

Protocol for sentinel surveillance  
of chronic hepatitis B and C  
treatment and outcomes  
in European Union and European Economic  
Area countries

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Final Version

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## Abbreviations

ALT	Alanine Amino Transferase
anti-HBc IgM	IgM hepatitis B core antibody
anti-HCV	Hepatitis C virus specific antibody
BBV	Blood Borne Viruses
DAA	Direct acting antiretrovirals
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EHR	Electronic Health Records
EU	European Union
FTP	File Transfer Protocol
HBV	Hepatitis B
HBeAg	Hepatitis B e antigen
HBsAg	Hepatitis B surface antigen
HBV-DNA	Hepatitis B virus nucleic acid
HCV	Hepatitis C
HCV RNA	Hepatitis C virus nucleic acid
HCV-core	Hepatitis C virus core antigen
ICJME	International Committee of Medical Journal Editors
MS	Member States
MSM	Men who have sex with men
PWID	Person Who Injects Drugs
SVR	Sustained Virological Response

## Acknowledgements

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## 1. Background

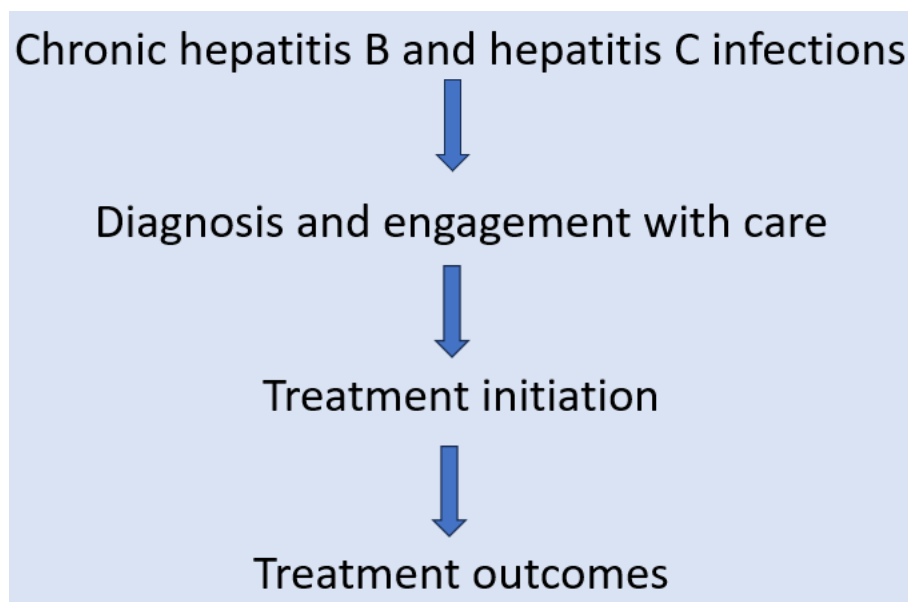
Hepatitis B (HBV) and hepatitis C (HCV) infections are important public health issues in Europe as they remain a major cause of morbidity and mortality from infectious diseases [1,2]. Both infections can present as acute and chronic hepatitis, chronic infections being a leading cause of liver cirrhosis, hepatocellular carcinoma and death [3].

The introduction of direct acting antivirals (DAAs) has provided a safe, effective and short curative treatment for HCV infection [4]. For HBV, longer term treatment with nucleos(t)ide analogues can suppress viral replication and reduce morbidity and mortality [5]. As hepatitis B and C treatment is able to suppress levels of the virus and prevent viral transmission, treatment is an additional approach to control hepatitis, especially for HCV where no vaccine is currently available [6, 7].

The global health sector strategies on HIV, viral hepatitis and STIs for 2022-2030 published by the World Health Organization Europe (WHO EURO) in 2022 [8] aimed to eliminate viral hepatitis as a major public health threat by 2030. Scaling up antiviral treatment is a critical component of the WHO strategy for the elimination of viral hepatitis. The WHO Global Health Sector Strategy target stipulates that 80% of eligible patients with chronic hepatitis B or C should be treated by 2030 [9].

An important public health metric for the prevention and control of hepatitis is the cascade of care (Figure 1) which aims to improve survival and reduce transmission by assessing the quality of viral hepatitis care delivery from diagnosis, access and retention in care and treatment, to viral suppression [10].

**Figure 1:** Cascade of care for hepatitis B and C infection



The European Centre for Disease Prevention and Control (ECDC) manages the collection and analysis of hepatitis B and hepatitis monitoring data in European Union (EU) and European Economic Area (EEA) countries. However, significant gaps remain in current monitoring data, especially regarding prevention, testing and treatment for HBV and HCV [11]. In a study published in 2020, only one quarter of European countries were able to provide estimates of the number of individuals treated for HBV. Regarding HCV, a majority of countries reported the number of people treated for HCV but only 39% were able to provide data on HCV treatment outcomes [12]. Thus, there is a need to enhance or supplement the national surveillance systems with alternative surveillance data sources.

Monitoring treatment and treatment outcomes is performed by a variety of designs in different European countries including treatment cohorts [13,14]. The treatment cohorts are often established by research projects recruiting specific populations and may not provide national coverage [15]. Enhanced sentinel reporting [16] has many advantages, including the relative simplicity of data collection.

A study pilot protocol developed in collaboration with participant countries (Croatia, Romania and Spain) and implemented in seven clinical sites (three in each of Croatia and Romania and one in Spain) between March and August 2020 showed that the WHO treatment targets were missed for HBV but achieved for HCV. [17]. The lessons learned from the pilot study and the subsequent discussions with all experts engaged in this project were used to develop this final version of the sentinel surveillance protocol.

ECDC plans to roll out a sentinel surveillance of hepatitis treatment and outcomes treatment (eligibility and outcomes) across the EU/EEA to fulfil the aim of collecting a limited set of detailed, high quality epidemiological data on chronic hepatitis B and C cases to provide a clearer understanding of the epidemiology and the response to these epidemics in EU/EEA countries.

## 2. General objective

ECDC want to support the establishment/development of a sentinel surveillance for chronic hepatitis B and C treatment and outcomes in each participating EU/EEA countries to fill the data gap on the linkage to care and the retention into care.

## 3. Specific objectives

To meet the local, national, and European needs for information, this protocol will be adapted:

1. To select and establish sentinel sites in participating countries
2. To develop data collection systems each contributing country
3. To collect core data, and relevant information considering national and local priorities
4. To develop a standardised system for the analysis of the data

Considering the lessons learned from the pilot study and the observations of participating countries, the priority data to be collected include:

- Linkage to care
- Treatment eligibility (for HBV)
- Treatment status
- Treatment outcomes
- Co-infections (HIV, HCV, HBV, HDV)
- Long terms complications

- According to national priorities and needs, each participating country could adapt the objectives for their sentinel surveillance. For example, countries may establish sentinel surveillance for chronic hepatitis B or hepatitis C only or for both.

- Tick bullet points are included to highlight issues within the generic protocol that participating countries should review and adapt according to national contexts and priorities.

## 4. Type of surveillance

The sentinel surveillance system will collect retrospective, anonymous and enhanced data from selected sentinel sites corresponding to the surveillance period.

- ☑ Considering the national priorities and capacity of participating countries and sites, the sentinel surveillance can be adapted by:
  - establishing prospective follow-up of chronic hepatitis (HBV and/or HCV) from the beginning of the surveillance period; or
  - combining retrospective and prospective data collection to cover the surveillance period.

## 5. Surveillance period

Information should be collected for all patients with a confirmed HBV and/or HCV infection who attended at least once the participating sentinel site during the 12-month surveillance period. A 12-month surveillance period is proposed as to obtain the treatment outcomes for hepatitis B and also to enable a better comparison with other participant countries.

The surveillance period will vary according to the start dates of sites participating in the project. For sites proposing to participate in 2024, the defined surveillance period will be 1 January 2023 to 31 December 2023. For those sites continuing or starting in 2025, the defined surveillance period will move on by one year to include the period 1 January 2024 to 31 December 2024.

- ☑ Sentinel sites or countries may decide that national needs require a shorter surveillance period than 12 months (e.g. quarterly). Sites can implement this change but any data collected for shorter periods than one year may need adjusting in order to obtain hepatitis B treatment outcomes, fulfil the European monitoring system specifications and enable comparison with other EU/EEA countries.

## 6. Population under surveillance

The target population will be all individuals with chronic hepatitis B or hepatitis C during the study period in the country or region of the sentinel system.

The population under surveillance will be the individuals with chronic hepatitis B or hepatitis C living in the catchment area of the participating sentinel sites who attended these sentinel centres during the surveillance period (see section 5).

For the retrospective data collection, all or a representative sample of patients attending the clinic (both new and on-going attendees) will be selected and a review of the medical records in the past for treatment information will be undertaken.

Another option could be to select a sample of newly diagnosed patients who attended for the first time during a 6-month period in the past (starting for example 18 months earlier) and then extract data from medical records up to the present time.

## 7. Selection of sentinel sites

The sentinel sites should be selected using a set of pre-defined criteria:

- Willingness to participate in the sentinel surveillance system
- Expertise and resources to extract information from patient records
- Representativeness of the patients for each centre: This will require an understanding of the local care pathways identifying all the treatment services.

To enable comparisons, each participating sentinel site should:

- Provide the size of the catchment population, total number of patients/attendees during the surveillance period as a proxy for level of activity and describe the methodology used to obtain this estimate. Guidance will be provided by the consortium to help site to estimate the size of the catchment population
- Describe the characteristics of their catchment population e.g. site main treatment centre for PWID population or for local prison population.
- Report sufficient numbers of cases so that the anticipated number of cases reported by the sentinel surveillance system will allow analyses of sufficient power to be performed [18].
- Submit securely data through using an appropriate platform for submission to national or European collection systems (see section 11).

To implement a robust sentinel surveillance system, the sites selected to participate in the study will need to be nationally representative of those that provide treatment and of the population of chronic hepatitis cases in contact with health services. Most individuals with chronic infection are diagnosed in primary or community services. Diagnosed individuals are subsequently likely to attend secondary or tertiary services (e.g. gastroenterology and infectious disease clinics) for treatment and further clinical investigations. However, antiviral treatments for hepatitis, and especially HCV, are increasingly being offered in primary care services to widen access [19]. The development of the sampling strategy will depend on the assets and infrastructures available nationally. According to the context of each country, one of the following three approaches will be undertaken:

- **Representative sample if sampling frame available:** This will require data on the healthcare centres providing hepatitis treatment and aggregate numbers of patients being treated in each.
  - The establishment of the sampling frame may use treatment registers, which may require data linkage between multiple information systems. The establishment of such a sampling frame is difficult and impediments include the time available, obtaining the agreement of the asset owner and national ethical or data protection regulations. The data source could be employed to construct a sampling frame of centres listed by the number of patients treated in the last available year.
  - Alternative data sources could include national sales and prescribing data for hepatitis treatment, serial patterns of HCV testing in laboratory or surveillance data, or the estimation of catchment populations for each site using administrative data.
  - Treatment centres could be selected using a stratified proportional sampling, ensuring that hospitals are ranked by number of patients and health service type (e.g. tertiary, secondary and primary) and other features (e.g. by geography) to ensure representativeness of the different types of hospitals.
- **Sample if sampling frame not available:** This option will seek to establish a sample of treatment sites as representative as possible of the treated population.
  - The first step of this process will be to establish a typology (e.g. tertiary, secondary, and primary care) of the care and treatment sites by working with national leads to define

the possible clinical pathways to care for patients with chronic HBV and/or HCV infection.

- Once a typology of all possible care sites has been established, national leads will need to provide an available list of centres by typology of care and treatment
  - This list of centres by typology of care and treatment will be used as a sampling basis to randomly selected the sentinel centres employing similar methodology as described above to obtain a sample of sites as representative as possible, considering available information health service type (e.g. tertiary, secondary and primary) and other features (e.g. by geography).
- **Convenient and purposive sample:** If none of the data sources identified healthcare sites by typology, national leads can select sites that would be to ensure that the sample includes services that are representative by region, type of service (e.g. tertiary, secondary, primary) and size.

## 8. Case definition

The case definition is a patient with a confirmed diagnosis of chronic HBV and/or chronic HCV who attended a participating site during the surveillance period. Participating sites should employ the EU 2012/EU 2018 definition (EU decision 2018/945) for chronic HBV and/or HCV [20].

**Table 1:** Case definitions for chronic hepatitis B and C

Stage	Definitions
<i>Chronic Hepatitis B</i>	<ul style="list-style-type: none"> <li>• Hepatitis B surface antigen (HBsAg) or hepatitis B e antigen (HBeAg) or hepatitis B nucleic acid (HBV DNA)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• IgM hepatitis B core antibody (anti-HBc IgM) negative <b>OR</b></li> <li>• Detection of HBsAg or HBeAg or HBV-DNA on two occasions that are <math>\geq 6</math> months apart (in the event that the case was not notified the first time).</li> </ul>
<i>Chronic Hepatitis C</i>	<ul style="list-style-type: none"> <li>• Hepatitis C nucleic acid (HCV RNA) or hepatitis C core antigen (HCV-core Ag)</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Hepatitis C specific-antibody (anti-HCV) positive <b>OR</b></li> <li>• Detection HCV RNA or HCV-core Ag in serum/plasma in two samples taken <math>\geq 12</math> months apart (in the event that the case was not notified the first time).</li> </ul>

- If the countries decided to employ national definitions of chronic hepatitis B or C, these case definitions should be reported. In this situation, additional diagnostic and/or symptomatic information will be reported with each case to enable comparison with countries applying the EU case definition.

## 9. Case identification

Participating sentinel sites may use a variety of methods to identify cases including an electronic search of hospital databases using for example ICD-10 codes (see Annex A) and/or a review of clinical notes. A suitable unique case-identifier will be used to match records and eliminate possible duplicates from the combined national dataset.

## 10. Data collection

At sentinel sites, needed data will be extracted from electronic health records by a clinical research staff using a standardised questionnaire completed:

- Directly into the HelicsWin.Net data collection tool provided by ECDC; or
- Directly into another customized electronic data collection tool proposed by the participating country; or
- Manually into a paper based standardised questionnaire.

Study sites to describe their data collection procedures at sentinel site

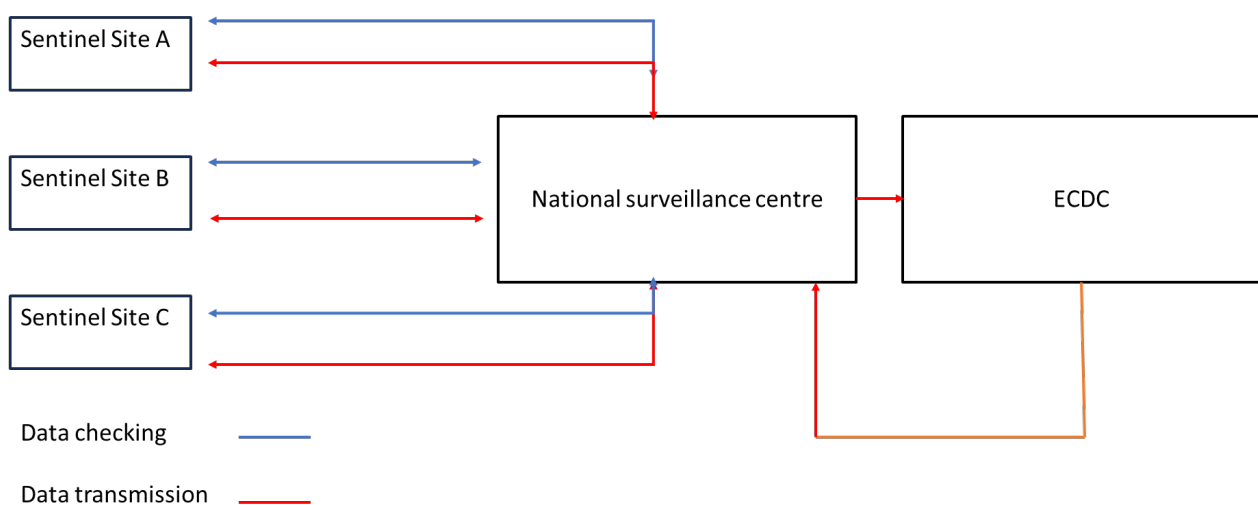
Data flows from sentinel sites will be as described in Figure 2.

Participating sentinel sites will submit case-based or aggregated data to national surveillance centre using a standardised questionnaire hosted on a platform that ensure data will be transferred via secured FTP (File Transfer Protocol). The platform should be dedicated to health data and benefit from the security elements required by national and European regulations (see section 15). The system should provide a daily encrypted backup procedure and be able to register all user actions (connections, disconnections, modifications, deletions, validations and submissions).

The national sites will undertake preliminary data validation checks (see section 11) and, if necessary, communicate with sentinel sites to clarify any issues. The national centre will submit a national data base combining the data transmitted by the participating sites to ECDC using the ECDC dedicated platform (Helics-Win.Net)<sup>1</sup> or any other secured platform dedicated to health data.

ECDC will undertake further checks, data quality checking and report on the combined national datasets and disseminate these to national public health sites and sentinel sites.

**Figure 2:** Data flows for chronic Hep B and Hep C sentinel surveillance system



<sup>1</sup> <https://www.ecdc.europa.eu/en/publications-data/helicswinnet-hwn>

## 11. Variables to be collected

The full detailed list of proposed variables to be collected are outlined in Annex B. Considering the lessons learned from the pilot, monitoring the continuum of care, including treatment and treatment outcomes for HBV and HCV are considered as priority variables to be classed as core, other variables being additional (Table 2).

**Table 2:** Individual variables to be collected for the chronic HCV and HCV sentinel surveillance

<b>Variables to be collected</b>	<b>Core</b>	<b>Additional</b>
<b>Sentinel site details</b>		
<i>Sentinel site ID</i>	x	
<i>Type of clinics/services (Primary, secondary or Tertiary care, Low threshold clinic for PWID), other)</i>	x	
<b>Patient details</b>		
<i>Patient unique ID</i>	x	
<i>Age</i>	x	
<i>Gender</i>	x	
<i>Country of birth</i>		x
<i>Date of first and last attendance during the surveillance period</i>	x	
<i>Patients' status in clinics during the surveillance period (under follow-up, referred to another service, lost contact, died – date and cause of death)</i>	x	
<i>Likely route of transmission</i>		x
<b>Clinical symptoms and history</b>		
<i>Highest concentration of Alanine Amino Transferase (ALT) and date of test</i>	x	
<i>Highest stage of fibrosis diagnosed and date of assessment</i>	x	
<i>Type of test employed to diagnose fibrosis</i>		x
<i>Cirrhosis diagnosed: date of diagnosis, stage and clinical symptoms</i>	x	
<i>Hepatocellular carcinoma: date of diagnosis</i>	x	
<i>Other late-stage disease: date of diagnosis</i>	x	
<b>Chronic Hep B diagnosis</b>		
<i>Chronic HBV Infection: date of first diagnosis,</i>	x	
<i>Location of first HBV positive result (same as reporting site, needle exchange, drug service (not needle exchange), sexual health service, detention centre/prison, community centre, other diagnostic and treatment centre, unknown)</i>		x
<i>Test results for chronic HBV diagnosis</i>	x	
<b>Co Infections at diagnosis</b>		
<i>Co-infection HBV–HCV</i>	x	
<i>Co-infection HBV Delta</i>	x	
<i>Co-infection HBV HIV</i>	x	
<i>Co-infection HCV HIV</i>	x	
<b>Hep B treatment</b>		

Date treatment start and ended (if treatment ended)	x	
Current treatment regimen	x	
Viral suppression achieved	x	
<b>Chronic Hep C diagnosis</b>		
Chronic HCV Infection Location of first HCV positive result (same as reporting site, needle exchange, drug service (not needle exchange), sexual health service, other treatment centre, unknown)		X
Date of first diagnosis of chronic HCV infection	X	
<b>Hep C treatment</b>		
Date treatment start and ended (if treatment ended)	x	
Current treatment regimen	x	
SVR achieved at last test and date of the test	x	

- Considering the national and local contexts, aggregated data could also be reported as an alternative choice (see Annex C). Aggregated data can also be customized by adding additional variable for countries
- Participating countries can decide to incorporate additional variables considering the national and local priorities

It should be noted that:

- Where relevant, variables collected will conform to the definitions and response options as outlined in the ECDC metadata file for hepatitis data collection [21];
- Advanced and late-stage liver diseases are defined as in the European consensus statement [22];
- The eligibility criteria for HBV treatment are those as identified in European Association for the Study of the Liver (EASL) 2017 clinical practice guidelines [23];

## 12. Data validation

Datasets will be validated at three levels: sentinel sites, national surveillance sites and at ECDC level to ensure that data are consistent and, where appropriate, complete.

The sentinel surveillance proposed the following rules:

- Case definitions: conform to European chronic HBV and/or chronic HCV case definitions or to national/local case definitions when these definitions are provided.
  - Surveillance period:
    - The surveillance period starts from 1st January to 31 December of the defined year (e.g. 2023 data will be collected to be analysed in 2024)
    - Patients will be included if date first their presentation at sentinel site falls within the defined surveillance period
  - Related information should be consistent and aligned:
    - Reported gender is male if group of transmission is reported as MSM
    - Occupational exposures are only identified among those aged 16 or older
    - Hepatitis treatment eligibility criteria should reflect EASL criteria or local ones if provided
    - Clinical stage and complications should reflect the level of fibrosis, cirrhosis corresponding to stage 4 fibrosis.
- Each national surveillance protocol should describe the data validation undertaken at sentinel site and national surveillance centre.

## 13. Data linkage procedures

If various databases will be linked, sentinel sites will describe at which level the match is performed. The matching procedures will include:

- Methods to identify duplicates
- Management of records present in one database but not in the other(s), (e.g. kept with variables missing, variables imputed)

## 14. Main surveillance indicators

Surveillance indicators will be prepared and presented for the combined sentinel sites datasets and by sentinel site.

Indicators for each sentinel surveillance system are assigned according to European objectives, national and local priorities considering the needs and additional information collected by the countries.

### **Indicator 1: to describe testing history and late diagnosis**

- Describe testing history
  - Proportion of new chronic cases diagnosed by surveillance period and if possible, by different service types (e.g. low-threshold service such as needle exchange, primary care, secondary care, tertiary care) (HBV and HCV will be presented separately)
  - Prevalence and Incidence of chronic cases by catchment area and by total numbers of attendees for each site during the surveillance period
- Describe sequelae for HBV and HCV cases
  - Proportion of chronic cases with advanced or late-stage liver disease at first diagnosis, proportion of advanced fibrosis/cirrhosis with markers and fibro scan, proportion of carcinoma and decompensated liver (HBV and HCV presented separately)
  - Prevalence and Incidence of chronic cases with advanced or late-stage liver disease by catchment area

### **Indicator 2: to describe coinfections (HIV, HCV, HBV)**

- Describe co-infections in HBV and HCV cases
  - Proportion of chronic cases with co-infection HBV Delta, HBV, HCV or HIV at first diagnosis (HBV and HCV presented separately)
  - Proportion of chronic cases with co-infection HBV Delta, HBV, HCV or HIV during the surveillance period (HBV and HCV presented separately)
  - Prevalence and incidence of chronic cases with co-infection by catchment area

### **Indicator 3: to describe treatment initiation and outcomes**

- Describe treatment initiation for HBV and HCV
  - Proportion of chronic HBV cases that are eligible for treatment during the surveillance
  - Proportion of chronic HBV cases eligible for treatment that are being treated at diagnosis,
  - Proportion of chronic HBV cases eligible for treatment that are being treated by route of transmission
  - Proportion of chronic HCV cases eligible for treatment
  - Proportion of chronic HCV cases eligible for treatment that are treated at diagnosis

- Proportion of chronic HCV cases eligible for treatment that are treated and by route of transmission
- Time between diagnosis and treatment initiation (median days) for chronic HBV and HCV cases
- Describe treatment outcomes
  - Proportion of treated chronic HBV cases achieving virological suppression
  - Proportion of treated chronic HCV cases achieving Sustained Virological Response (SVR)<sup>2</sup>
  - Proportion of treated chronic HCV cases who died
  - Proportion of treated chronic HCV cases lost to follow up
  - Proportion of treated chronic HCV cases still under treatment
  - Proportion of treated chronic HCV cases with complication after treatment

## 15. Plan of analysis

The following descriptive analyses are proposed.

### 1. Description of cases at European level

The number of diagnoses of chronic HBV or HCV is defined as those individuals that are identified through the sentinel site(s).

- Number of prevalent chronic HBV and HCV cases identified through the sentinel sites and by country
- Number of incident chronic HBV and HCV cases identified through the sentinel sites and by country
- Number and proportion of prevalent and incident chronic HBV and HCV cases by sentinel surveillance sites

Sentinel site	Collection period	Number chronic HBV diagnoses			Number chronic HCV diagnoses		
		Total n (%)			Total n (%)		
		Incident case	Prevalent case	Total	Incident case	Prevalent case	Total
1	dd/mm/yy- dd/mm/yy	xa1	xb1	xc1	ya1	yb1	yc1
2	dd/mm/yy- dd/mm/yy	xa2	xb2	xc2	ya2	yb2	yc2
n	dd/mm/yy- dd/mm/yy	Xan	xbn	xc3	yan	ybn	ycn
<b>Country Total</b>	<b>dd/mm/yy-</b>	<b>Σxa</b>	<b>Σxb</b>	<b>Σxc</b>	<b>Σya</b>	<b>Σyb</b>	<b>Σyc</b>

- Number and proportion of prevalent and incident chronic HBV and HCV cases by age and gender

Variable	Total Chronic HBV diagnoses (N)		Total Chronic HCV diagnoses (N)	
	Number	(%)	Number	(%)

<sup>2</sup> SVR is defined as an undetectable viral load (HCV RNA) in patient serum using an assay with a minimum sensitivity of 50IU/ml.

Gender	Male	y1	(y1/N)	b1	(c1/N)
	Female	y2	(y2/N)	b2	(c2/N)
	Unknown	y3	(y3/N)	b3	(c3/N)
Age Group	<25	z1	(z1/N)	c1	(c1/N)
	25-50	z2	(z2/N)	c2	(c2/N)
	51-60	z3	(z3/N)	c3	(c3/N)
	≥61	z4	(z4/N)	c4	(c4/N)
	unknown	z5	(z5/N)	c5	(c5/N)

2. Clinical history chronic HBV and HCV cases

- Number and proportion of prevalent and incident chronic HBV and HCV cases at diagnosis by co-infections with other blood borne viruses (BBV), stage of fibrosis diagnosed and diagnosis of cirrhosis or hepatocellular carcinoma.

Variable	Total	
	Chronic HBV infections Nb (%)	Chronic HCV infections Nc (%)
Co-infections	HBV	-
	HCV	U1(u1/Nb)
	HDV	U2 (u2/Nb)
	HIV	U3 (u3/Nb)
Stage of fibrosis	No fibrosis (F0)	Z1 (z1/Nc)
	Minimal (F1)	-
	Significant (F2)	Z2 (z2/Nc)
	Severe (F3)	Z3 (z3/Nc)
	Cirrhosis/Advanced(F4)	
	Unknown	
Cirrhosis	Diagnosed	
	Not diagnosed	
Hepatocellular carcinoma	Diagnosed	
	Not diagnosed	

3. Treatment outcomes for chronic HBV and HCV

- Number and proportion of HBV and HCV prevalent and incident chronic cases treatment and treatment outcomes for all cases and by key transmission groups. Data will be presented for the major transmission groups.

Variable	Chronic HBV diagnoses (N)	
	Number	(%)
Number on treatment	Number eligible for treatment (overall)	x1 (x1/N)
	Number eligible for treatment by specific EASL criteria	
	Number treated in surveillance period	x2 (x2/x1)
	Number virally suppressed	x3 (x3/x2)
Time from first diagnosis to treatment start	< 6 months	m1 (m1x2)
	6-12months	m2 (m2x2)
	≥13 months	m3 (m3/( x2)

Variable	Chronic HCV diagnoses (N)	
	Number	(%)

Number on treatment	Number eligible for treatment	x1 (x1/N)
	Number started treatment in surveillance period	x2 (x2/x1)
	Number achieving sustained virological suppression	x3 (x3/x2)
Time from first diagnosis to treatment start	< 3months	m1 (m1/x2)
	3-<6 months	m2 (m2/x2)
	6-12months	m3 (m3/x2)
	≥13 months	m4 (m4/x2)

## 16. Data protection and ethical approval

It will be the responsibility of each sentinel site to request and obtains ethical approval from appropriate ethics board review and, if necessary, approval from national committee. European data protection regulations will be applied.

Patient records will be anonymised with study unique identifier (Patient unique ID). A unique identifier will be allocated by each sentinel site (Sentinel Site ID).

## 17. Limitations

- Ensuring that the cases reported by sentinel sites are representative of chronic HBV or HCV infections identified could be challenging
- Retrospective and prospective data reporting may result in missing data.
- In case of aggregate data reporting, duplicates might not be eliminated from combined datasets
- In case of no national unique case ID across the health system, some duplicates might not be eliminated from combined datasets. A combination of several variables, if the data quality is good, could be used to deduplicates some cases.

Data quality and consistent reporting by participating sites should be ensured by a variety of means including provision of sufficient training, regular monitoring and sites visits.

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## Annex A: International Classification of Disease for Hepatitis B and C

The following International Classification Disease (ICD-10) codes published by the World Health Organization are suggested that could be employed to search hospital databases to identify cases of Hepatitis B and C.

### **B18 Chronic viral hepatitis**

B18.0 Chronic viral hepatitis B with delta-agent

B18.1 Chronic viral hepatitis B without delta-agent Hepatitis B (viral) NOS

B18.2 Chronic viral hepatitis C

### **B19 Unspecified viral hepatitis**

B19.1 Unspecified viral hepatitis B without (B19.10) or with (B19.11) hepatic coma

B19.2 Unspecified viral hepatitis C without (B19.20) or with (B19.21) hepatic coma

### **B94 Sequelae of other and unspecified infectious and parasitic diseases**

B94.2 Sequelae of viral hepatitis

### **C22 Malignant neoplasm of liver and intrahepatic bile ducts**

C22.0 Liver cell carcinoma: Hepatocellular carcinoma; Hepatoma

C22.1 Intrahepatic bile duct carcinoma: Cholangiocarcinoma

C22.9 Liver unspecified

### **K74 Fibrosis and cirrhosis of liver**

Excludes: alcoholic fibrosis of liver (K70.2); cardiac sclerosis of liver (K76.1); cirrhosis (of liver): alcoholic (K70.3); congenital (P78.8); with toxic liver disease (K71.7)

K74.0 Hepatic fibrosis

K74.1 Hepatic sclerosis

K74.2 Hepatic fibrosis with hepatic sclerosis

K74.3 Primary biliary cirrhosis. Chronic nonsuppurative destructive cholangitis

K74.4 Secondary biliary cirrhosis

K74.5 Biliary cirrhosis, unspecified

K74.6 Other and unspecified cirrhosis of liver. Cirrhosis (of liver): NOS; cryptogenic; macronodular; micronodular; mixed type; portal; post-necrotic

### **Z94.4 Liver transplant status**

## Annex B: Data dictionary for Chronic Hepatitis B and C sentinel surveillance

### Sentinel site details

Questions	Variables	Data format	Code	Core or Additional	Comments
1	Country		Text or code	Core	
2	Site name/code	Numeric	_____	Core	Code for participating site will be generated for data extraction (e.g. 1, 2, 3...n). The number will remain unchanged for all cases reported by the same site
3	Type of site	Numeric	1=Tertiary care 2=Secondary care 3=Primary care 4= clinic for PWID 5=Other	Core	
4	Catchment Area population	Numeric	_____	Additional	
5	Methods to determine the catchment area population	Numeric	1=Survey 2=Systematic review 3=Administrative reports 4=Other	Additional	
6	Total number of persons attending or visiting the sites per year	Numeric	_____	Core	

### Patient details

Question	Variables	Data format	Code	Core or Additional	Comments
1	Unique individual code	Alphanumeric		Core	Anonymous identifier will be automatically generated for each case
2	Participating sentinel site	Numeric		Core	Code for participating site will be generated for data extraction (e.g. 1, 2, 3...n). This number will remain unchanged for all cases reported by the same site.
3	Date first attendance service/clinic in surveillance period	Date	dd/mm/yy or yy if precise date unknown	Core	Enter date in surveillance period for patient attending the service (i.e has not

Question	Variables	Data format	Code	Core or Additional	Comments
					attended the service before).
5	Date last attendance service/clinic in surveillance period	Date	dd/mm/yy or yy if precise date unknown	Core	Must enter last attendance date in surveillance period
6	Patients' status in clinics	Numeric	Core	1=under follow-up 2=referred to another service 3=lost contact 4=died	Lost contact=missed 2 or more appointments since last seen
<b>If died:</b>					
6a	Date of death	Date		Additional	
6b	Cause of death	Numeric		Additional	
7	Gender	Numeric	1=male; 2=female; 3=Transgender 4=other; 9=unknown	Core	
8	Age	Numeric	1-99; Unknown=999	Core	
9	Country of Birth	Text	Name of country; 99=unknown/not recorded	Additional	If possible, to use a list in data collection tool for consistent wording
<b>Likely route transmission</b>					
10a	Sexual transmission among MSM/homo or bisexual male	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
10b	Heterosexual contact	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
10c	Sexual transmission (unspecified)	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
10d	Mother-to-child transmission	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
10e	Household contact with a chronic case	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
10f	Injecting drug use	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
10g	Nosocomial transmission	Numeric	1=Yes; 2=No; 9=Unknown	Additional	(includes hospital, nursing home, psychiatric institutions, dental)
10h	Occupational exposure	Numeric	1=Yes; 2=No; 9=Unknown	Additional	(includes needle stick injuries among healthcare workers)
10i	Non-occupational exposures	Numeric	1=Yes; 2=No; 9=Unknown	Additional	(community needle stick injuries, bites, tattoos, piercings)
10j	Blood and blood products	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
10k	Organ and tissues	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
10l	Haemodialysis	Numeric	1=Yes; 2=No; 9=Unknown	Additional	

Question	Variables	Data format	Code	Core or Additional	Comments
10m	Through selling sex	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
<b>If yes</b>					
10ma	Sexual transmission mode	Numeric	1=MSM 2=Heterosexual 3=Other	Additional	
10n	Other	Numeric	1=Yes; 2=No; 9=Unknown	Additional	Transmission route is known, but is not mentioned in the list
11	If the patient reports injecting drugs, when was the last time	Numeric	1= <4 months 2 = 4-5 months 3 = 6-12 months 4= 13 - 24 months 5=>24 months 9= Unknown	Additional	
<b>Testing history</b>					
12	Highest Alanine Amino Transferase (ALT) level	Numeric	_____	Core	Highest reported results during surveillance period
12.a	Date of test of highest concentration ALT	Date	dd/mm/yy or 99/99/99=unknown	Core	
<b>Diagnosis of liver Fibrosis</b>					
13	Has an assessment of liver fibrosis been undertaken?	Numeric	1=Yes; 2=No; 9=Unknown	Core	Questions 13a-e if answer is Yes
13a	During the surveillance period, what was the highest stage of fibrosis diagnosed?	Numeric	0=F0 - No fibrosis 1=F1 – Moderate 2=F2 - Significant 3=F3 - Severe 4=F4 - Cirrhosis/Advanced 9=Unknown	Core	
13b	Date of assessment of fibrosis	Date	dd/mm/yy or 99/99/99=unknown	Core	
<b>Which test were employed to diagnose the highest stage of fibrosis?</b>					
13c	Blood/serum tests (i.e. APRI score, FIB-4 and/or Fibrotest):	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
13d	Transient elastography:	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
13e	Liver biopsy (≥METAVIR stage F3):	Numeric	1=Yes; 2=No; 9=Unknown	Additional	
<b>During the surveillance period, were any of the following complications diagnosed?</b>					
14	Cirrhosis	Numeric	1=Yes; 2=No;	Core	

			9=Unknown		
	<b>If yes</b>				
14a	Date of first diagnosis for cirrhosis	Date	dd/mm/yy or 99/99/99=unknown	Core	
14b	Compensated or decompensated cirrhosis?	Numeric	1 Compensated 2 Decompensated 9=Unknown	Core	
	<b>If decompensated</b>				
14c	Jaundice	Numeric	1=Yes; 2=No; 9=Unknown	Core	
13d	Hepatic encephalopathy	Numeric	1=Yes; 2=No; 9=Unknown	Core	
14e	Clinically detectable ascites	Numeric	1=Yes; 2=No; 9=Unknown	Core	
14f	Variceal bleeding	Numeric	1=Yes; 2=No; 9=Unknown	Core	
15	Hepatocellular carcinoma	Numeric	1=Yes; 2=No; 9=Unknown	Core	
15a	If yes, date of first diagnosis	Date	dd/mm/yy or 99/99/99=unknown	Core	
16	Other late-stage disease	Numeric	1=Yes; 2=No; 9=Unknown	Core	
16b	If yes, date of diagnosis	Date	dd/mm/yy or 99/99/99=unknown	Core	
16a	If yes, please specify	Text		Additional	
17	HIV status	Numeric	1=HIV+ 2=HIV- 9=Unknown	Additional	
<b>Chronic HBV Diagnosis</b>					
18	Chronic HBV Infection	Numeric	1=Yes; 2=No; 9=Unknown	Core	If 2 (no) or 9 (unknown) skip to question 27
19	Date of first diagnosis of chronic HBV infection	Date	dd/mm/yy, mm/yy OR 99/99	Core	
20	Location of first HBV positive result	Numeric	1=Same as reporting site; 2=Needle exchange; 3=Drug service (not needle exchange) 4= Drug service and needle exchange 5= Sexual health clinics 6= Infectious diseases	Core	

			7= Hepatitis services 8=Other 9=unknown		
<b>21. Test and results for chronic HBV diagnosis</b>					
21.a	Result anti-HBc IgM first test	Numeric	1=Positive; 2=Equivocal; 3=Negative; 9= Not done/unknown	Core	Test confirming the diagnosis for the first time
21b	Date of the anti-HBc IgM first test	Date	dd/mm/yy or 99/99/99=unknown	Core	Test confirming the diagnosis for the first time
21c	Result anti-HBc IgM latest test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	
21d	Date of the anti-HBc IgM latest test	Date	dd/mm/yy or 99/99/99=unknown	Core	
21e	Result HBsAg first test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	Test confirming the diagnosis for the first time
21f	Date of the first positive HBsAg first test	Date	dd/mm/yy or 99/99/99=unknown	Core	Test confirming the diagnosis for the first time
21g	Result HBsAg latest test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	
21h	Date of the HBsAg latest test	Date	dd/mm/yy or 99/99/99=unknown	Core	
21i	Result HBeAg first test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	Test confirming the diagnosis for the first time
21j	Date of the HBeAg first test	Date	dd/mm/yy or 99/99/99=unknown	Core	Test confirming the diagnosis for the first time
21k	Result HBeAg latest test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	
21l	Date of the HBeAg latest test	Date	dd/mm/yy or 99/99/99=unknown	Core	
21m	Result HBV DNA first test	Numeric	0=Detectable 1=Undetectable 9=Unknown/unrecorded	Core	Test confirming the diagnosis for the first time. Lower limit of detection according to the kit's producer

21n	Date of the HBV-DNA first test	Date	dd/mm/yy or 99/99/99=unknown	Core	Test confirming the diagnosis for the first time
21o	Result HBV DNA latest test	Numeric	_____	Core	
21.o	Date of the HBV-DNA latest test	Date	dd/mm/yy or 99/99/99=unknown	Core	
21.p	Result Hepatitis anti-HDV first test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	Test confirming the diagnosis for the first time
21q	Date of the first anti-HDV test	Date	dd/mm/yy or 99/99/99=unknown	Core	Test confirming the diagnosis for the first time
21r	Result Hepatitis anti-HDV latest test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	
21.s	Date of the latest anti-HDV test	Date	dd/mm/yy or 99/99/99=unknown	Core	
21t	Result HDV RNA first test	Numeric	0=Detectable 1=Undetectable 9=Unknown/unrecorded	Core	Test confirming the diagnosis for the first time Lower limit of detection according to the kit's producer
21u	Date of the first HDV RNA test	Date	dd/mm/yy or 99/99/99=unknown	Core	
21v	Result HDV RNA latest test	Numeric	0=Detectable 1=Undetectable 9=Unknown/unrecorded	Core	Lower limit of detection according to the kit's producer
21w	Date of the latest HDV RNA test	Date	dd/mm/yy or 99/99/99=unknown	Core	

Treatment of chronic HBV					
22	Patient on treatment in surveillance period	Numeric	1=Yes; 2=No; 9=Unknown	Core	If 2 (no) or 9 (unknown) go to question 27
23	Treatment eligible criteria used	Numeric	1= EASL 2= WHO criteria 3= Other 9= Unknown	Core	
Chronic HBV Treatment					
24	Date treatment start	Date	dd/mm/yy or 99/99/99=unknown	Core	
25	Treatment ended	Numeric	1=Yes; 2=No; 9=Unknown	Core	
25a	Date treatment end (if treatment ended)	Date	dd/mm/yy or 99/99/99=unknown	Core	
25b	If treatment ended, why?	Numeric	1=referred to another service	Core	

			2=lost to follow up 3=died 4= Other 9= Unknown		
26	Current treatment regimen	Numeric	1=Entecavir ; 2=Tenofovir disoproxil 3. Tenofovir alafenamide 4=Lamivudine ; 4=Other/multiple regimens ; 9=Unknown	Core	
27	Viral suppression achieved	Numeric	1=Yes; 2=No; 9=not done/unknown	Core	
<b>HCV Diagnosis</b>					
28	Chronic HCV Infection	Numeric	1=Yes; 2=No; 9=Unknown	Core	If 2 (no) or 9 (unknown), skip to end
29	Date first HCV diagnosis	Date	mm/yy or 99/99=unknown	Core	Test confirming the diagnosis for the first time
30	Location of first HCV positive result	Numeric	1=same as reporting site; 2=needle exchange 3=drug service (not needle exchange) 4=drug service and needle exchange 5= Sexual health clinics 6= Infectious diseases 7= Hepatitis services 8=Other treatment centre 9=unknown	Core	
<b>31. Test and results for chronic HCV diagnosis</b>					
31a	Result HCV RNA first test	Numeric	0=Detectable 1=Undetectable 9=Unknown/unrecorded	Core	Test confirming the diagnosis for the first time Lower limit of detection according to the kit's producer
31b	Date of the HCV RNA first test	Date	dd/mm/yy or 99/99/99=unknown	Core	Test confirming the diagnosis for the first time
31c	Result HCV RNA last test	Numeric	0=Detectable 1=Undetectable 9=unknown/unrecorded	Core	
32d	Date of the HCV RNA latest test	Date	dd/mm/yy or 99/99/99=unknown	Core	
32e	Result HCV-core Ag first test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	Test confirming the diagnosis for the first time
32f	Date of HCV-core Ag first test	Date	dd/mm/yy or 99/99/99=unknown	Core	Test confirming the diagnosis for the first time
32g	Result HCV-core Ag last test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	
32h	Date of the HCV-core Ag latest test	Date	dd/mm/yy or 99/99/99=unknown	Core	

32i	Result anti-HCV first test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	Test confirming the diagnosis for the first time
32j	Date of the first anti-HCV test	Date	dd/mm/yy or 99/99/99=unknown	Core	Test confirming the diagnosis for the first time
32k	Result anti-HCV last test	Numeric	1=positive; 2=equivocal; 3=negative; 9= not done/unknown	Core	
32l	Date of the last anti-HCV test	Date	dd/mm/yy or 99/99/99=unknown	Core	
<b>Treatment of chronic HCV</b>					
33	Patient on treatment in surveillance period	Numeric	1=Yes; 2=No; 9=Unknown	Core	If 2 (No) or 9 (Unknown), skip to the end
33a	If No (2), Why?	Numeric	1= Contra indication 2= Other reasons 9= Unknown	Additional	
34	Date treatment start	Date	dd/mm/yy or 99/99/99=unknown	Core	
35	Current treatment regimen	Numeric	1= DAA 2= other 3= multiple regimens	Core	
36	Treatment completed	Numeric	1=Yes; 2=No; 9=Unknown	Core	
36a	Date treatment end (if treatment completed)	Date	dd/mm/yy or 99/99/99=unknown	Core	Only if answer to question 32 is Yes
37	SVR achieved at last test	Numeric	1=Yes; 2=No; 9=not done/unknown	Core	
38	Date last SVR test	Date	dd/mm/yy or 99/99/99=unknown	Core	

## Annex C: Template/metadata to report aggregated data for Chronic HBV and HCV cases by participating sentinel site

	Total nb of Chronic HBV cases Collected	Total Nb of Chronic HCV cases Collected	Core or Additional	Comment
<b>Sentinel site details</b>				
<b>Country</b>			Core	
<b>Site code</b>			Core	
<b>Surveillance period</b>			Core	
<b>Patient details</b>				
<b>Age group (years)</b>			Core	
<5				
5–14				
15–19				
20–24				
25–34				
35–44				
45–54				
55–64				
≥65				
<b>Gender</b>			Core	
Female				
Male				
Transgender				
Other				
Unknown				
<b>Location at first diagnostic</b>			Core	
Same as reporting site				
Needle exchange				
Drug service (not needle exchange);				
Drug service and needle exchange				
Sexual health clinics				
Infectious diseases				
Hepatitis services				
Other treatment centre				
Unknown				
<b>Patient status in clinics</b>			Core	
Under follow up				
Referred to another service				
<b>Likely route of transmission</b>			Additional	
MSM/homo or bisexual male				

Heterosexual contact				
Sexual transmission (unspecified)				
Mother-to-child transmission				
Household contact of chronic case				
Injecting drug use				
Nosocomial transmission (includes hospital, nursing home, psychiatric institutions, dental)				
Any occupational exposure (includes needle stick injuries among healthcare workers)				
Blood and blood products				
Organ and tissues				
Haemodialysis				
Through selling sex				
<i>If yes</i>				
MSM				
Heterosexual				
Other				
Other (transmission route is known, but is not mentioned in the list)				
<b>Long term complications at diagnosis time</b>			Core	
Liver Fibrosis diagnosed				
Cirrhosis diagnosed				
Compensated				
Decompensated				
Hepatocellular carcinoma				
Other late-stage disease				
<b>Co infections</b>			Core	
Co-infection HBV and HCV				
Co-infection HBV Delta, HBV				
Co-infection HIV, at first diagnosis				
<b>Treatment</b>			Core	
Patient eligible for treatment				
Patient eligible for treatment and treated				
<b>Treatment outcomes</b>			Core	
Death				
Lost to follow up				

Viral suppression achieved				
Sustainable Virological Response				
Complication after treatment				