

TESSy - The European Surveillance System

Vaccine Preventable Diseases (VPD) Reporting Protocol 2019

Diphtheria, Invasive *H. influenzae* Disease, Invasive Meningococcal disease, Invasive Pneumococcal Disease, Pertussis, Measles, Mumps, Poliomyelitis, Rubella and Tetanus Surveillance data for 2018 (2019 for measles and rubella)

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Introduction

This reporting protocol is for the 2019 data call for vaccine preventable diseases (VPD) surveillance. This data call covers cases diagnosed in 2018 for diphtheria, invasive *H. influenzae* disease, invasive meningococcal disease, invasive pneumococcal disease, pertussis, mumps, poliomyelitis and tetanus whereas for measles and rubella, the monthly data collection covers cases diagnosed in 2019. The separate reporting protocol for invasive bacterial diseases was discontinued in 2016 and the meningococcal, pneumococcal disease and *Haemophilus influenzae* invasive diseases are now included in the VPD Reporting Protocol.

ECDC's Reporting Protocols are data collection guidelines for reporting countries' data managers, and the design is intended to ensure user-friendliness by:

- Introducing a uniform structure to make it easier for data managers to find data collection information across different subjects.
- Removing information not relevant to data managers.

Because reporting countries' data managers sometimes play multiple roles, it is sometimes relevant to distribute subject-specific material together with a Reporting Protocol. To maintain the uniform structure, this sort of material is now included in *Annex 2*.

How to use this document

This Reporting Protocol provides information for reporting countries' data managers in three main sections:

- Reporting to TESSy contains guidelines on how to prepare data for submission to TESSy, deadlines, subject-specific information (e.g. new changes to metadata), and links to further information.
- Annex 1 contains:
 - o A history of metadata changes for the subject(s) covered by this Reporting Protocol.
 - The metadata set for the subject(s) covered by this Reporting Protocol.
- Annex 2 contains subject-specific material relevant for distribution with the Reporting Protocol, for example:
 - o Guidelines for data collection in the field.
 - o Abbreviations.

Finding further information

Paragraphs denoted by the information icon tell where you can find further information.

Updated links to all the schedules, documentation and training materials mentioned in this Reporting Protocol are included in the *TESSy document section*, including:

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

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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 complies 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

1 The latest data collection schedule is available in the TESSy website.

The deadline for the submission of all VPD data, with the exception of measles and rubella, is 15 October 2019. The deadline for the reporting of data on measles and rubella is the 25th of each month (reporting data up to the end of the previous month). See also VPD reporting frequency on page 18.

Preparing data

After you have exported the data from your national database, you need 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 requirements for the data to be 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 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 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.

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.

A single metadata set 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 that apply to these fields.

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.

1n-depth information on the data source variables is available in the TESSy user documentation.

Submitting your data

Data is submitted through the TESSy web interface (go to **Upload**).



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 you file has been validated and you are satisfied that all corrections have been made, please ensure prompt approval – unapproved uploads can block the approval of other uploads.

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

TESSy HelpDesk

Email: TESSy@ecdc.europa.eu

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

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

Changes to current VPD metadata

The previous metadata changes are described in *Annex 1*.

Information on changes to the metadata for other subjects is available on the TESSy documentation website.

Variables	Description	Validation rule
ResultFetVR, ResultPorA1, ResultPorA2, ResultMLST	Update coded value lists for the variables ResultFetVR, ResultPorA1, ResultPorA2, ResultMLST – the new codes added from the list: http://neisseria.org/nm/typing/tessy/	
ClinicalCriteria	Add variable	(Error) if not completed when Classification is 'CONF' and VaccStatus' is not 'NOTVACC' and 'VaccStatus' is not 'UNK'
ClinicalCriteria; Classification; VaccStatus	Add validation rule	(Error) if ClinicalCriteria is not 'Yes', 'No' or 'UNK', if Classification is 'CONF' and VaccStatus' is not 'NOTVACC' and 'VaccStatus' is not 'UNK'
Classification; ResultIgG; ResultIgM; ResultVirDetect	Add validation rule	(Error) If Classification is 'CONF' and (ResultVirDetect is not 'POS' or ResultIgM is not 'POS' or ResultIgG is not 'POS')
		Validation message: Confirmed cases should have evidence of laboratory confirmation, so should be 'POS' for at least one of ResultVirDetect, ResultIgM or ResultIgG
	ResultFetVR, ResultPorA1, ResultPorA2, ResultMLST ClinicalCriteria ClinicalCriteria; Classification; VaccStatus Classification; ResultIgG;	ResultFetVR, ResultPorA1, ResultPorA2, ResultMLST Update coded value lists for the variables ResultFetVR, ResultPorA1, ResultPorA2, ResultMLST – the new codes added from the list: http://neisseria.org/nm/typing/tessy/ ClinicalCriteria ClinicalCriteria; Classification; VaccStatus Add validation rule Classification; ResultIgG; Add validation rule

Note: the above changes to measles were implemented following discussion at the Advisory Forum in September 2018 about modified measles. Vaccinated, laboratory confirmed cases must have the Clinical criteria field completed. The intention is to be able to identify modified measles cases, i.e. that are vaccinated and laboratory confirmed but don't meet the entire clinical criteria of the EU case definition.

Annex 1 VPD metadata

This section describes:

- The VPD metadata set
- Changes to the VPD metadata

VPD metadata set

Current record type versions

 ${\sf Table\ 1\ shows\ the\ record\ type\ versions\ to\ be\ used\ when\ reporting\ 2018\ VPD\ surveillance\ data\ to\ TESSy.}$

We strongly encourage **case-based reporting**.

If case-based data are not available, aggregated data may be reported.

Table 1: VPD record type versions

Disease	Case-based record type version	Aggregated record type version
Diphtheria	DIPH.8	AGGR.1
Invasive Haemophilus influenzae disease	HAEINF.7	AGGR.1
Measles	MEAS.7	AGGRVPD.1
Invasive meningococcal disease	MENI.11	AGGR.1
Mumps	MUMP.5	AGGRVPD.1
Pertussis	PERT.5	AGGRVPD.1
Invasive pneumococcal disease	PNEU.5	AGGR.1
Polio	POLI.5	AGGR.1
Rubella	RUBE.6	AGGRVPD.1
Tetanus	TETA.5	AGGR.1
Neisseria Meningitidis Isolates (Molecular surveillance)	MENIISO.1	

Comment: An **aggregated format** called "**AGGRVPD**" has been available for measles, mumps, pertussis and rubella since 2013. This format is the same as the "AGGR" format, but with "Vaccination Status" as an additional variable. This variable is not compulsory.

Aggregated reporting

Please refer to Table 1 to see the format for aggregated reporting for each disease.

If only a few variables can be reported, it is recommended to give the following priority for reporting: AgeClass, Classification, VaccStatus, Gender.

When reporting age the age classes listed in Table 2 (first preference) or Tables 3 and 4 (second preference for measles, rubella, mumps and pertussis only) should be used.

Table 2: Categories compatible with VPD reports, ECDC Annual Epidemiological Report and the Surveillance Atlas of Infectious Diseases for all VPDs

Narrative description	Variable	Coded value in TESSy of the variable AgeClass
<1 year	AgeClass	0
1-4 years	AgeClass	01-04
5-9 years	AgeClass	05-09
10-14 years	AgeClass	10-14
15-19 years	AgeClass	15-19
20-24 years	AgeClass	20-24
25-29 years	AgeClass	25-29
30-34 years	AgeClass	30-34
35-39 years	AgeClass	35-39
40-44 years	AgeClass	40-44
45-49 years	AgeClass	45-49
50-54 years	AgeClass	50-54
55-59 years	AgeClass	55-59
60-64 years	AgeClass	60-64
65 and over	AgeClass	65+

Alternative categories (option 1) for measles, rubella, mumps and pertussis

Table 3: Alternative categories (option 1) compatible with VPD reports, the ECDC Annual Epidemiological Report and the Surveillance Atlas of Infectious Diseases for <u>measles, rubella, mumps and pertussis only</u>

Narrative description	Variable	Coded value in TESSy of the variable AgeClass
<1 year	AgeClass	0
1-4 years	AgeClass	01-04
5-9 years	AgeClass	05-09
10-14 years	AgeClass	10-14
15-19 years	AgeClass	15-19
20-24 years	AgeClass	20-24
25-29 years	AgeClass	25-29

Alternative categories 2 for measles, rubella, mumps and pertussis

Table 4: Alternative categories (option 2) compatible with VPD reports, the ECDC Annual Epidemiological Report and the Surveillance Atlas of Infectious Diseases for <u>measles, rubella, mumps</u> and pertussis only

Narrative description	Variable	Coded value in TESSy of the variable AgeClass
<1 year	AgeClass	0
1-4 years	AgeClass	01-04
5-9 years	AgeClass	05-09
10-14 years	AgeClass	10-14
15-19 years	AgeClass	15-19
20-29 years	AgeClass	20-29
30 and over	AgeClass	30+

VPD metadata change history

Metadata changes prior to 2014 can be found on the TESSy documents website.

2018 VPD metadata changes

Subject	Description
MENI	Update coded value lists for the variables ResultFetVR, ResultPorA1, ResultPorA2, ResultMLST – the new codes added from the list: http://neisseria.org/nm/typing/tessy/
MEAS	 The variable 'ClinicalCriteria' was reactivated for use in the event of vaccinated cases with classification 'CONF'; whether these cases met the clinical criteria of the EU case definition should be recorded here. A new validation rule was added for 'Classification', 'ResultIgG', 'ResultIgM' and 'ResultVirDetect' so that cases with classification 'CONF' should also have at least one positive laboratory marker.

2017 VPD metadata changes

Table 4: Summary of implemented changes in case-based record types for VPD in 2017

Subject	Description
All diseases	The description of the variable 'DateLastVaccDose' was updated to specify that the date given should be the date of last dose before disease onset.

Subject	Description
Diphtheria	 The validation rules regarding the variables 'Classification' and 'Pathogen' were changed to 'error' so that cases with Classification==CONF could not be reported with unknown or missing data on Pathogen.
	 A validation rule (warning) was added for cases reported as Classification==CONF but ClinicalPresentation=="UNK".
	 A validation rule (warning) for cases of Pathogen==ULC with ClinicalPresentation!=CUTA was removed.
	 For the variable 'ClinicalPresentation', the coded value 'NUS' (not under surveillance) was dropped.
	 For the variable 'ClinicalPresentation', the coded values 'CONJ' (conjunctival) and "GEN" (genital) were added.
	The variable 'ClinicalPresentation' was made a mandatory variable.
	The variable `TestMethod' was made a mandatory variable.
	 A validation rule (warning) was added where, for cases reported as Classification==CONF, at least one of TestMethod1 or TestMethod2 must be reported as 'PCR', 'RTPCR', 'ELEK' or 'O'.
Measles	 A validation rule was changed, so that cases reported with ResultVirDetect==POS, must have Classification==CONF or DISCARDED. Previously, these cases could only be reported as Classification==CONF.
Rubella	 A validation rule was changed, so that cases reported with ResultVirDetect==POS, must have Classification==CONF or DISCARDED. Previously, these cases could only be reported as Classification==CONF.
Invasive meningococcal disease	 The available coded values for all fine typing variables (ResultFetVR, ResultPorA1, ResultPorA2, ResultMLST) were updated from http://neisseria.org/nm/typing/tessy/.
Mumps	For the variable `Genotype', the coded value `NA' (not applicable) was added.
Pertussis	 For the variable 'TestMethod', the coded value 'ORALFLUIDIgG' (IgG in oral fluid) was added.

2016 VPD metadata changes

Table 5: Summary of implemented changes in case-based record types for VPD in 2016

Subject	Description
Diphtheria	 The variables `TestMeth1' and TestMeth2' were renamed `TestMethod1' and `TestMethod2', in line with other VPDs. The variable `AgeMonth' was added.
	The description of the variable 'ClinicalPresentation' was edited to match other VPDs.
Invasive H.	The variables `Specimen1' and `Specimen2' were dropped.
<i>influenzae</i> disease	 The description of the variable `TestMethod1' was edited to highlight that this is the laboratory method used on the primary laboratory specimen with a positive result for case confirmation and further characterisation.
	The description of the variable `TestMethod2' was edited to highlight that this is the laboratory method used on the second type laboratory specimen with a positive result (if taken) for diagnosis or further characterisation.
	The description of the variable 'Age' was edited to match other VPDs.
	The coded value 'PROB' was removed from the variable 'Classification', as the EU case definition for invasive <i>H. influenzae</i> disease does not include probable cases
	 The validation rule and message, warning if cases were reported as Classification is not 'UNK', and ClinicalPresentation is 'EPIG' were removed.
	The variable 'DateLastVaccDose' was added.
	The variable 'Pathogen' was dropped.
	The description of the variable 'ClinicalPresentation' was edited to match other VPDs.

Subject	Description
Invasive meningococcal disease	 The description of the variable 'TestMethod1' was edited to highlight that this is the laboratory method used on the primary laboratory specimen with a positive result for case confirmation and further characterisation.
	 The description of the variable 'TestMethod2' was edited to highlight that this is the laboratory method used on the second type laboratory specimen with a positive result (if taken) for diagnosis or further characterisation.
	The descriptions of the variables `ResultPorA1', `ResultPorA2' and `ResultMLST' were edited to improve clarity.
	The available coded values for all fine typing variables (ResultFetVR, ResultPorA1, ResultPorA2, ResultMLST) were updated from http://neisseria.org/nm/typing/tessy/
	The variable `DateLastVaccDose' was added.
	The variable 'Pathogen' was dropped.
Invasive	The variables 'Specimen' and 'DateOfSpecimen' were dropped.
pneumococcal disease	 The description of the variable `TestMethod1' was edited to highlight that this is the laboratory method used on the primary laboratory specimen with a positive result for case confirmation and further characterisation.
	The description of the variable `TestMethod2' was edited to highlight that this is the laboratory method used on the second type laboratory specimen with a positive result (if taken) for diagnosis or further characterisation.
	 The coded values for the variable 'ClinicalPresentation' were edited. 'Bacteraemia' was replaced with 'Septicaemia', and 'Meningitis' was split into 'Meningitis' and 'Meningitis' and Septicaemia'.
	The variable 'DateLastVaccDose' was added.
	The description of the variable 'VaccType' was edited to improve clarity.
Mumps	The description of the variable 'ClinicalPresentation' was edited to match other VPDs.
Polio	The variable 'DateLastVaccDose' was added.
Tetanus	The variable 'DateLastVaccDose' was added.

2015 VPD metadata changes

General note:

Please be aware that since metadataset 27 (15.03.2013) additional coded values were added to the variable 'Specimen' for **invasive pneumococcal disease**. These additional coded values included; JOINT = Joint fluid, O = Other (any other sterile site), PERIT = Peritoneal fluid and PLEURAL = Pleural fluid. This change was not noted in the reporting protocol at the time.

Table 5: Summary of implemented changes in case-based record types for VPD in 2015

Subject	Description
All diseases	The variables EpiLink, ClinicalCriteria and Labresult were removed.
Diphtheria	The description of the variable 'Classification' was edited to ensure consistency with the EU case definition.
	The RecordType 'HAGGR' was removed.
	The variable `DateLastVaccDose' was added.
	Two new coded values were added to the variable 'Pathogen'. The coded value were PSEU=Corynebacterium pseudotuberculosis and NUS = Not under surveillance. This change reflects the update of the case definition in 2012.
Invasive H.	The description of the variable 'Clinical Presentation' was edited to improve clarity.
<i>influenzae</i> disease	The description of the variable 'Vaccination Status' was edited to include the text 'against serotype b'.
	The RecordType 'HAGGR' was removed.

Subject	Description
Invasive meningococcal disease	 The description of the variable 'Clinical Presentation' was edited to improve clarity. The variables 'Specimen1' and 'Specimen2' were dropped. The description of the variable 'Vaccination Status' was edited to include the text 'against the serogroup of meningococcus that was the cause of his/her infection'. In the variable 'Serogroup' the coded value W135 was replaced with W, due to a recent reclassification. The RecordType 'HAGGR' was removed. The available coded values for all fine typing variables were updated from http://neisseria.org/nm/typing/tessy/
Invasive pneumococcal disease	 The description of the variable 'Clinical Presentation' was edited to improve clarity. The description of the variable 'Classification' was edited to ensure consistency with the EU case definition. The description of the variable 'Vaccination Status' was edited to include the text 'if vaccine series was initiate with a vaccine different than the last one, indicate last vaccine of the series'. The RecordType 'HAGGR' was removed.
Measles	 The description and coded values for the variable 'Imported' were edited to ensure consistency with the Surveillance Guidelines for measles, rubella and congenital rubella syndrome in the WHO European Region1. The description of the variable 'Classification' was edited to ensure consistency with the EU case definition.
Mumps	 The description of the variable 'Classification' was edited to ensure consistency with the EU case definition. The variable 'Genotype' was added.
Pertussis	The description of the variable 'Classification' was edited to ensure consistency with the EU case definition.
Rubella	 The description and coded values for the variable 'Imported' were edited to ensure consistency with the Surveillance Guidelines for measles, rubella and congenital rubella syndrome in the WHO European Region1. The description of the variable 'Classification' was edited to ensure consistency with the EU case definition.

2014 VPD metadata changes

General note:

The description of the coding for DOSEUNK (VaccStatus variable) was changed in the 2014 metadata for Measles, Mumps, Rubella, Pertussis, and Diphtheria. The name of the DOSEUNK coding was changed from "Unknown number of doses" to "Vaccinated with unknown number of doses". This modification did not imply any operational change during data upload.

Table 6: Summary of implemented changes in case-based record types for VPD in 2014

Subject	Description
MENI	The following variables were removed: • MIC_CIP • MIC_CTX • MIC_PEN • MIC_RIF The following variables should be used from now onwards: • ResultMICValueCIP • ResultMICValueCTX_CFX • ResultMICValuePEN • ResultMICValueRIF

Subject	Description
MENI	The following variables were added: SIR_CIP SIR_CTX_CFX SIR_PEN SIR_RIF
MENI, HAEINF	The requirements for the following variables were decreased: • Specimen1 • Specimen2 • LabMethod1 • Labmethod2
MENI, HAEINF	Validation rules were removed for the following variables: • Specimen1 • Specimen2 • LabMethod1 • Labmethod2
PNEUMO	A validation rule was updated: (Warning) If ClinicalPresentation is 'MENI' and Specimen is not CSF and Specimen is not UNK Message: If Clinical presentation is MENI, then Specimen should be CSF or UNK. Change to: (Warning) If ClinicalPresentation is 'MENI' and Specimen is not CSF and Specimen is not BLOOD and Specimen is not UNK Message: If Clinical presentation is MENI, then Specimen should be CSF or BLOOD or UNK.
All VPD	Improve description of vaccination status coded value list
All	Update NUTS codes according to the NUTS Codes 2010 classification from EUROSTAT

References

- 1. Surveillance guidelines for measles, rubella and congenital rubella syndrome in the WHO European Region, update December 2012. http://www.euro.who.int/en/health-topics/communicable-diseases/measles-and-rubella/publications/2012/surveillance-guidelines-for-measles,-rubella-and-congenital-rubella-syndrome-in-the-who-european-region,-update-december-2012
- 2. Renewed commitment to measles and rubella elimination and prevention of congenital rubella syndrome in the WHO European Region by 2015. Regional Committee for Europe. Sixtieth session. Moscow, 13–16 September 2010. http://www.euro.who.int/_data/assets/pdf_file/0008/119546/RC60_edoc15.pdf
- 3. Guidelines for measles and rubella outbreak investigation and response in the WHO European Region, 2013. http://www.euro.who.int/__data/assets/pdf_file/0003/217164/OutbreakGuidelines-updated.pdf
- European Centre for Disease Prevention and Control. Long-term surveillance strategy 2014–2020. Stockholm: ECDC; 2013. http://www.ecdc.europa.eu/en/publications/Publications/long-term-surveillance-strategy-2014-2020.pdf
- 5. WHO Vaccine-Preventable Diseases Surveillance Standards, Measles, update 15 October 2018. https://www.who.int/immunization/monitoring_surveillance/burden/vpd/WHO_SurveillanceVaccinePreventable 11 Measles R2.pdf
- 6. Manual for the Laboratory-based Surveillance of Measles, Rubella, and Congenital Rubella Syndrome. https://www.who.int/immunization/monitoring_surveillance/burden/laboratory/manual_chapter8/en/

Annex 2 VPD-specific material

Case definitions

Countries are encouraged to use the 2018 EU case definitions for the 2019 data collection. The case definitions for measles, rubella, pertussis, poliomyelitis, tetanus remain the same as in the 2008 edition/version of the EU case definitions, while the case definitions for diphtheria and mumps have been updated (see paragraph *Changes in 2012 EU case definitions as compared to 2008* on page 20).

An updated case definition for pertussis has been proposed and is currently going through the European Commission's approval process. No major changes in the metadata in relation to this new case definition are envisaged.

For a list of 2018 EU Case Definitions, see:

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D0945&from=EN or https://ecdc.europa.eu/en/surveillance-and-disease-data/eu-case-definitions

VPD reporting frequency

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.

In 2019, the surveillance data of the VPD that will be uploaded into TESSy will relate to cases with date used for statistics in 2018, except for measles and rubella (see below).

(New) reporting of meningococcal disease isolates: deadline to be updated

As of 14 March 2019, a new record type was created in order to capture information on the WGS (whole genome sequence) typing of *Neisseria meningitidis*. However the specificities as well as the timeframe of such data collection is still under finalization and will be included in a separate reporting protocol and summarized here when these are available.

Annual reporting: deadline 15 October 2018

Invasive *H. influenzae disease*, invasive meningococcal disease and invasive pneumococcal disease (enhanced surveillance)

Data should be uploaded annually. Possible, probable and confirmed cases should be reported for invasive meningococcal disease. Confirmed cases only should be reported for invasive *H. influenzae* disease and invasive pneumococcal disease.

Mumps and pertussis

Data should be uploaded annually. Possible, probable and confirmed cases should be reported.

Diphtheria

Cases should be reported on a monthly basis as they are identified. An annual data call will still be carried out in order to finalise datasets for the previous year for use in the annual epidemiological report. In the annual data call it will also be necessary to report "zero cases" if no cases have occurred.

Once the data are checked by the disease experts at ECDC, they are made publically available on the *Surveillance Atlas of Infectious Diseases* with a choice of weekly, monthly and annual temporal resolution, and through annual surveillance reports on the ECDC website.

Polio and tetanus

Polio data should be uploaded annually. Confirmed cases should be reported, including "zero cases".

Tetanus data should be uploaded annually. Probable and confirmed cases should be reported.

Monthly reporting: deadline 25th of each month

Measles and Rubella (enhanced surveillance)

Measles and rubella surveillance data should be uploaded to TESSy on a monthly basis. The deadline for upload is the 25th of each calendar month, and the data to be uploaded is up to the end of the previous calendar month. On the morning of the 26th of each month, the dataset available in TESSy is validated by disease experts at ECDC and forwarded to the WHO Regional Office for Europe.

Once the data are checked by the disease experts at ECDC, they are then made publically available on the *Surveillance Atlas of Infectious Diseases*, with a choice of monthly and annual temporal resolution and through *monthly* and *annual surveillance reports* on the ECDC website.

Collection of discarded cases

Possible, probable, confirmed and <u>discarded</u> cases of measles and rubella should be reported to ECDC. The collection of discarded cases is important to monitor progress towards the measles and rubella elimination goal¹⁻³. The metadata variable "Classification" for measles and rubella includes five different values (possible, probable, confirmed discarded and unknown).

Discarded cases are defined according to WHO guidelines¹ as suspected cases which were investigated and discarded either through negative results of adequate laboratory testing for measles/rubella or by an epidemiological link to a laboratory-confirmed case of another disease. Suspected cases are defined as cases with signs and symptoms consistent with the clinical criteria of measles.

Collection of modified measles/cases that don't fully meet the clinical criteria

Please see comments on page 9.

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 TESSV.

Changes in 2018 EU case definitions as compared to 2012

Changes are indicated in red

Rubella

Clinical criteria

Any person with sudden onset of generalised maculo-papular rash

AND

At least one of the following five:

- Cervical adenopathy
- Sub-occipital adenopathy
- Post-auricular adenopathy
- Arthralgia
- Arthritis

Laboratory criteria

At least one of the following four:

- Isolation of rubella virus from a clinical specimen
- Detection of rubella virus nucleic acid in a clinical specimen
- Rubella IgM antibody detection (*)
- Rubella IgG seroconversion or significant rise in rubella IgG antibody titre in paired specimens tested in parallel.

Laboratory results need to be interpreted according to the vaccination status (possible persistence of IgM antibodies upon vaccination).

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 with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria who has not been recently vaccinated. In case of recent vaccination, a person meeting the clinical criteria with detection of wild-type rubella virus strain is considered as a confirmed case.

Note: When rubella in pregnancy is suspected, further confirmation of a positive rubella IgM results is required for case management (for example, a rubella specific IgG avidity test, rubella IgM and comparison of rubella IgG levels on paired sera conducted in a reference laboratory).

(*)In elimination settings, additional testing may be considered in certain situations to exclude false-positive IgM results (WHO Manual for the Laboratory-based Surveillance of Measles, Rubella, and Congenital Rubella Syndrome).

Pertussis

Laboratory Criteria

Any person with a cough lasting at least two weeks AND

- at least one of the following three:
 - Paroxysms of coughing
 - Inspiratory 'whooping'
 - Post-tussive vomiting

OR

Any person diagnosed as pertussis by a physician

OR

Apnoeic episodes in infants

Notes:

All individuals including adults, adolescents or vaccinated children can present with atypical symptoms. Characteristics of cough should be investigate roxysmal in nature, increases during the night and occurs in the absence of fever.

Laboratory Criteria

At least one of the following three:

- Isolation of Bordetella pertussis from a clinical specimen
- Detection of *Bordetella pertussis* nucleic acid in a clinical specimen
- Bordetella pertussis specific antibody response

Direct diagnosis (i)-(ii): *Bordetella pertussis* and its nucleic acid are best isolated/detected from nasopharyngeal samples.

Indirect diagnosis (iii): if possible ELISA should be performed using highly purified Pertussis Toxin and WHO reference sera as a standard. Results need to interpreted according to pertussis vaccination status. If vaccinated within the last few years before specimen collection, the titre of specific antibodies against *Bordetella pertussis* toxin may be a consequence of, or modified by, previous vaccination.

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 with an epidemiological link

C. Confirmed case

Any person meeting the clinical and the laboratory criteria

Streptococcus pneumonia infection, invasive disease

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 NA

Case Classification

- A. Possible case NA
- B. Probable case NA
- 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 European Antimicrobial Resistance Surveillance Network (EARS-Net)

Changes in 2012 EU case definitions as compared to 2008

Changes are indicated in red

Diphtheria

(*Corynebacterium diphtheriae, Corynebacterium ulcerans* and *Corynebacterium pseudotuberculosis*)
Clinical Criteria

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

Classic Respiratory Diphtheria:

An upper respiratory tract illness with laryngitis or nasopharyngitis or tonsillitis AND

an adherent membrane/pseudomembrane

Mild Respiratory Diphtheria:

An upper respiratory tract illness with laryngitis or nasopharyngitis or tonsillitis WITHOUT

an adherent membrane/pseudomembrane.

Cutaneous Diphtheria:

Skin lesion

Diphtheria of other sites:

Lesion of conjunctiva or mucous membranes

Laboratory Criteria

Isolation of toxin-producing *Corynebacterium diphtheriae, Corynebacterium ulcerans* or *Corynebacterium pseudotuberculosis* from a clinical specimen.

Epidemiological Criteria

At least one of the following epidemiological links:

- Human to human transmission
- Animal to human transmission

Case Classification

A. Possible case

Any person meeting the clinical criteria for classical respiratory diphtheria

B. Probable case

Any person meeting the clinical criteria for diphtheria (Classic Respiratory Diphtheria, Mild Respiratory Diphtheria, Cutaneous Diphtheria, Diphtheria of other sites) with an epidemiological link to a human confirmed case or with an epidemiological link to animal to human transmission

C. Confirmed case

Any person meeting the laboratory criteria AND at least one of the clinical forms

Mumps

(Mumps virus)

Clinical Criteria

Any person with

— Fever

AND

At least one of the following three:

- Sudden onset of unilateral or bilateral tender swelling of the parotid or other salivary glands without other apparent cause
- Orchitis
- Meningitis

Laboratory Criteria

At least one of the following three:

- Isolation of mumps virus from a clinical specimen
- Detection of mumps virus nucleic acid
- Mumps virus specific antibody response characteristic for acute infection in serum or Saliva Laboratory results need to be interpreted according to the vaccination status

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 not recently vaccinated and meeting the laboratory criteria

In case of recent vaccination: any person with detection of wild-type mumps virus strain