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TESSy - The European Surveillance System

Hepatitis B and C Reporting Protocol 2019

Surveillance data for 2018

February 2019

Contents

Introduction

This reporting protocol is for the 2019 data call for hepatitis B and C surveillance data for 2018.

ECDC's Reporting Protocols are data collection guidelines for reporting countries' data managers, and the new Reporting 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 not relevant to data managers.

The Reporting Protocols are supplemented by the Technical Annex, which contains updated generic information for each data collection.

Likewise, the Surveillance Protocol will contain some of the generic information previously contained in the Reporting Protocols.

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 1 and 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:
    - The metadata set for the subject(s) covered by this Reporting Protocol.
    - A history of metadata changes for the subject(s) covered by this Reporting Protocol.
- *Annex 2* – contains subject-specific material relevant for distribution with the Reporting Protocol, for example:
    - Guidelines for data collection in the field.
    - Abbreviations.
- *Annex 3* – contains EU case definition for Hepatitis B and C (2012)
- *Annex 4* – contains Implementation of case definitions with StageHEP variable. This variable is based on specific serological markers as outlined in the framework for Enhanced hepatitis B and C Surveillance in Europe

Finding further information

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

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

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

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

Checking the data collection schedule

 An updated link to the current data collections schedule is provided in the *Technical Annex*.

The deadline for the hepatitis B and C data collections is 16 September 2019.

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 to 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.
- *Hepatitis B and C metadata change history* – all preceding changes.

It is especially important to focus on:

- **Field formats**

  Many fields require that data are formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.

- **Coded values**

  Some fields only permit the use of specific values (coded values). For example, **M**, **F**, **UNK**, or **Other** are the coded values for *Gender* and any other value in a *Gender* field will be rejected.

The metadata file contains all the definitions and rules you need to comply with to format your data correctly for every subject (usually a disease). The file can be downloaded as an Excel file from the TESSy documents website.

By filtering the fields in the file by subject, you can see the fields required for your subject and the rules applying to these fields.

The *Technical Annex* provides an overview of how you work with the metadata file, and the TESSy user documentation provides in-depth details on metadata.

Checking your data source profile

Before submitting your file(s), please review the profile for your data source(s) in TESSy (go to **Data Sources**), and update the information, if necessary.

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

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

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

Submitting your data

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

The *Technical Annex* provides an overview of how you submit files to TESSy, and the TESSy user documentation provides in-depth descriptions of all the upload methods.

Finalising your submission

The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process.

The result of your upload – i.e. rejected or validated – is displayed immediately after the conclusion of the check in the **Validation details** webpage. Please review the result carefully:

- If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that you need to correct.
- If your file has been validated, there might be warnings and remarks relating to possible data quality issues or to potential overwriting of existing records that you should consider.

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

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

TESSy HelpDesk

Email: *TESSy@ecdc.europa.eu*

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

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

Changes to current metadata

Several changes have been made to the hepatitis B and C metadata in 2019.

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.

Annex 1 Hepatitis B and C metadata

This section describes:

The hepatitis B and C metadata set

Current record type versions

Table shows the record type versions to be used when reporting 2018 Hepatitis B and C surveillance data to TESSy.

Table 1: Current record version types for Hepatitis B and C

Disease	Case-based record type version	Aggregated record type version
Hepatitis B	HEPB.4	AGGR.1 ; HAGGR.1
Hepatitis C	HEPC.4	AGGR.1 ; HAGGR.1

Table lists the metadata variables for hepatitis B and C.

The common variables apply to reporting case-based data for hepatitis B and C and consist of 17 variables. These variables are described in more detail in Common variables on page 10.

There are 18 disease-specific variables for hepatitis B and C. These variables are described in more detail in Disease-specific variables on page 14.

The variables used for reporting aggregated data include age class, gender, case classification, date used for statistics, reporting country and the number of cases. The hierarchy for aggregated reporting is as follows:

1. Gender
2. Age class

Table 2: Hepatitis metadata variables

Variable Name	Mandatory	Hepatitis B	Hepatitis C
Common variables			
RecordId	Y	√	√
RecordType	Y	√	√
RecordTypeVersion	N	√	√
Subject	Y	√	√
DataSource	Y	√	√
ReportingCountry	Y	√	√
DateUsedForStatistics	Y	√	√
Status	N	√	√
DateOfNotification	N	√	√
DateOfDiagnosis	Y	√	√
PlaceOfResidence	N	√	√
PlaceOfNotification	N	√	√
Age (years)	Y	√	√
Gender	Y	√	√
DateOfOnset	N	√	√
Disease-specific variables			
StageHEP	Y	√	√
CountryOfBirth	N	√	√

Variable Name	Mandatory	Hepatitis B	Hepatitis C
CountryOfNationality	N	√	√
Imported	N	√	√
ProbableCountryOfInfection	N	√	√
Transmission	Y	√	√
OtherProbableTransmission	N	√	√

In the descriptions of the Common variables and Disease-specific variables the following conventions are used:

VariableName Literal name of a variable. This never contains spaces. Case is only used to improve readability.

Coding Code as accepted by the system.

Description of code Description of the meaning of a possible value for a specific variable.

Example: The gender of a case is described in the variable **Gender**, that can have the possible values ***M*** for 'Male', ***F*** for 'Female', ***O*** for 'Other' and ***Unk*** for 'Unknown'.

Common variables

RecordID (mandatory)

The identifier should be provided by the MS. It should be unique (within and across the national surveillance system - per 'Subject – DataSource' combination) and anonymous for each record.

Disease: Hepatitis B

Hepatitis C

Coding: Text (max 80 characters)

Please note that ID must be unique if they are derived from the same national reporting system; records with the same ID will be overwritten.

RecordType (mandatory)

The record type defines the structure and the format of the data reported. The record types are defined by ECDC. It specifies what data values TESSy expects to receive. The record type is related with the 'subject'. Only valid combinations of record type, subject and datasource will be accepted.

Disease: Hepatitis B

Hepatitis C

Coding: HEPB, HEPC

RecordTypeVersion

The version of the record type defines the current structure of the data reported. If the original dataset for any particular disease is changed, the versioning will change according to increasing numbering. All record types started at v1 with the launch of TESSy in 2008. This variable can be omitted if a valid Metadataset is provided. The current record type version for hepatitis B and hepatitis C is 4.

Disease: Hepatitis B

Hepatitis C

Coding: 4

Subject (mandatory)

The subject describes the disease associated to the reported case(s).

Disease: Hepatitis B

Hepatitis C

Coding: Hepatitis B = HEPB

Hepatitis C = HEPC

DataSource (mandatory)

The data source specifies the surveillance system from which the data on this particular disease originates. The list of available Surveillance Systems per country is an integral part of TESSy and will be generated and revised/updated in bilateral collaboration with the nominated contact points for surveillance in each MS.

Disease: Hepatitis B

Hepatitis C

Coding: See list of surveillance systems

TESSy currently contains a list of surveillance systems which has been provided by each MS (variable 'DataSource'). The descriptions of the surveillance systems submitted to TESSy should be kept up to date and will be used to assist with data interpretation. If a MS decides to submit a combined dataset, this should be specified in the 'DataSource' field.

Please note that it is the responsibility of each MS to decide which data best reflect the hepatitis situation in their country and therefore which data should be submitted to TESSy. Each MS will needs to specify the surveillance system from which the data originates through the MAIN contact point for surveillance. It is permissible for countries to combine data from different national surveillance systems and to submit this combined dataset to TESSy.

ReportingCountry (mandatory)

This variable identifies the country that reports the case. The list of countries is provided according to ISO codes. This variable should be included by the MS by default. This is a mandatory variable.

Disease: Hepatitis B

Hepatitis C

Coding: Country = ISO 3166-1 alpha-2, (two-letter code).

DateUsedForStatistics (mandatory)

This is the date used by the national surveillance institute/organisation in the national case-reports and other official statistics. The date used for statistics varies from country to country and could be either the date of diagnosis or the date of notification (or any other date applicable). This is a (technical) compulsory variable and unknown is not allowed. Incomplete dates are allowed as well (quarters, months, years) in case the exact date is not available. For hepatitis B and C, the date of diagnosis will be the main time related variable used in the analysis.

Disease: Hepatitis B

Hepatitis C

Coding: Date = YYYY-MM-DD (preferred), YYYY-MM, YYYY, YYYY-Www or YYYY-Qq

Status

The status is used for updating data; the default is New/Update. By choosing Delete, the selected record (or batch of data) will be marked as inactive, but will remain in TESSy to reconstruct the data for a given date in the past.

Disease: Hepatitis B

Hepatitis C

Coding: NEW/UPDATE

DELETE

DateOfNotification

The date when the case is notified for the first time to the place of notification. Date should be provided or coded as Unknown.

Disease: Hepatitis B

Hepatitis C

Coding: Date = YYYY-MM-DD

Unknown = UNK

Validation rule: Warning if DateOfOnset is after DateOfNotification

Error if DateOfNotification is before DateOfDiagnosis

DateOfDiagnosis (mandatory)

Date of diagnosis refers to the date of first laboratory confirmative diagnosis (either date of specimen taken or date of laboratory confirmation received or date of clinical diagnosis confirmed). For hepatitis B and C, the date of diagnosis will be used for the analysis and the report: for that reason this is a compulsory variable. Date should be provided or coded as Unknown.

Disease: Hepatitis B

Hepatitis C

Coding: Date = YYYY-MM-DD

Unknown = UNK

Validation rule: DateOfDiagnosis for hepatitis B must be after 1965 and for hepatitis C after 1989

PlaceofResidence

The place of residence of the patient at the time of disease onset.

Disease: Hepatitis B

Hepatitis C

Coding: NUTS codes, levels 1 – 3.

Unknown = UNK

PlaceofNotification

The place of first notification of the case to a regional authority.

Disease: Hepatitis B

Hepatitis C

Coding: NUTS codes, levels 1 – 3.

Unknown = UNK

Age (mandatory)

This is the age of the person in years as reported in the national system of the MS. Age can be calculated from date of birth at time of diagnosis.

Disease: Hepatitis B

Hepatitis C

Coding: Age = Num (0-120)

Unknown =UNK

Validation rule: a warning will be sent for a person older than 80 years if StageHEP=Acute

a warning will be sent for a person younger than 16 years if HealthCareWorker=Y

a warning will be sent for a person younger than 16 years if SexWorker=Y

a warning will be sent for a person younger than 16 if Testinglocation=DRUG

a warning will be sent for a person younger than 16 if Testinglocation=PRIS

a warning will be sent for a person younger than 10 if Testinglocation=ANC

Gender (mandatory)

This is the gender of the infected person. Transsexuals should be classified as other.

Disease: Hepatitis B

Hepatitis C

Coding: Male = M

Female = F

Other = O

Unknown =UNK

Validation rule: If reported transmission category is men who have sex with men (Transmission = MSM), then Gender should be male (M)

a warning will be sent if Gender=M and Testinglocation=ANC

DateOfOnset

The date of onset of disease is the day that first symptoms appeared. For most chronic cases of hepatitis B and C this will be recorded as 'unknown'.

Disease: Hepatitis B

Hepatitis C

Coding: Date = YYYY-MM-DD

Unknown = UNK

Validation rule: DateOfDiagnosis cannot be before DateOfOnset

DateOfNotification cannot be before DateOfOnset

Disease-specific variables

StageHEP (mandatory)

The stage of infection at the time of diagnosis.

Disease: Hepatitis B
Hepatitis C

Coding: ACUTE
CHRONIC
UNKNOWN

Validation rule: a warning will be sent for a person older than 80 years if StageHEP=Acute

CountryOfBirth

The country where the patient was born.

Disease: Hepatitis B
Hepatitis C

Coding: Country ISO 3166-1 alpha 2
Unknown = UNK

CountryOfNationality

The country where the patient is registered as a citizen.

Disease: Hepatitis B
Hepatitis C

Coding: Country ISO 3166-1 alpha 2
Unknown = UNK

Imported

Is the infection likely to have been acquired outside the reporting country?

Disease: Hepatitis B
Hepatitis C

Coding: Yes = Y
No = N
Unknown = UNK

ProbableCountryOfInfection

The country(ies) where infection of the patient is likely to have occurred. If both country and region are known it is recommended to enter the country.

Disease: Hepatitis B
Hepatitis C

Coding: Country ISO 3166-1 alpha 2
Unknown = UNK

Please note that this is a repeatable variable; if a patient has visited multiple countries and the most likely country of infection is unknown, the variable should be repeated with all known countries.

Transmission (mandatory)

This variable specifies the most probable route of transmission. If the national system collects sexual orientation data the variable should be coded as Men who have Sex with Men (MSM) if the case is a homosexual male or bisexual male. If the case is a heterosexual male or female the variable should be coded as "heterosexual contact". If the national system collects information on the gender of partners the variable should be coded as MSM if the case is male and has had one or more male sexual partners. For congenitally acquired cases the variable should be coded as "Mother-to-child transmission".

Disease: Hepatitis B

Hepatitis C

Coding: MSM/homo or bisexual male = MSM
Heterosexual contact = HETERO
Sexual transmission (unspecified) = SEX
Mother-to-child transmission = MTCT
Household contact of chronic case = HOUSE
Injecting drug use = IDU
Nosocomial transmission (includes hospital, nursing home, psychiatric institutions, dental) = NOSO
Any occupational exposure (includes needle stick injuries among healthcare workers)= OCCUP
Non-occupational exposures (community needle stick injuries, bites, tattoos, piercings)= NONOCCUP
Blood and blood products = BLOOD
Organ and tissues = TRANSPLANT
Heamodialysis = HAEMO
Through selling sex = SEXWORK
Other (transmission route is known, but is not mentioned in the list) = O
Unknown = UNK

Validation rule: if MSM is selected, gender should be Male.

a warning will be sent if OCCUP is selected for a person younger than 16

OtherProbableTransmission

This variable specifies other possible routes of transmission in addition to the most probable route. More than one category may be selected (repeatable variable).

Disease: Hepatitis B
Hepatitis C

Coding: MSM/homo or bisexual male = MSM
Heterosexual contact = HETERO
Sexual transmission (not unspecified) = SEX
Mother-to-child transmission = MTCT
Household contact of chronic case = HOUSE
Injecting drug use = IDU
Nosocomial transmission (includes hospital, nursing home, psychiatric institutions, dental) = NOSO
Any occupational exposure (includes needle stick injuries among healthcare workers)= OCCUP
Non-occupational exposure (community needle stick injuries, bites, tattoos, piercings)= NONOCCUP
Blood and blood products = BLOOD
Organ and tissues = TRANSPLANT
Heamodialysis = HAEMO

Through selling sex = SEXWORK
Other (transmission route is known, but is not mentioned in the list) = O

Validation rule: if MSM is selected, gender should be Male.

a warning will be sent if OCCUP is selected for a person younger than 16

Annex 1 Hepatitis B and C metadata change history

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

Metadata changes from 2014 onwards are summarised in Table 3.

Table 3: Hepatitis B and C metadata change history

Year	Subject	Description
2019	**HEPB** **HEPC**	The following variables were removed: Outcome Classification Testing Location Sex Worker HeathCareWorker HIVStatus Complications Genotype RecentInjectorStatus
	HEPB	The following variables were removed: HBeAgStatus HCVStatus VaccStatus
	HCV	The following variables were removed: HBVStatus HCVRNAAntigen

HEPB **HEPC**	The coded value list of the variable Transmission was modified: NEW: BLOOD = Blood and blood products HAEMO = Haemodialysis HETERO = Heterosexual contact HOUSE = Household contact of chronic case IDU = Injecting drug use MSM = MSM (homo or bisexual male) MTCT = Mother-to-child transmission NONOCCUP = Non-occupational exposure (community needle stick injuries, bites, tattoos, piercings) NOSO = Nosocomial transmission (includes hospital, nursing home, psychiatric institutions, dental) O = Other (transmission route is known, but is not mentioned in the list) OCCUP = Any occupational exposure (includes needle stick injuries among healthcare workers) SEX = Sexual transmission (unspecified) SEXWORK = Through selling sex TRANSPLANT = Organs and tissues UNK = Unknown *OLD:* *BLOOD = Blood and blood products* *HAEMO = Haemodialysis* *HETERO = Heterosexual contact* *HOUSE = Household contact of chronic case* *IDU = Injecting drug user* *MSM = MSM (homo or bisexual male)* *MTCT = Mother-to-child transmission* *NONOCCUP = Non-occupational injuries (needle stick, bites, tattoos, piercings)* *NOSO = Nosocomial transmission (includes hospital, nursing home, psychiatric institutions, dental)* *O = Other (transmission route is known, but is not mentioned in the list)* *OCCUP = Needle stick injury and occupational exposure (includes healthcare workers and needle stick injuries)* *SEX = Sexual transmission (not specified)* *TRANSPLANT = Organs and tissues* *UNK = Unknown*

	HEPB **HEPC**	The following variable was added: OtherProbableTransmission *This variable specifies other possible routes of transmission in addition to the most probable route. More than one category may be selected (repeatable variable).* BLOOD = Blood and blood products HAEMO = Haemodialysis HETERO = Heterosexual contact HOUSE = Household contact of chronic case IDU = Injecting drug use MSM = MSM (homo or bisexual male) MTCT = Mother-to-child transmission NONOCCUP = Non-occupational exposure (community needle stick injuries, bites, tattoos, piercings) NOSO = Nosocomial transmission (includes hospital, nursing home, psychiatric institutions, dental) O = Other (transmission route is known, but is not mentioned in the list) OCCUP = Any occupational exposure (includes needle stick injuries among healthcare workers) SEX = Sexual transmission (unspecified) SEXWORK = Through selling sex TRANSPLANT = Organs and tissues
2018	No changes to the hepatitis B and C metadata.	
2017	No changes to the hepatitis B and C metadata.	
2016	**HEPB** **HEPC**	A new code was added to coded value list for the "TestingLocationHEP" variable: • OHD = Other hospital department
	HEPB **HEPC**	An update was made to a name of the code in the coded value list for the "TransmissionHEP" variable: O = Other (transmission route is known, but is not mentioned in the list)
	HEPB **HEPC**	The following variable was added "Recent injector status": • Y = Yes • N = No • Unk = Unknown
	HEPC	The following variable was added "HCVRNAAntigen / Hepatitis C RNA or antigen": • DET = Detectable • NDET = Not detectable • NTEST = Not tested • UNK = Unknown
2015	No changes to the hepatitis B and C metadata.	
2014	No changes to the hepatitis B and C metadata.	

Annex 2 Subject-specific material

- *Hepatitis B and C data collection*
- Contact information (disease experts and others)

Hepatitis B and C data collection

In 2019, the surveillance data on hepatitis B and C are collected as part of the enhanced surveillance programme and concern cases that were diagnosed in 2018. **Case-based data is preferred**. If case-based data are not available, the aggregate format broken down by 1) gender and 2) age class may be used. Please note that reporting in aggregated format means that your country's data might not be used for some of the more detailed analyses.

In the Annual Epidemiological Report, the date of diagnosis (as a proxy for date of consultation) is used for all analyses. If possible, please report this date as the Date used for Statistics.

For hepatitis B and C, only confirmed cases should be reported at EU level. Cases should be classified according to EU 2012 case definitions. If different case definitions are used, please specify this in the Data Source data.

Historical data (2006 - 2015)

Data for 2006-2015 have been collected in previous data collections and have been published in previous surveillance reports. Historical data can be corrected by re-uploading to TESSy. These updates are taken into account if done before the deadline.

Annex 3: EU case definitions for hepatitis B and C

Source: 2012/506/EU: Commission Implementing Decision of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document C(2012) 5538)

HEPATITIS B
(*Hepatitis B virus)*)

Clinical Criteria

Not relevant for surveillance purposes

Laboratory Criteria
Positive results of at least one or more of the following tests or combination of tests:

- IgM hepatitis B core antibody (anti-HBc IgM)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B e antigen (HBeAg)
- Hepatitis B nucleic acid (HBV-DNA)

Epidemiological Criteria

Not relevant for surveillance purposes

Case Classification

A. Possible case
NA
B. Probable case
NA
C. Confirmed case
Any person meeting the laboratory criteria

Comments/Notes
NOTE : The following combination of lab tests shall not be included or reported:
- — Resolved hepatitis - Hepatitis B total core antibody (anti-HBc) positive and hepatitis B surface antibody (anti-HBs) positive
- — Immunity following vaccination - Hepatitis B total core antibody (anti-HBc) negative and hepatitis B surface antibody (anti-HBs) positive
- — Anti-HBc IgG positivity only

NOTE : Elevated levels of IgM in some chronic cases may result in misclassification which could overestimate the number of acute cases
NOTE: When reporting cases of Hepatitis B, the Member States should distinguish between acute and chronic disease, according to ECDC requirements.

Rationale
The revised case definition has been proposed by the Hepatitis Coordination Group as part of the introduction of enhanced surveillance for hepatitis B. One of the aims of enhanced surveillance for Hepatitis B is to allow the reporting and differentiation of acute and chronic stages of the infection. The original case definition was limited to acute cases; however countries varied in what they reported, with some reporting only acute cases and others a mixture of acute and chronic cases. The new case definition should therefore capture cases which fall in either stages of the infection (or where the stage is unknown). The differentiation between the two stages at the time of diagnosis will be done when reporting cases through a new variable (STAGEHEP). This variable is based on specific serological markers as outlined in the framework for Enhanced Hepatitis B and C Surveillance in Europe. The case definition now also clarifies which combinations of tests should not be reportable.

HEPATITIS C
(*Hepatitis C virus)*)

Clinical Criteria

Not relevant for surveillance purposes

Laboratory Criteria
At least one of the following three:

- Detection of hepatitis C virus nucleic acid (HCV RNA)
- Detection of hepatitis C virus specific antigen (HCVcore)
- Hepatitis C virus specific antibody (anti-HCV) response confirmed by a confirmatory (e.g. immunoblot) antibody test in persons older than 18 months without evidence of resolved infection

Epidemiological Criteria

Not relevant for surveillance purposes

Case Classification

A. **Possible case**
NA

B. **Probable case**
NA

C. **Confirmed case**
Any person meeting the laboratory criteria

Comments/Notes
NOTE: The following combination of lab tests shall not be included or reported:

— Resolved infection: Detection of hepatitis C virus antibody and no detection of hepatitis C virus nucleic acid (HCV RNA negative result) or hepatitis C virus core antigen (HCV-core negative result) in serum/plasma

NOTE: When reporting cases of Hepatitis C, the Member States should distinguish between acute and chronic disease, according to ECDC requirements.

Rationale
The revised case definition has been proposed by the Hepatitis Coordination Group as part of the introduction of enhanced surveillance for hepatitis C. The 2008 Hepatitis C case definition includes both acute and chronic cases; however countries vary in what they collect and report, with all countries reporting acute cases and only two thirds reporting chronic cases. The case definition still captures cases which fall in either stages of the infection (or where the stage is unknown). The differentiation between the two stages at the time of reporting will be done when reporting cases through a new variable (STAGEHEP). This variable is based on specific serological markers as outlined in the framework for Enhanced hepatitis B and C Surveillance in Europe. The case definition also now refers to resolved infection as these should not be reported.

Annex 4: Implementation of case definitions with StageHEP variable

Disease	*Codes*	*Description*
Hepatitis B	Acute	Detection of IgM antigen specific antibody (anti-HBc IgM) *or* Detection of hepatitis surface antigen (HBsAg) and previous negative HBV markers less than 6 months ago *or* Detection of hepatitis B nucleic acid (HBV-DNA) and previous negative HBV markers less than 6 months ago Any of the above with or without symptoms and signs (e.g. jaundice, elevated serum aminotransferase levels, fatigue, abdominal pain, loss of appetite, intermittent nausea, vomiting, fever)
	Chronic	Detection of HBsAg or HBeAg or HBV-DNA *and* No detection of anti-HBc IgM (negative result) *or* Detection of HBsAg or HBeAg or HBV-DNA on two occasions that are 6 months apart[1]
	UNK	Any newly diagnosed case which cannot be classified according the above description of acute or chronic infection
Hepatitis C	Acute	Recent HCV seroconversion (prior negative test for hepatitis C in last 12 months) *or* Detection of hepatitis C virus nucleic acid (HCV RNA) or hepatitis C virus core antigen (HCV-core) in serum/plasma and no detection of hepatitis C virus antibody (negative result)
	Chronic	Detection of hepatitis C virus nucleic acid (HCV RNA) or hepatitis C core antigen (HCV-core) in serum/plasma in two samples taken at least 12 months apart[1]
	UNK	Any newly diagnosed case which cannot be classified according the above description of acute or chronic infection

[1] In the event that the case was not notified the first time

Contact information

If you have any questions relating to the hepatitis B and C data collection please contact the hepatitis expert Lina Nerlander *Lina.nerlander@ecdc.europa.eu*.