPNE_35F" "36" to "STRPNE_36" "37" to "STRPNE_37" "38" to "STRPNE_38" "39" to "STRPNE_39" "4" to "STRPNE_4" "40" to "STRPNE_40" "41" to "STRPNE_41" "41A" to "STRPNE_41A" "41F" to "STRPNE_41F"

			"17F" to "STRPNE_17F" "18" to "STRPNE_18" "18A" to "STRPNE_18A" "18B" to "STRPNE_18B" "18C" to "STRPNE_18C" "18F" to "STRPNE_18F" "19" to "STRPNE_19" "19A" to "STRPNE_19A" "19B" to "STRPNE_19B" "19C" to "STRPNE_19C" "19F" to "STRPNE_19F" "2" to "STRPNE_2" "20" to "STRPNE_20" "21" to "STRPNE_21" "22" to "STRPNE_22" "22A" to "STRPNE_22A" "22F" to "STRPNE_22F" "23" to "STRPNE_23" "23A" to "STRPNE_23A" "23B" to "STRPNE_23B" "23F" to "STRPNE_23F" "24" to "STRPNE_24" "24A" to "STRPNE_24A" "24B" to "STRPNE_24B" "24F" to "STRPNE_24F" "25" to "STRPNE_25" "25A" to "STRPNE_25A" "25F" to "STRPNE_25F" "27" to "STRPNE_27" "42" to "STRPNE_42" "43" to "STRPNE_43" "44" to "STRPNE_44" "45" to "STRPNE_45" "46" to "STRPNE_46" "47" to "STRPNE_47" "47A" to "STRPNE_47A" "47F" to "STRPNE_47F" "48" to "STRPNE_48" "5" to "STRPNE_5" "6" to "STRPNE_6" "6A" to "STRPNE_6A" "6B" to "STRPNE_6B" "6C" to "STRPNE_6C" "6D" to "STRPNE_6D" "7" to "STRPNE_7" "7A" to "STRPNE_7A" "7B" to "STRPNE_7B" "7C" to STRPNE_7C" "7F" to "STRPNE_7F" "8" to "STRPNE_8" "9" to "STRPNE_9" "9A" to "STRPNE_9A" "9L" to "STRPNE_9L" "9N" to "STRPNE_9N" "9V" to "STRPNE_9V" "NTYP" to "STRPNE_NTYP" "UNK" to "STRPNE_UNK"
	HAEINF MENI PNEU HAEINFAGGR MENIAGGR PNEUAGGR	Gender	Discontinued "UNK" categorical value and "O" remapped to "OTH"
	HAEINFAGGR MENIAGGR PNEUAGGR	AgeGroup	Discontinued "UNK" categorical value
		SubjectCode	"AGGRVPD" value remapped to "HAEINFAGGR" / "MENIAGGR" / "PNEUAGGR"
	HAEINFAGGR PNEUAGGR	CaseClassification	Discontinued "UNK", "POSS" and "PROB" categorical values
	MENIAGGR	CaseClassification	Discontinued "UNK" categorical value
2023	MENI	ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	Update coded values once a year or upon request from the following list: http://neisseria.org/nm/typing/tessy/
2022	MENI	ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	Update coded values once a year or upon request from the following list: http://neisseria.org/nm/typing/tessy/
2021	MENI	ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	Update coded values once a year or upon request from the following list: http://neisseria.org/nm/typing/tessy/
		ReportedEMERTII	New variable: Describe if the isolate related to the case was reported to EMERT II

2020	MENI	ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	Update coded values once a year or upon request from the following list: http://neisseria.org/nm/typing/tessy/
	MENIISO	DateUsedForStatistics	Change to date format to allow other date formats like: yyyy, yyyy-Qq, yyyy-mm, yyyy-Www, yyyy-mm-dd
2019	MENI	ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	Update coded values once a year or upon request from the following list: http://neisseria.org/nm/typing/tessy/
	MENIISO	New record type added	
2018	MENI	ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	Update coded values once a year or upon request from the following list: http://neisseria.org/nm/typing/tessy/
2017	MENI	ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	Update coded values once a year or upon request from the following list: http://neisseria.org/nm/typing/tessy/
2016	HAEINF	Specimen1; Specimen2; Pathogen	Variables dropped
		TestMethod1; TestMethod2; Age; ClinicalPresentation	Description changed
		DateLastVaccDose	Variable added
		Classification	Coded value 'PROB' removed, as EU case definition disease does not include probable cases
	MENI	TestMethod1; TestMethod2; ResultPorA1; ResultPorA2; ResultMLST	Description changed
		ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	The available coded values for all fine typing variables were updated from http://neisseria.org/nm/typing/tessy/
		DateLastVaccDose	Variable added
		Pathogen	Variable dropped
	PNEU	Specimen; DateOfSpecimen	Variables dropped
		TestMethod1; TestMethod2; VaccType	Description changed
		DateLastVaccDose	Variable added
		ClinicalPresentation	The coded values were edited. 'Bacteraemia' was replaced with 'Septicaemia', and 'Meningitis' was split into 'Meningitis' and 'Meningitis and Septicaemia'.
2015	HAEINF MENI PNEU	EpiLink; ClinicalCriteria; Labresult	Variables dropped
	HAEINF	ClinicalPresentation; VaccinationStatus	Description changed
	HAGGR	All variables	Record type removed
	MENI	ClinicalPresentation; VaccinationStatus	Description changed
		Specimen1; Specimen2	Variables dropped
		Serogroup	The coded value W135 was replaced with W
		ResultFetVR; ResultPorA1; ResultPorA2; ResultMLST	The available coded values for all fine typing variables were updated from http://neisseria.org/nm/typing/tessy/
	PNEU	ClinicalPresentation; Classification; VaccinationStatus	Description changed
2014	MENI	MIC_CIP; MIC_CTX; MIC_PEN; MIC_RIF	Variables dropped
		SIR_CIP; SIR_CTX_CFX; SIR_PEN; SIR_RIF; ResultMICValueCIP; ResultMICValueCTX_CFX; ResultMICValuePEN; ResultMICValueRIF	Variables added

Annex 2. IBD-specific material

IBD data reporting frequency

The surveillance data for the IBDs (invasive *H. influenzae* disease, invasive meningococcal disease and invasive pneumococcal disease) should be uploaded **annually**. In 2024, uploaded data will relate to cases with date used for statistics in 2023.

The deadline for uploading all data for invasive *H. influenzae* disease, invasive meningococcal disease, and invasive pneumococcal disease is 15 October 2024.

As per the case definition for invasive meningococcal disease: possible, probable and confirmed cases should be reported. For invasive *H. influenzae* disease and invasive pneumococcal disease, the case definition requires only confirmed cases to be reported. See below for further details of the case definition for each disease.

It is also possible to update case information retrospectively, i.e. for cases reported in previous years with a date used for statistics prior to 2023. For all diseases, any update of previously reported cases should be done before the reporting deadline in order for data to be included in the annual epidemiological report and surveillance atlas.

Once the data are validated by the disease experts at ECDC, they are then made publicly available on the *Surveillance Atlas of Infectious Diseases* and through *annual surveillance reports* on the ECDC website.

Reporting of meningococcal disease isolates (MENIISO)

ECDC recently launched a project for genomic-based EU/EEA surveillance for invasive meningococcal disease, in which Member States submit genomic data from linked *N. meningitidis* isolates to the European Meningococcal Epidemiology in Real Time II (EMERT-II), for sequence analysis and definition of sequence-derived isolate characterisation data and nomenclature. Sequence-derived data are then imported to Epipulse Cases and linked to the case-based epidemiological data for integrated analysis. Data visualisation and joint interpretation are conducted and presented in EpiPulse.

In preparation of this genomic surveillance, in 2019 a subject called "*Neisseria Meningitidis* Isolate" and a new record type (MENIISO) were created to capture information on the WGS (whole genome sequence) typing of *Neisseria meningitidis* submitted to the EMERT II database. The MENIISO records hold the sequence-derived data imported from EMERT-II, as well as information on relevant dates for cases, and country of the submitting user, and the EMERT-II ID.

To facilitate linkage of the MENI and MENIISO datasets, two variables were added to the MENI subject code: IsolateId and ReportedEMERTII. The IsolateId variable is used in the linking of a MENI record (with epidemiological and microbiological characterisation data) with a MENIISO record (with genomic data). The variable "ReportedEMERTII" is used to include information on whether the isolate related to the case has been reported in EMERT-II.

The specificities of MENIISO data collection are included in a separate reporting protocol "Protocol for genomic-based EU/EEA surveillance of invasive meningococcal disease" which is available in the Epipulse platform.

During the pilot phase, ECDC encourages data submission as close to real time as possible, for both the genomic and epidemiological data. If epidemiological data aimed to be submitted directly to Epipulse Cases is not available, genomic data could be reported to EMERT-II and epidemiological data submitted at the earliest convenience.

In the event of an investigation of a signal detected from molecular typing data, Member States may be asked to submit relevant and selected epidemiological information to EpiPulse or Epipulse Cases for the cases included in the signal to ECDC for EU-level analysis.

Starting in September 2023, a monthly cluster analysis will be done at the end of each month, with the clusters being refreshed in the EpiPulse molecular typing tool.

Narrative information

Changes over time in the number of cases reported in a surveillance system do not always reflect true changes in the incidence of disease. New reporting practices, improved laboratory capacities and changes in legislation are some of the factors that can influence the number of cases reported. It is important to be aware of such "surveillance artefacts" when analysing surveillance data and countries are encouraged to describe changes in the surveillance environment that may impact on the number of cases reported. It is equally important to report if the surveillance environment has remained the same from one year to the next. We encourage reporting countries to provide this information at the same time as data submission to TESSy and to *VPD.VPD@ecdc.europa.eu*.

Invasive *H. influenzae* disease data collection and case definitions

Prior to 2007, data on invasive disease caused by *H. influenzae* were collected by The European Union Invasive Bacterial Infections Surveillance Network (EU-IBIS) and subsequently transferred to The European Surveillance System (TESSy).

From 2018, confirmed cases should be reported according to the following 2018 EU case definition[5]:

Clinical criteria

Not relevant for surveillance purposes

Laboratory criteria

At least one of the following two:

— Isolation of *Haemophilus influenzae* from a normally sterile site

— Detection of *Haemophilus influenzae* nucleic acid from a normally sterile site

Epidemiological criteria

Not applicable

Case classification

A. Confirmed case**:** Any person meeting the laboratory criteria

Previous versions of the case definition were published in 2012, 2008 and 2002. The 2018, 2012 and 2008 EU case definitions are identical and differ from the 2002 case definition in (i) their specification of invasive *H. influenzae* type b (Hib), and (ii) definition of possible and probable cases.

[5]Commission Implementing Decision 2018/945/EU of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.

Invasive meningococcal disease data collection and case definitions

Prior to 2007, data on IMD were collected by The European Union Invasive Bacterial Infections Surveillance Network (EU-IBIS) and subsequently imported into The European Surveillance System database (TESSy).

From 2018, cases (possible, probable and confirmed) should be reported according to the following 2018 case definition[6]:

Clinical criteria

Any person with at least one of the following symptoms:

— Meningeal signs

— Haemorrhagic rash

— Septic shock

— Septic arthritis

Laboratory criteria

At least one of the following four:

— Isolation of *Neisseria meningitidis* from a normally sterile site, or from purpuric skin lesions

— Detection of *Neisseria meningitidis* nucleic acid from a normally sterile site, or from purpuric skin lesions

— Detection of *Neisseria meningitidis* antigen in CSF

— Detection of gram-negative stained diplococcus in CSF

Epidemiological criteria

An epidemiological link by human-to-human transmission

Case classification

A. Possible case: Any person meeting the clinical criteria

B. Probable case: Any person meeting the clinical criteria and with an epidemiological link

C. Confirmed case: Any person meeting the laboratory criteria

Previous versions of the case definition were published in 2002, 2008 and 2012. The EU case definitions of 2018 and 2012 differ in the clinical criteria; in 2018 fever was removed, and petechial rash was replaced with haemorrhagic rash. In 2008, the case definition removed (from the 2002 definition) reporting of a probable case when *N. meningitidis* was identified from a non-sterile site. From 2008 onwards, only isolations from sterile sites are to be considered for reporting.

[6]Commission Implementing Decision 2018/945/EU of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.

Invasive pneumococcal disease data collection and case definitions

Data on IPD have been reported by the EU/EEA Member States from 2010, when enhanced surveillance of IPD was first implemented on a European level and the majority of Member States began reporting case-based data from national reference laboratories.

From 2018, confirmed cases should be reported according to the following 2018 EU case definition[7]:

Clinical criteria

Not relevant for surveillance purposes.

Laboratory criteria

At least one of the following three:

— Isolation of *Streptococcus pneumoniae* from a normally sterile site

— Detection of *Streptococcus pneumoniae* nucleic acid from a normally sterile site

— Detection of *Streptococcus pneumoniae* antigen from a normally sterile site

Epidemiological criteria

Not applicable

Case classification

A. Possible case – Not applicable

B. Probable case – Not applicable

C. Confirmed case – Any person meeting the laboratory criteria

Antimicrobial resistance

The results of antimicrobial susceptibility tests must be reported according to the methods and criteria* agreed between ECDC and Member States as specified by ECDC's European Antimicrobial Resistance Surveillance Network (EARS-Net)

* The criteria for reporting are published each year as part of the Antimicrobial resistance (AMR) reporting protocol. See: TESSy Antimicrobial resistance (AMR) reporting protocol 2023. European Antimicrobial Resistance Surveillance Network (EARS-Net).

Previous versions of the case definition were published in 2002, 2008 and 2012. The 2018 and 2012 case definitions do not differ with the exception of the note on antimicrobial resistance, which was added to the 2018 case definition. The 2012 and 2008 case definitions were identical but differed from the 2002 EU case definition. The 2002 EU case definition included possible and probable cases, and considered detection of *S. pneumoniae* antigen from a normally sterile site a probable case.

[7] Commission Implementing Decision 2018/945/EU of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.