



TECHNICAL REPORT

Hepatitis B and C testing activities, needs, and priorities in the EU/EEA

ECDC TECHNICAL REPORT

Hepatitis B and C testing activities, needs, and priorities in the EU/EEA



This report of the European Centre for Disease Control and Prevention (ECDC) was coordinated by Lara Tavoschi, Erika Duffel, Cornelia Adlhoch (ECDC) and authored by Esther Aspinall, Sharon Hutchinson, David Goldberg (Glasgow Caledonian University/Health Protection Scotland).

Acknowledgements

ECDC acknowledges the following Member State focal points that responded to the surveys: Gaetan Muyldermans (Belgium), Nadezdha Vladimirova (Bulgaria), Tajana Nemeth Blazic (Croatia), Jan Fouchard (Denmark), Jevgenia Epstein and Irina Fillippova (Estonia), Sophie Vaux and Cecile Brouard (France), Ruth Zimmerman and Angela Neumyer-Gromen (Germany), Maria Takacs and Agnes Csohan (Hungary), Lelia Thornton (Ireland), Maria Elena Tosti (Italy), Raina Nikiforova (Latvia), Irma Caplinskiene (Lithuania), Tanya Melillo and Kathleen England (Malta), Birgit van Benthem (Netherlands), Kathrine Stene-Johansen and Astrid Lovl (Norway), Odette Popovici (Romania), Irena Klavs (Slovenia), Ana Avellon and Raquel Boix (Spain), Maria Axelsson and Ann-Sofi Duberg (Sweden), Koye Balogun, Andrew McAuley, Allan McLeod and Lesley Wallace (UK).

Suggested citation: European Centre for Disease Prevention and Control. Hepatitis B and C testing activities, needs, and priorities in the EU/EEA. Stockholm: ECDC; 2017.

Stockholm, May 2017

ISBN 978-92-9498-065-6

doi: 10.2900/05014

Catalogue number TQ-02-17-594-EN-N

Cover photo: Victor Casale, licensed under a Creative Commons attribution 2.0 generic license

© European Centre for Disease Prevention and Control, 2017

Reproduction is authorised, provided the source is acknowledged

Contents

Abbreviations	V
Executive summary	1
1 Background	2
2 Methods	3
2.1. Aims and objectives of the project	3
2.2. Survey respondents	3
2.3. Format and content of surveys	3
2.4. Piloting of surveys	3
2.5. Distribution of surveys	3
2.6. Analysis of survey data	3
2.7. Validation of survey data	4
3 Results and discussion	5
3.1. Response rates to surveys	5
3.2. Existence and content of national guidance on HBV and HCV testing	5
3.2.1 Policy on frequency of HBV/HCV testing for those at continued risk	8
3.3. Testing practice for HBV and HCV in EU/EEA Member States	8
3.3.1. Testing in prison settings	8
3.2.2. Use of point of care or dried blood spot testing for HBV/HCV	9
3.3.3. Funding of HBV/HCV testing	9
3.3.4. Linkage to care for people diagnosed with HBV and HCV	10
3.4. Monitoring and evaluation of testing for HBV and HCV	10
3.5. HBV and HCV testing needs and priorities	12
3.5.1 Gaps in HBV/HCV testing policy	12
3.5.2 Gaps in HBV/HCV testing practice	12
3.5.3 Need for HBV and HCV testing guidance	12
3.6. Availability of data on HBV/HCV liver-related morbidity and mortality	14
4 Discussion and conclusions	16
4.1 Testing policy and practice	16
4.2 Monitoring of testing, diagnosis and treatment	16
4.3 Availability of HBV/HCV morbidity and mortality data	17
4.4 Testing needs and priorities	17
4.5 Limitations	17
4.6 Conclusion	17
References	18
Appendix 1. Web links to EU/EEA Member State guidance that covers HBV/HCV testing	19
Appendix 2. Member States able to report on WHO core HBV/HCV indicators	20

Figures

Figure 3.1: EU/EEA Member States with dedicated HBV testing guidance*	6
Figure 3.2: EU/EEA Member States with dedicated HCV testing guidance*	7
Figure 3.3: HBV and HCV testing practices at prisons in EU/EEA countries	9
Figure 3.4: Funding of HBV and HCV testing in EU/EEA countries	10
Figure 3.5: Number of countries that report HBV/HCV risk groups not targeted effectively (N=21)	12

Tables

Table 2.1: Aims and objectives of Streams A and B of the project	3
Table 2.2: Content of the two HBV/HCV surveys	3
Table 3.1: Main sources of guidance covering HBV/HCV testing in EU/EEA Member States	5
Table 3.2: Number of countries that have national policy for testing of risk groups	7
Table 3.3: Countries with policy on frequency of HBV and HCV testing for those at continued risk	8
Table 3.4: Settings where HBV/HCV point of care and dried blood spot testing is offered	9
Table 3.5: Existence of care pathways for people diagnosed with HBV and HCV	10
Table 3.6: Countries that are monitoring testing, diagnosis and treatment of HBV/HCV	11
Table 3.7: Estimates of HBV/HCV tests performed and proportion of cases undiagnosed	11
Table 3.8: Gaps in HBV and HCV testing policy and practice in EU/EEA countries	12
Table 3.9: Need for European-level HBV/HCV testing guidance	13
Table 3.10: Topics that should be covered in HBV/HCV testing guidance	13
Table 3.11: Format and dissemination of any HBV/HCV testing guidance	14
Table 3.17: Availability of and feasibility of sharing liver-related morbidity and mortality data	14
Table A2.1: Number of Member States able to report on WHO core HBV/HCV indicators, based on information obtained from the survey	20

Abbreviations

BBV	Blood-borne virus
CDC	US Centers for Disease Control
DBS testing	Dried blood spot testing
EASL	European Association for the Study of Liver Disease
EEA	European Economic Area
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
GCU	Glasgow Caledonian University
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HPS	Health Protection Scotland
PWID	People who inject drugs
PoC testing	Point of care
Member States	Member State
MSM	Men who have sex with men
WHO	World Health Organization

Executive summary

ECDC undertook a survey to assess needs and priorities prior to developing guidance on testing and screening for hepatitis B and C (HBV/HCV) in the EU/EEA, and to update the existing evidence on the burden of HBV/HCV morbidity and mortality across EU/EEA Member States. The purpose of this work was to provide a baseline situation assessment to inform the guidance development process, and to assess the availability and feasibility of collecting additional morbidity and mortality data from EU/EEA Member States. As a subsidiary objective, the availability of information to monitor the HBV and HCV epidemic was assessed against the core indicators defined in the WHO Regional Action Plan for viral hepatitis¹.

Two semi-structured surveys were undertaken, covering 1) HBV/HCV testing policy, practices, needs and priorities, and 2) the availability of data on HBV/HCV liver morbidity and mortality. There were 21 individual responses to Survey 1, and 22 responses to Survey 2. Two sets of survey responses were received from the UK (England, Wales, and Scotland). Therefore, the response rate was 20 Member States out of 31 (65%), and 21 out of 31 (68%), respectively.

Nineteen countries (90%) had national testing guidance that included HBV, and 18 (86%) had national testing guidance that included HCV. Of these, six countries (29%) had specific HBV guidance on testing, and ten countries (48%) had specific HCV guidance. Thirteen countries had policy on testing of HBV/HCV among people who inject drugs (PWID). Key risk groups most frequently omitted from testing guidance were commercial sex workers, men who have sex with men (MSM), people receiving tattoos or piercings in an unregulated setting, and people who are homeless. At the policy level, the most commonly stated gap was a lack of policy documents or guidance for HBV or HCV testing (nine [43%] and eight countries [38%], respectively). At the implementation level, the most commonly cited gap was that risk groups were not targeted effectively (17 countries [81%] for HBV, and 16 countries [76%] for HCV).

Among those responding, eleven (52%) countries thought that there was a need for European-level HBV/HCV testing guidance, with the most commonly reported reason being that European guidance would assist in developing national policy, or add value to existing policy. 'Who to test', 'how to target those at risk', and 'monitoring and evaluation of testing initiatives' were the most commonly cited topics that should be included in any guidance.

The most frequently collected morbidity and mortality indicators were data on liver cancer (20 and 21 countries, respectively). HBV or HCV status in morbidity and mortality data was recorded by only a small number of countries, and was not consistently reported across different morbidity and mortality indicators.

The results of the surveys suggest there is a wide variation in HBV/HCV testing policy and practice, significant gaps in the existence of testing guidance, and a lack of HBV/HCV monitoring at national level. Many Member States expressed a need for European-level practical guidance on how testing initiatives should be conducted and indicated a need for EU support for the development of their own national-level guidance. Further work is likely to be required around HBV/HCV monitoring in order to meet the requirements of the WHO HBV/HCV core indicators.

¹ WHO Regional Office for Europe. Action plan for the health sector response to viral hepatitis in the WHO European Region. Copenhagen: WHO Regional Office for Europe; 2016. Available from: <http://www.euro.who.int/en/health-topics/communicable-diseases/hepatitis/publications/2016/action-plan-for-the-health-sector-response-to-viral-hepatitis-in-the-who-european-region.-draft-2016>

1 Background

Hepatitis B and C virus infections are associated with a considerable burden of disease in Europe. In high-income countries, transmission of hepatitis B (HBV) may occur through injecting drug use, but most cases in Europe now occur through heterosexual transmission or transmission between men who have sex with men (MSM). Chronic infection with HBV is associated with an increased risk of liver cirrhosis (between 8% and 20% within five years of diagnosis) and liver failure [1]. Hepatitis C (HCV) is mainly transmitted through injecting drug use [2], with a historical contribution from transfusion of infected blood products prior to the introduction of screening in the 1990s [3,4]. Up to 24% of people infected with chronic HCV will develop liver cirrhosis within 20 years of infection, with consequent risk of liver cancer and liver failure.

A recent report commissioned by ECDC ('Hepatitis B and C in the EU neighbourhood: prevalence, burden of disease, and screening policies' [5]) highlighted a wide range in HBV and HCV prevalence across Europe; for example HBV (HBsAg) prevalence was estimated to be <0.5% in Sweden and Finland, compared to 2–4% in Greece. HCV prevalence was <0.5% in Germany, compared with 1.4–2.6% in Spain. Reliable prevalence estimates were not available for nearly half of all European Union/European Economic Area (EU/EEA) Member States. The report also identified a range of testing practices and policies across Member States; for example, Ireland and Spain reported antenatal screening policies for both HBV and HCV, whereas most other countries screen for HBV alone [5]. Among people who inject drugs (PWID), testing for HCV has been supported by a number of national policies and consensus statements [6,7], but the report highlighted a lack of national-level policy on testing for HBV. There was also a lack of information from published sources on HBV and HCV testing practice among men who have sex with men and migrant populations.

An estimated 9–10 million individuals have been infected with HBV or HCV in the EU/EEA [5], with a considerable burden of undiagnosed infection likely to exist across Member States. The proportion of the HCV-infected population who remain undiagnosed is estimated to be 45% in Scotland (2013), 62% in Germany (2004), 43% in France (2004), and 88% in Italy (2004) [8]. Among PWID, data are available for only a small number of countries, of which the percentage of those undiagnosed ranges between 25% in Spain, 30% in France, and 59% in the UK [9]. Published data for HBV are not currently available, although the burden of undiagnosed infection is likely to be considerable, given the increased risk of HBV among 'hidden' populations such as new migrants and PWID.

Given the burden of HBV/HCV infection, and in particular the burden of undiagnosed infection, the contribution of viral hepatitis to liver-related morbidity and mortality is likely to be considerable. ECDC recently reviewed evidence on the burden of cirrhosis and liver cancer due to HBV/HCV across Member States; however, such evidence was limited as the available country-level data were not HBV/HCV-specific and included liver morbidity related to all causes, including obesity and alcohol [5].

ECDC undertook a survey to assess the level and the nature of the need for guidance on testing and screening for HBV and HCV in the EU/EEA, and to update the existing evidence on the burden of HBV/HCV morbidity and mortality across EU/EEA Member States. The purpose of this project was to provide a baseline EU/EEA situation assessment to inform the guidance development process and to update the previous work by ECDC on viral hepatitis testing practices [5]. ECDC is also exploring the possibility of complementing routine case-based surveillance of HBV/HCV using data from alternative sources. With regard to this objective, this assessment appraised the availability and feasibility of collecting additional data such as liver-related morbidity and mortality data among Member States. Finally, as a subsidiary objective, the availability of information to monitor the HBV and HCV epidemic was assessed against the core indicators defined in the WHO Regional Action Plan for viral hepatitis.

2 Methods

2.1. Aims and objectives of the project

This project formed part of a wider assessment of testing, diagnosis, and surveillance of viral hepatitis (B, C and E) being undertaken by ECDC and Glasgow Caledonian University (GCU)/Health Protection Scotland (HPS). The HBV/HCV testing study constituted Streams A and B of the project, while HEV constituted Stream C and is reported elsewhere. The aims and objectives of the study are outlined below.

2.2. Survey respondents

The target audience for Stream A (HBV/HCV testing needs and priorities) and Stream B (Burden of HBV/HCV-related disease) was the ECDC National Focal Points for HBV/HCV.

Table 2.1: Aims and objectives of Streams A and B of the project

Stream	Aims	Objectives
Stream A	Assess the need for European-level HBV/HCV testing guidance, and what format it should take	Describe and collect existing policies and guidelines on HBV and HCV testing in EU/EEA Member States and at supranational level.
		Describe current activities relating to HBV/HCV testing in Member States.
		Identify current needs and priority areas related to HBV and HCV testing in Member States.
Stream B	Obtain data on the burden of HBV and HCV morbidity and mortality for use by ECDC	Describe sources of data on morbidity and mortality attributable to HBV or HCV infection and assess the suitability and feasibility of sharing these data at the EU/EEA level.

2.3. Format and content of surveys

Two surveys were designed by GCU/HPS in consultation with the ECDC project team. The surveys were designed in electronic PDF format to allow respondents to complete their answers on-screen and submit responses by email. Survey content is outlined in Table 2.2.

Table 2.2: Content of the two HBV/HCV surveys

Stream	Survey	Content of survey
A	Survey 1: HBV and HCV testing policy, practice, needs, and priorities	<ul style="list-style-type: none"> • Existence of country-level guidance • Use of alternative guidance • Who/how/where testing is conducted • Testing monitoring or targets • Care pathways • Existence of gaps in testing policy or practice • Need for EU/EEA level guidance • Format of any guidance
B	Survey 2: HBV and HCV morbidity and mortality data	<ul style="list-style-type: none"> • Availability of liver-related morbidity and mortality data, • Which organisation holds data • Whether HBV/HCV status available • Possibility of sharing data with ECDC

2.4. Piloting of surveys

Surveys 1 and 2 were piloted with six HBV/HCV ECDC Disease Network members (from France, Poland, Romania, Ireland, Denmark, and Belgium), during January 2016. Respondents provided detailed feedback that was used to prepare final versions of the surveys for circulation.

2.5. Distribution of surveys

Surveys 1 and 2 were distributed to the ECDC National Focal Points for viral hepatitis in March 2016. A maximum of three contacts were made with each Focal Point: the initial group email invitation and two subsequent individual reminders.

2.6. Analysis of survey data

Survey data were extracted manually into Excel, and all data were double-checked. Descriptive analyses were conducted in Excel and Stata version 13. The denominator used for analyses was the total number of responses

received for each respective survey. Results for the two separate UK survey responses (from England and Wales, and Scotland) were presented separately (except for the calculation of survey response rate), due to differences in responses between the countries. For the purposes of this report, the term 'Member State' refers to when the UK has been considered as a single country in a survey response, and the term 'country' refers to responses that are specific to either England and Wales or Scotland.

Survey respondents reported that the survey had been challenging to complete from a national perspective, due to the variation in practice in most countries at the subnational level which was difficult to capture. An early draft of the results was shared with all members of the HBV/HCV Coordination Committee to ensure that responses were correctly interpreted and presented in the final report.

2.7. Validation of survey data

The final report presenting the findings from the survey was shared with ECDC National Focal Points for viral hepatitis in January 2017 for validation. In total, seven Member States provided feedbacks, mostly related to new elements available since the data collection of the survey.

3 Results and discussion

3.1. Response rates to surveys

Survey 1: There were 21 individual responses to Survey 1. Two responses were received from the UK; one from England and Wales, and one from Scotland. Therefore, the response rate was 20 Member States out of 31 (65%).

Survey 2: There were 22 individual responses to Survey 2. Two responses were received from the UK: England and Wales, and Scotland. Therefore, the response rate was 21 Member States out of 31 (68%).

Responses to Survey 1 and Survey 2 were received from the following Member States: Belgium, Bulgaria, Croatia, Denmark, Estonia, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Romania, Slovenia (Survey 2 only), Spain, Sweden, and the UK.

The number of respondents to Survey 1 and 2 were used as denominators in all subsequent analyses.

3.2. Existence and content of national guidance on HBV and HCV testing

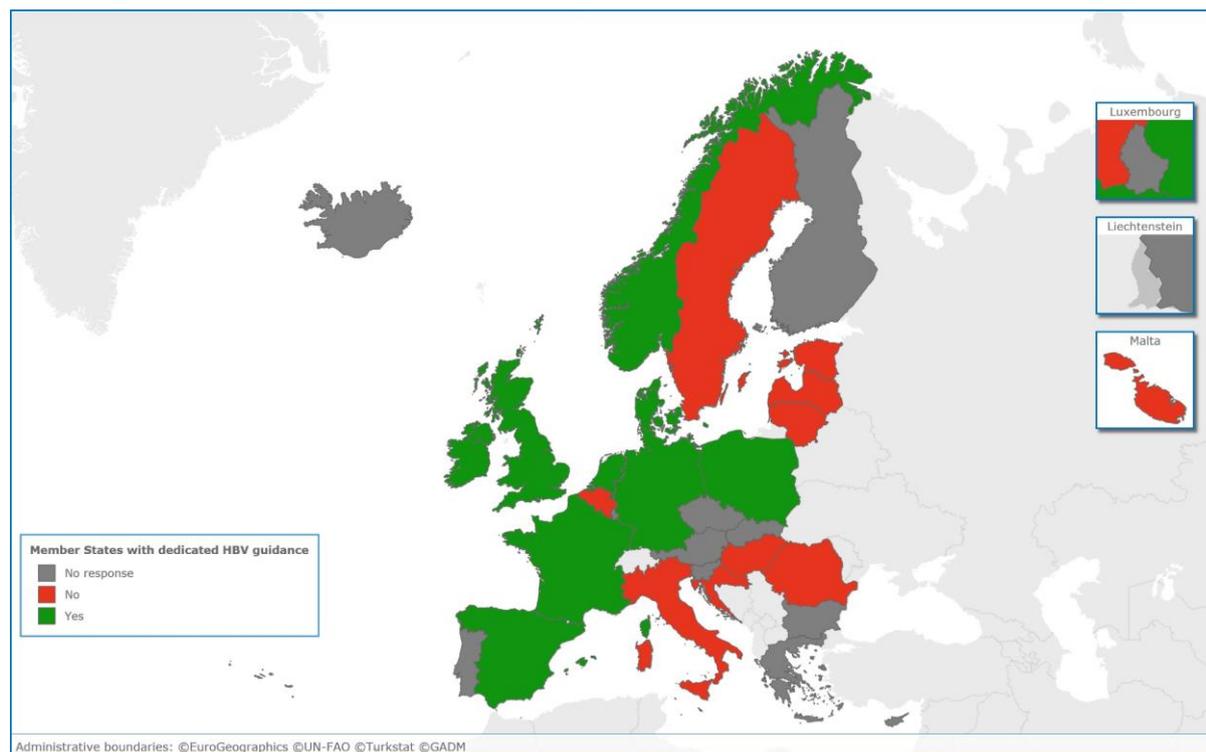
Of 21 countries responding to Survey 1, 19 (90%) had national-level testing guidance covering HBV, and 18 (86%) had national-level testing guidance covering HCV. Web links to guidance are provided in Appendix 1. For the purpose of this report, the definition of 'dedicated testing guidance' was that the primary topic of the document is HBV and/or HCV, and that testing is the main component, or forms a component, of the guidance. Using this definition, six countries (29%) were considered to have dedicated HBV guidance, and ten countries (48%) were considered to have dedicated HCV guidance (Figures 3.1 and 3.2). Nine countries reported that HBV or HCV testing guidance was covered in other documents, e.g. guidelines on screening during pregnancy, or blood donation policy. One country reported using European Association for the Study of Liver Disease (EASL) guidelines as their main source of guidance, and a further four countries reported using either EASL, World Health Organization (WHO), European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), or Centers for Disease Control (CDC) guidelines as additional sources of guidance. Five countries reported that they were in the process of either developing or updating national guidance on HBV and/or HCV. The list of testing guidance and guidance in development is shown in Table 1 and Appendix 1, with documents considered to be dedicated HBV/HCV testing guidance shown in bold.

Table 3.1: Main sources of guidance covering HBV/HCV testing in EU/EEA Member States

	Guidance covering HBV testing	Guidance covering HCV testing
Belgium	No national guidance but EASL guidance used	No national guidance but EASL guidance used
Bulgaria	Guidance available – no detail provided	Guidance available – no detail provided
Croatia	HBV immunisation policy Guidance on the management of HBV, HCV and HIV exposure currently in development	
Denmark	Guidance for HIV, HBV, and HCV: Prevention of BBV infection, diagnostics, and management in healthcare and other workplaces	
Estonia	Guidance covering pregnant women and blood donors	Guidance covering blood donors
France	Dedicated national guidance for HBV and HCV (2011 and 2014) and for HCV (2016)	
Germany	Dedicated national guidance on HBV prophylaxis, diagnosis, and treatment (2011)	Dedicated national guidance on HCV prophylaxis, diagnosis, and treatment (2012)
Hungary	HBV and HCV included in policy on the prevention of infectious diseases (2007); HBV included in policy on migration and free movement of people (2007)	
Ireland	Infectious disease assessment for migrants (2015); national hepatitis C strategy, 2011–2014; prevention of transmission of BBV in healthcare settings (2005); prevention of BBV in the renal setting (2014); prison service healthcare standards (2011); policy of testing all blood donations for HBV, HCV, and HIV. Perinatal HBV prevention policy and programme, and a HCV testing policy on who, where, and how frequently to test are both in development	
Italy	Policy on screening pregnant women and blood donors	Guidance available – no detail provided
Latvia	Guidance covering pregnant women, blood donors, post-exposure, healthcare workers, and prisoners Action plan for preventing the spread of HBV/HCV, HIV, and sexually transmitted infections is in development	
Lithuania	Guidance covering blood donors, prisoners, people who are HIV positive, healthcare workers (post-exposure), tissue donors, haemodialysis patients, statutory officer, patients in substitution methadone maintenance treatment	
Malta	Communicable disease strategy includes policy on HBV and HCV	
Netherlands	National hepatitis plan that covers testing policy is in development ; additional policy on screening for pregnant women, blood donors, at STI clinics and GP practices (for HBV), and blood donors and people who are HIV positive (for HCV)	
Norway	Draft national viral hepatitis strategy completed and awaiting government approval (2016)	
Poland	Policy that covers pregnant women, blood donors, patients using dialysis, and refugees	HCV testing guidelines for PWID, and HCV testing guidelines for the general population at GP level

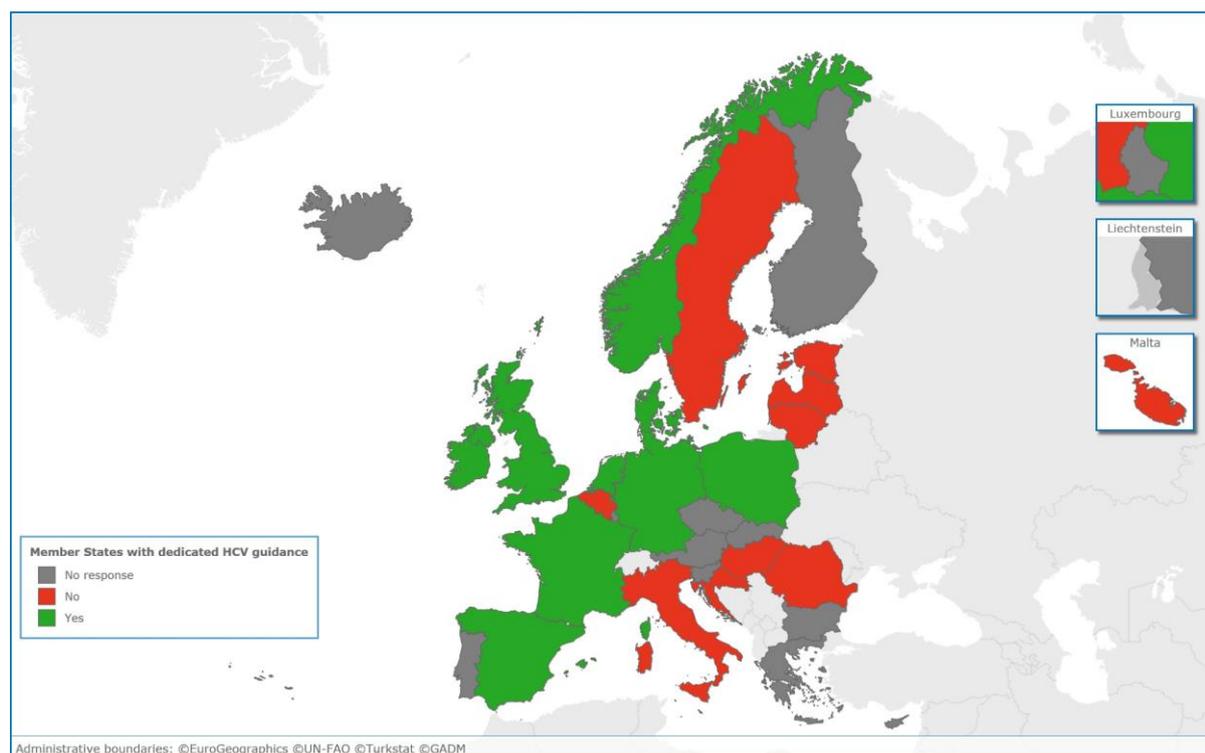
	Guidance covering HBV testing	Guidance covering HCV testing
Romania	Policy covering people with HIV, blood donors, pregnant women and newborn care	No guidance
Spain	Policy on blood donors, pregnant women and people in prison, recommendations on management of adults co-infected with HIV and viral hepatitis	Strategic plan for tackling hepatitis C in the Spanish national health system (2015)
Sweden	Health promotion and prevention of hepatitis and HIV for people who inject drugs: a guide (2015)	
England and Wales	Dedicated national testing guidance on HBV and HCV (2013)	
Scotland	Policy covering pregnant women, policy covering HBV vaccination in needle exchanges	Dedicated national guidance on HCV testing, diagnosis, and treatment (2013) Policy covering HCV testing in needle exchanges

Figure 3.1: EU/EEA Member States with dedicated HBV testing guidance*



* Availability of dedicated HBV national testing guidance may in some cases only apply to selected population groups or settings.

Figure 3.2: EU/EEA Member States with dedicated HCV testing guidance*



* Availability of dedicated HCV national testing guidance may in some cases only apply to selected population groups or settings.

The inclusion of key HBV/HCV risk groups in national testing policy is shown in Table 3.2. Of 21 countries responding to the survey, thirteen (62%) had a policy on testing of HBV/HCV among people who inject drugs (PWID). The main risk groups most frequently omitted from testing guidance were commercial sex workers, men who have sex with men (MSM), people receiving tattooing or piercings in an unregulated setting, people who are homeless, recipients of blood products prior to BBV screening, and recipients of dental treatment in a high-prevalence setting. The main difference between HBV and HCV was the existence of policy on pregnant women: 18 countries (86%) had a policy on testing for HBV among pregnant women, compared to only six countries (29%) for HCV.

Table 3.2: Number of countries that have national policy for testing of risk groups

Risk group	Number (%) of countries that have testing policy covering risk groups (N=21)					
	HBV			HCV		
	Yes	No	DK ^	Yes	No	DK ^
People who currently inject drugs	13 (62%)	4 (19%)	4 (19%)	13 (62%)	4 (19%)	4 (19%)
People who formerly injected drugs	12 (57%)	5 (24%)	4 (19%)	12 (57%)	5 (24%)	4 (19%)
People who snort or inhale drugs	7 (33%)	7 (33%)	7 (33%)	8 (38%)	7 (33%)	6 (29%)
People who are homeless	1 (5%)	13 (62%)	7 (33%)	1 (5%)	14 (67%)	6 (29%)
Commercial sex workers	6 (29%)	6 (29%)	9 (43%)	3 (14%)	9 (43%)	9 (43%)
Migrants*	7 (33%)	6 (29%)	8 (38%)	6 (29%)	7 (33%)	8 (38%)
People donating blood/products	18 (86%)	0 (0%)	3 (14%)	18 (86%)	0 (0%)	3 (14%)
Blood product recipients**	5 (24%)	10 (48%)	6 (29%)	10 (48%)	6 (29%)	5 (24%)
Abnormal liver function tests	11 (52%)	5 (24%)	5 (24%)	13 (62%)	3 (14%)	5 (24%)
People in prison	11 (52%)	4 (19%)	6 (29%)	10 (48%)	5 (24%)	6 (29%)
Men who have sex with men	6 (29%)	6 (29%)	9 (43%)	4 (19%)	9 (43%)	8 (38%)
Pregnant women	18 (86%)	0 (0%)	3 (14%)	6 (29%)	9 (43%)	6(29%)
Healthcare workers	12(57%)	5 (24%)	4 (19%)	10 (48%)	8 (38%)	3 (14%)
Children of mothers with HBV/HCV	14 (67%)	3 (14%)	4 (19%)	11 (52%)	6 (29%)	4 (19%)
Tattoos or body piercing***	5 (24%)	10 (48%)	6 (29%)	7 (33%)	7 (33%)	7 (33%)
Medical or dental treatment****	4 (19%)	10 (48%)	7 (33%)	5 (24%)	8 (38%)	8 (38%)

Risk group	Number (%) of countries that have testing policy covering risk groups (N=21)					
	HBV			HCV		
People who are HIV positive	15 (71%)	2 (10%)	4 (19%)	16 (76%)	1 (5%)	4 (19%)
Birth cohort	0 (0%)	13 (62%)	8 (38%)	0 (0%)	13 (62%)	8 (38%)
General population	1 (5%)^{^^}	13 (62%)	7 (33%)	1 (5%)^{^^}	13 (62%)	7 (33%)

* Migrants from countries with high HBV/HCV prevalence; ** Prior to screening of blood for HBV and HCV; *** People receiving tattoos or body piercings in an unregulated setting; **** Medical or dental treatment in a country where HBV or HCV is common; ^ Includes 'Don't know' and no response; ^^ Belgium responded that their testing is not limited to target groups, and that there is a policy to reimburse all tests conducted in the general population.

3.2.1 Policy on frequency of HBV/HCV testing for those at continued risk

Countries with policy on the frequency of HBV/HCV testing are shown in Table 3.3. The majority of countries reported that they did not have policy on the frequency of HBV testing. Three countries stated that this was because all individuals at risk who were negative for HBV were offered HBV vaccination. Five countries reported that they had policy on how often to test for HCV, 15 countries had no policy, and one country said that they did not know if there was any testing frequency policy. A small number of countries reported the frequency of testing of dialysis patients. Given that this group had not been included as a group of interest in the survey question, it is likely that other countries also had testing policy for dialysis patients but did not include these in their survey response. Responses related to dialysis patients are therefore not included in Table 3.3.

Table 3.3: Countries with policy on frequency of HBV and HCV testing for those at continued risk

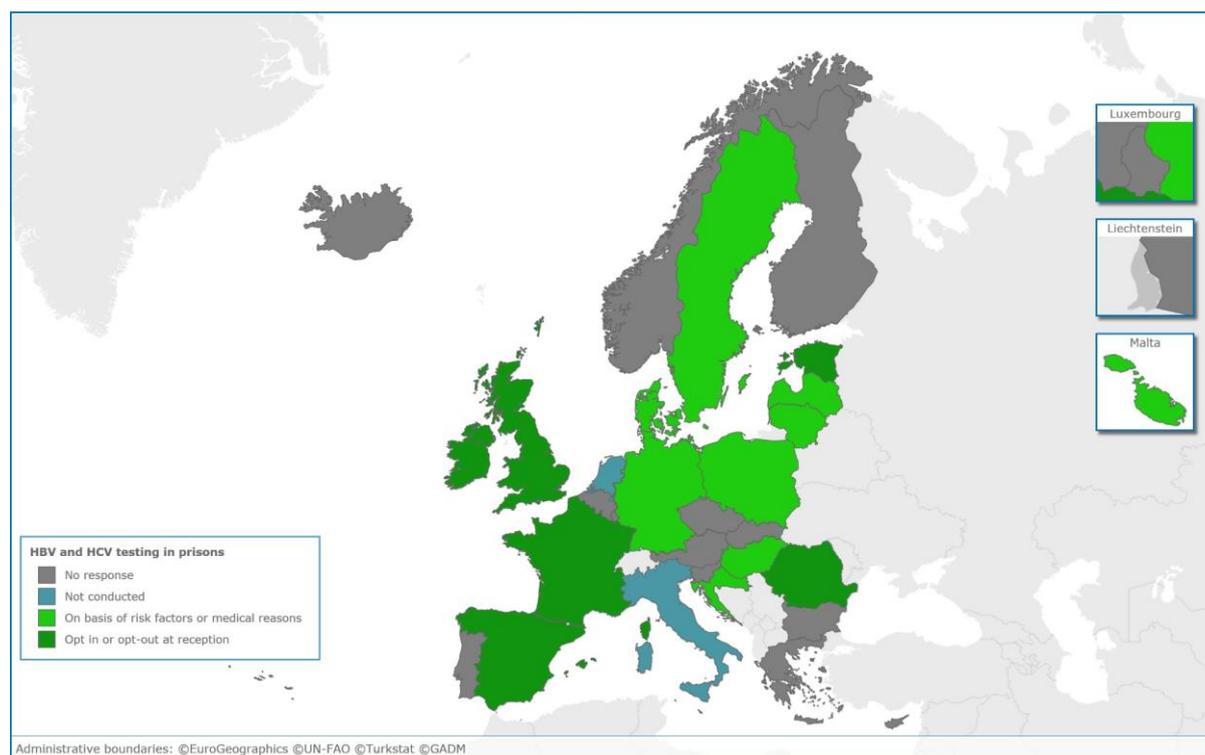
	Policy on frequency of testing
Croatia	PWID are tested for HCV at the beginning of their treatment and care for drug dependence, and subsequently when and if they are exposed to a new risk for infection
France	PWID should be tested for HCV at least once per year (every 6 months for active drug injectors)
Germany	PWID should be tested for HCV at least once per year
Netherlands	PWID should be tested for HCV once per year
United Kingdom	Offer annual HCV testing for all people who test negative but remain at risk of infection

3.3. Testing practice for HBV and HCV in EU/EEA Member States

3.3.1. Testing in prison settings

HBV/HCV testing practice in prisons by country is shown in Figure 3.3. Seventeen countries provided information on testing practice for HBV and HCV in prison settings. Responses to this survey question were the same for both HBV and HCV. The majority of countries that responded (nine countries [43%]) stated that HBV and HCV testing were only offered on the basis of risk factors or medical reasons, either at reception or during prison stay. Seven countries offered HBV/HCV testing to all prisoners at reception in at least some prisons (four countries on an opt-in basis, two countries on an opt-out basis, and one country on both an opt-in and opt-out basis).

Figure 3.3: HBV and HCV testing practices at prisons in EU/EEA countries



3.2.2. Use of point of care or dried blood spot testing for HBV/HCV

Nine countries were able to provide information on whether they used point of care (PoC) or dried blood spot (DBS) tests. Six countries (29%) reported using PoC tests, four countries (19%) reported using DBS tests, and one country reported that they used neither type of test. The remaining 12 countries (57%) either did not know whether PoC or DBS were used, or did not answer the question.

The most common settings in which PoC tests for HBV/HCV were reported to be used were community outreach settings (four countries [19%]). The most common settings in which DBS tests were reported to be used were community outreach (three countries [14%]), and additions services (three countries for HCV [14%]). One country (Ireland) reported that a pilot of rapid tests for HBV and HCV was currently taking place in community outreach settings.

Table 3.4: Settings where HBV/HCV point of care and dried blood spot testing is offered

Country	Point-of-care testing*	Dried blood spot*
Croatia	Outreach, voluntary anonymous testing and counselling centres	
Estonia	Not used	
France	Additions services (HCV only), outreach, community-based testing sites (HCV only; since 2016)	
Germany	No national programme, but may be used by individual services	
Ireland	Pilot currently taking place in outreach settings	
Latvia	Outreach	Low-threshold settings (e.g. HIV prevention points) and blood donation services (HCV only),outreach
Romania	Prison, outreach	
England and Wales	Primary care, sexual health services, hospitals, prison, addiction services	Primary care, sexual health services, hospitals, prison, addiction services, outreach
Scotland		Pharmacies, prison, addiction services (all HCV only)

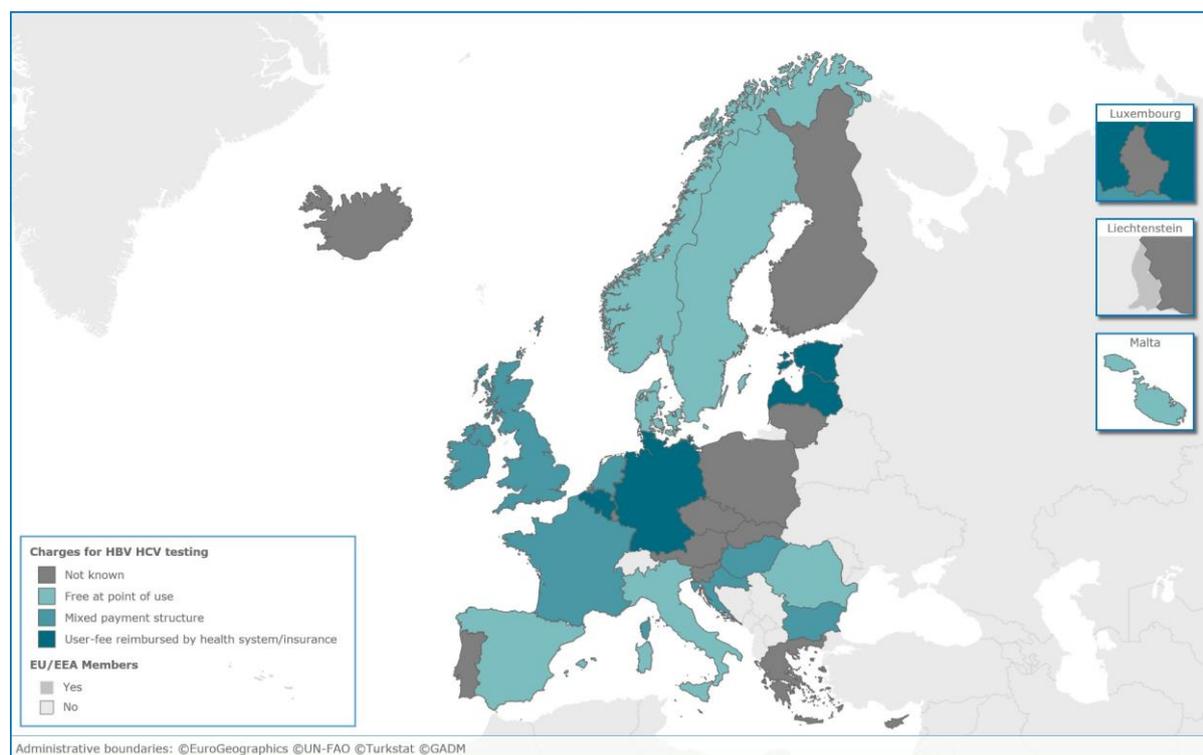
* Not known or no response from the following countries: Belgium, Bulgaria, Denmark, Hungary, Italy, Lithuania, Malta, Netherlands, Norway, Poland, Spain, and Sweden

3.3.3. Funding of HBV/HCV testing

Funding of HBV/HCV testing by country is shown in Figure 3.4. Most countries reported more than one type of approach to the funding of HBV/HCV testing. Fifteen of the countries that responded to this part of the survey (71%) reported that HBV/HCV testing was offered free at the point of use in at least some settings. Nine countries (43%) reported that there were reimbursed user-fees to access HBV/HCV testing in at least some settings, and

three (14%) countries reported using non-reimbursed user-fees. There were no countries where non-reimbursed user-fees were applied in all settings.

Figure 3.4: Funding of HBV and HCV testing in EU/EEA countries



3.3.4. Linkage to care for people diagnosed with HBV and HCV

The majority of countries (17 [81%]) reported that there were care pathways to link people diagnosed with HBV and HCV into treatment and care. Some countries reported that there were care pathways for all persons and care pathways for certain groups, as practice could differ across the country. Germany reported that there were national guidelines for treatment and care, but that there was a wide variation in how care pathways were put into practice, particularly in the prison setting (depending on the prison healthcare system and directives from the Federal Government). Ireland reported that care pathways only existed for prison and drug treatment clinics, and in areas where local arrangements had been set up between primary care and hospital services.

Table 3.5: Existence of care pathways for people diagnosed with HBV and HCV

Type of care pathway	Number (%), N=21 *
Care pathways exist to link all diagnosed persons to treatment and care	17 (81%)
Care pathways exist to link certain groups to treatment and care	7 (33%)
No care pathways exist	1 (5%)
Not known	0 (0%)

* Some countries provided more than one response.

3.4. Monitoring and evaluation of testing for HBV and HCV

Nineteen (90%) countries conducted monitoring of at least one testing, diagnosis, or treatment indicator for HBV. The most commonly monitored indicator was the number of positive cases detected (16 countries [76%]). Countries that monitored the largest number of HBV indicators included: Scotland (five indicators), Hungary (four indicators), and Croatia, Denmark, Romania, and England and Wales (three indicators each).

Sixteen countries (76%) conducted monitoring of at least one testing, diagnosis or treatment indicator for HCV. The most commonly monitored indicators were the number of positive cases detected (13 countries [62%]) and the number of people treated for HCV (12 countries [57%]). Countries that monitored the largest number of HCV indicators included Scotland (six indicators), Hungary and Latvia (five indicators each), and France, Ireland, and England and Wales (four indicators each). Monitoring of HBV and HCV testing and treatment indicators are shown in Table 3.6.

Table 3.6: Countries that are monitoring testing, diagnosis and treatment of HBV/HCV

	Tests performed	Positive cases	Proportion diagnosed	Number treated	Treated in time frame	Genotype
Belgium						
Bulgaria						
Croatia		*	*			
Denmark						
Estonia						
France						
Germany	Not known					
Hungary						
Ireland						
Italy	Not known					
Latvia						
Lithuania						
Malta	Not monitored					
Netherlands		*				
Norway						
Poland						
Romania						
Spain						
Sweden						
England and Wales						
Scotland						

Cell shaded in blue = indicator monitored for HBV; cell shaded in pink= indicator monitored for HCV; Number of people offered a HBV/HCV test and number of HBV/HCV tests offered were not monitored in any EU/EEA country
 * Monitoring done at national level for certain population groups or for acute cases only.

There were no countries that monitored either the number of HBV/HCV tests offered, or the number of people offered a test. However, a small number of countries were able to provide estimates of the tests conducted (Table 3.7). Similarly, very few countries could provide data on the proportion of HBV/HCV cases that are undiagnosed. Croatia, France, England and Wales, and Scotland reported that they monitored the proportion of HBV and/or HCV cases likely to be undiagnosed, but of these countries only France and Scotland could provide estimates of the undiagnosed population. Estimates of the proportion of HBV cases undiagnosed ranged from 45% (Scotland) to 55% (France). Estimates of the proportion of HCV cases undiagnosed ranged from 43% (France) to 78% (Poland). Country-level estimates are shown in Table 3.7.

Table 3.7: Estimates of HBV/HCV tests performed and proportion of cases undiagnosed

	HBV		HCV	
	Number of tests [year]	% undiagnosed [source of estimate and year]	Number of tests [year]	% undiagnosed [source of estimate and year]
Belgium		-	740 000 tests on 616 000 individuals [2013]	-
Denmark		50% [Expert opinion, 2013]		20% [Expert opinion, 2013]
France	2.9 million tests [2013]	55% [National seroprevalence survey, 2004]	2.8 million tests [2013]	43% [National seroprevalence survey, 2004]
Hungary	200 000 HBV tests conducted [2015]	-	100 000 HCV tests conducted [2015]	-
Ireland	-	-		50-67% [Expert opinion, 2014]
Poland	-	-		78% [Cross-sectional population study, 2015]
Romania	341 719 people tested [2015]	-	315 932 people tested [2015]	
England and Wales	297 631 people tested [2014]	-	183 001 people tested [2014]	
Scotland	At least 116 000 people tested [2014]	45% [Data modelling using population datasets, 2014]	At least 74 533 people tested [2014]	42% [Data modelling using population datasets, 2014]

3.5. HBV and HCV testing needs and priorities

3.5.1 Gaps in HBV/HCV testing policy

Respondents were asked to provide their opinion on existing gaps in HBV/HCV testing policy in their country. The most commonly reported gap was a lack of testing policy for HBV or HCV (nine [43%] and eight countries [38%] respectively (Germany, Ireland, Italy, Latvia, Malta, Poland, Romania, Sweden, and Scotland [HBV only])). The large majority of the countries had policies that covered some areas of HBV/HCV testing (e.g. covered in pregnancy guidelines or prison healthcare policy), but did not have dedicated HBV or HCV testing guidance.

3.5.2 Gaps in HBV/HCV testing practice

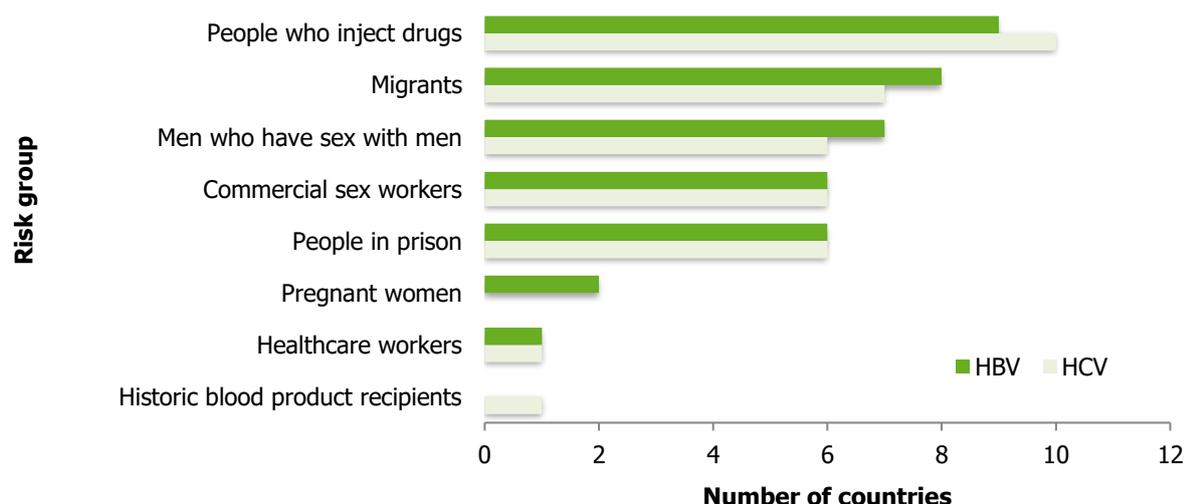
Countries were asked about gaps in HBV/HCV testing practice. The most commonly reported gap in practice was that risk groups were not targeted effectively (17 countries [81%] for HBV and 16 countries [76%] for HCV). The risk groups mentioned most frequently as not being targeted effectively were PWID and migrants from higher prevalence countries (Table 3.8 and Figure 3.5).

Table 3.8: Gaps in HBV and HCV testing policy and practice in EU/EEA countries

Gap in testing policy	Number (%) of countries (N=21)	
	HBV	HCV
No testing policy	9 (43%)	8 (38%)
Risk groups missing from testing policy		
Current or former People Who Inject Drugs	5 (24%)	6 (29%)
Migrant groups	5 (24%)	5 (24%)
Men who have sex with men	6 (29%)	7 (33%)
People in prison	4 (19%)	4 (19%)
Healthcare workers	2 (10%)	3 (14%)
Commercial sex workers	3 (14%)	2 (10%)
Policy does not adequately cover specific settings		
Community or outreach settings	4 (19%)	5 (24%)
Primary care	5 (24%)	5 (24%)
Hospital/secondary care	2 (10%)	2 (10%)
Gap in testing practice		
Risk groups not targeted effectively *	17 (81%)	16 (76%)
Lack of practitioner awareness of HBV/HCV	10 (48%)	9 (43%)
Lack of practitioner awareness of national HBV/HCV testing policy	6 (29%)	6 (29%)
Lack of public awareness of HBV/HCV and/or risk factors	9 (43%)	9 (43%)
Lack of access to or use of point-of-care or rapid diagnostic tests	7 (33%)	8 (38%)
User-fee to access testing	6 (29%)	6 (29%)

* Key risk groups are summarised in Figure 3.5

Figure 3.5: Number of countries that report HBV/HCV risk groups not targeted effectively (N=21)



3.5.3 Need for HBV and HCV testing guidance

Eleven (52%) countries considered that there was a need for HBV testing guidance at the EU/EEA level, and 12 (57%) countries thought there was a need for HCV testing guidance. The most common reasons for reporting a need for European-level testing guidance were that it would assist in developing national policy, or add value to

existing policy. One country noted that policy depended on the epidemiological situation within countries and considered there was no need for Europe-wide guidance. Conversely, another country suggested that a standardised approach to European guidance would be helpful, because populations were similar and there was increasing movement of populations across national borders. The various reasons given by country respondents are summarised in Table 3.9.

Table 3.9: Need for European-level HBV/HCV testing guidance

Need for European HBV/HCV testing guidance	Number (%)	Country	Reasons for response
Yes	12 (57%)	Croatia, Estonia, Germany, Hungary, Ireland, Latvia, Lithuania, Malta, Netherlands, Romania, Scotland, Spain	'To provide assistance in developing national guidance, policies, and strategies' 'A standardised approach would be helpful as the risk groups are the same throughout Europe and there is increasing movement of populations.' 'Would assist in developing national testing policy.' 'Would add value to existing guidance.' 'Would help to develop the national strategy'.
No	6 (29%)	Belgium, Denmark, Italy, Norway, Poland, Sweden	'EASL guidelines are already available.' 'Local guidelines are not always followed.' 'Each country has different epidemiological background, risk factors, and access to health services.' 'Policies need to be based on local epidemiological settings.' 'Each Member State differs in terms of epidemiological situation, risk factors, and organisation of healthcare'.
Don't know	3 (14%)	Bulgaria, France, England and Wales	'Each Member State has its own policy on HBV/HCV control.' 'There may be a need for guidance for Member States that do not have adequate national arrangements/policies in place for targeted settings'.

Of the countries that thought there was a need for testing guidance, 'who to test', 'how to target those at risk', and 'monitoring and evaluation of testing initiatives' were the most commonly cited topics for inclusion in any guidance (100% of respondents who agreed there was a need for HBV/HCV testing guidance) (Table 3.10). Of those countries reporting that guidance was needed, the majority considered that their preferred format was practical guidance (e.g. a toolkit with implementation-oriented tool) which should be published on the ECDC website. One country considered that case studies or a peer-reviewed publication were not necessary, for either HBV or HCV testing guidance (Table 3.11).

Table 3.10: Topics that should be covered in HBV/HCV testing guidance

Topics that should be covered in HCV/HCV testing guidance	Number (%) of countries (N=21)	
	HBV**	HCV**
Who to test (i.e. which risk groups)	11 (52%)	12 (57%)
Where to test	8 (38%)	9 (43%)
Types of diagnostic test	9 (43%)	9 (43%)
How often to test	11 (52%)	12 (57%)
How best to target individuals at risk of HBV/HCV	12 (57%)	13 (62%)
How best to target those who would most benefit from treatment *	9 (43%)	10 (48%)
How best to link diagnosed individuals into treatment and care	10 (48%)	11 (52%)
Economic appraisal of testing	10 (48%)	11 (52%)
Monitoring and evaluation of testing initiatives	11 (52%)	12 (57%)

* E.g. individuals with advanced liver disease ** One Member State responded to the questions about what should be covered in the guidance, but also added that guidance was not required.

Table 3.11: Format and dissemination of any HBV/HCV testing guidance

Format of HCV/HCV testing guidance	Number (%) of countries (N=21)	
	HBV	HCV
Separate HBV and HCV testing guidance	7 (33%)	
Collection of documents tailored to specific users, e.g. policy briefs, evidence summaries	8 (38%)	9 (43%)
Practical guidance, e.g. toolkit with implementation-oriented tools	10 (48%)	11 (52%)
Provision of additional resources, e.g. leaflets and posters for download	9 (43%)	10 (48%)
Collection of case studies and service models from EU/EEA countries	9 (43%)	10 (48%)
Dissemination of HBV/HCV testing guidance	HBV	HCV
Publication on ECDC website	12 (57%)	13 (62%)
Publication on additional websites other than ECDC	8 (38%)	9 (43%)
Peer-reviewed publication	9 (43%)	10 (48%)
Organise workshops to promote implementation	8 (38%)	9 (43%)

The European Liver Patients Association (ELPA) and the World Hepatitis Association (WHA) were also asked for their views on the need for European-level HBV/HCV testing guidance. ELPA responded that there was a need for European guidance, that the guidance should be incorporated into a single (rather than multi-part) document, and that it should ideally cover the following questions and topics: who, where, how often to test, types of diagnostic test, how best to target individuals at risk of HBV/HCV and at risk of advanced liver disease, how to link diagnosed individuals into treatment and care, economic appraisal of testing, and monitoring and evaluation of testing initiatives. ELPA suggested that the guidance should be in the form of practical guidance and/or a collection of case studies and service models from EU/EEA countries. This could be disseminated via ECDC and other websites, peer-reviewed publications, or through workshops to promote guidance implementation.

The WHA response suggested that there was a need for practical guidelines that enable hepatitis care to be integrated into health systems at the lowest marginal cost. It was suggested that there needs to be guidance that demonstrates to government how to make testing cost-effective.

3.6. Availability of data on HBV/HCV liver-related morbidity and mortality

The most frequently collected morbidity and mortality indicators were data on liver cancer (20 and 21 countries respectively). HBV or HCV status was recorded by only a small number of countries and was not consistently reported across different morbidity and mortality indicators. The availability of liver morbidity and mortality data is shown in Tables 3.17 and 3.18.

Table 3.17: Availability of and feasibility of sharing liver-related morbidity and mortality data

Country	Morbidity data					Mortality data			
	Liver cirrhosis	Chronic liver disease	Liver cancer	End stage liver disease	Liver transplant	Liver cirrhosis	Chronic liver disease	Liver cancer	End stage liver disease
Belgium*	x					x			
Bulgaria*			X					?	
Croatia*	x	x	X	x	✓	x	x	x	x
Denmark*	?	?	?	?	?	?	?	?	?
Estonia	x		X		x	x	x	x	
France*	✓	✓	✓	✓	?	✓	✓	✓	
Germany*	x		X		✓			x	
Hungary	x	x	?		?	x		x	
Ireland*	x		X		?	x	?	x	?
Italy*	x	x	X	x	x	x	x	x	x
Latvia*			✓					✓	
Lithuania*	✓	✓	✓	✓	✓	✓	✓	✓	✓
Malta*						?	?	?	
Netherlands*	x	x	X	x	?	x	x	x	x
Norway*	?	?	x	?	?	?	?	?	?
Poland (*)		✓^	x		✓		x	?	
Romania*	✓	✓	✓	✓	✓	✓	✓	✓	✓
Slovenia (*)	✓	✓	x	✓	x	x	x	x	x
Spain*	?		?		?	?		?	
Sweden*	x	x	x	x	x	x	x	x	x

Country	Morbidity data					Mortality data			
	Liver cirrhosis	Chronic liver disease	Liver cancer	End stage liver disease	Liver transplant	Liver cirrhosis	Chronic liver disease	Liver cancer	End stage liver disease
UK-E and W*	✓	✓	✓	✓	✓	✓	✓	✓	✓
UK-Scotland*	✓	✓	✓	✓	✓	✓	✓	✓	✓
Total **	6 (18)	7 (14)	6 (20)	6 (12)	7 (18)	5 (18)	5 (16)	6 (21)	4 (12)

Cell shaded = data available; ✓ = HBV/HCV status available in the data; X = HBV/HCV status not available in data; ? = HBV/HCV status not known; * = Data sharing may be possible; (*) = Data sharing may be possible for morbidity data only; ^ = Only HCV status available; cell not shaded = data not available or not known; ** = Shows total number of countries with data available AND HBV/HCV status reported; and (total number of countries with data available)

* Data sharing may be possible

4 Discussion and conclusions

This report outlines current HBV and HCV testing policy and practice, needs and priorities, and the availability of HBV/HCV morbidity and mortality data across 21 EU/EEA Member States. Despite the somewhat low response rate (65% and 68% for surveys 1 and 2, respectively), there was a range of responses from different geographic regions, including northern, southern, and eastern Europe.

4.1 Testing policy and practice

The survey findings reveal a wide variation in testing policy and practice across the EU/EEA, and a number of significant gaps. Less than half of EU/EEA countries have dedicated HBV or HCV testing guidance (29% and 48%, respectively), with the remainder having either a number of unrelated policies where HBV/HCV is covered, or no testing policy at all. As a result, many Member States have no policy covering the key risk groups; only two thirds of Member States have policy covering testing for PWID, and one third have testing policy that covers commercial sex workers, men who have sex with men, or recipients of blood products prior to BBV screening. Many countries reported that they had policy covering some areas of HBV/HCV testing (e.g. testing covered in pregnancy guidelines or prison healthcare policy), but not dedicated HBV/HCV testing guidance. Nine countries (43%) thought that the lack of HBV testing guidance was a significant gap in policy in their country, and eight (38%) reported the same for HCV, suggesting a need for HBV and/or HCV testing guidance to be developed at country level.

Similarly, there was a wide range of testing practice across Member States responding to the survey. The three main topic areas covered in the survey were testing in prisons, existence of point-of-care tests, and how testing was funded. In the prison setting, there appeared to be a lack of routine testing policy. Only eight countries offered HBV/HCV testing at prison reception, despite evidence that routine testing and treatment in the prison setting is likely to be cost-effective in the era of directly acting antiviral (DAA) HCV therapies [10,11]. Only two Member States reported using PoC or DBS testing in the prison setting, and there was a lack of use of these tests more generally, even in Addictions or Outreach settings. A recent systematic review of DBS and PoC tests found that DBS may increase the uptake of testing among high-risk populations (and also increase HCV diagnosis in a small number of studies), but there was a lack of evidence around point-of-care testing [12]. Only a third of survey respondents felt that the lack of access to these tests constituted an important gap in testing practice; with gaps more frequently reported around how to target those at risk, rather than how the test itself is conducted.

HBV/HCV testing in most Member States was offered free at the point of use or through reimbursed user fees. Only four Member States (19%) reported that non-reimbursed user fees were sometimes charged, and there were no Member States where this was the only means of accessing testing. Despite the limited comparability, this appears to represent progress since the 2012 WHO HBV/HCV survey, which reported that at least 40% of all countries in the European region charged for testing among at least some population groups [13]. A small number of Member States considered that user-fees constituted a significant barrier to accessing testing in their country. The majority of these countries had mixed payment structures (i.e. some free at point of use, some reimbursed or non-reimbursed fees), possibly creating confusion as to what services might be available free of charge.

4.2 Monitoring of testing, diagnosis and treatment

The survey findings suggest that limited monitoring of HBV/HCV testing, diagnosis, and treatment is taking place across EU/EEA Member States. The most frequently monitored indicator for HCV was the number of people treated (12 countries), whereas the number treated for HBV is only monitored in seven countries. This difference may reflect the variable length of HBV treatment, making the number of HBV treatment episodes much harder to monitor. There are no HBV or HCV indicators that are monitored by all responding Member States, meaning that further work would be required for any Europe-wide monitoring. Indeed, the HBV/HCV monitoring framework recently published by the World Health Organization [14] includes a number of indicators that appear to be measured by very few EU/EEA Member States: across four WHO core indicators, the number of Member States able to provide relevant data ranges from 14% to a maximum of 57% (Table 3.18). A further two indicators: C.8.a (proportion of patients on HBV treatment in whom viral load is suppressed) and C.8b (proportion of patients with HCV who are cured among those who completed treatment) are also likely to be difficult to report, given the lack of monitoring of the number of people starting treatment. The lack of monitoring taking place in high-income European countries bodes poorly for the feasibility of data collection and reporting in low- and middle-income countries.

4.3 Availability of HBV/HCV morbidity and mortality data

Although the majority of EU/EEA Member States reported that they collected data on liver-related morbidity and mortality, only a small number of Member States collected data on the HBV/HCV status of those with liver disease. The most frequently available data were HBV/HCV chronic liver disease (both morbidity and mortality), and HBV/HCV liver cancer mortality. Comparisons with previous ECDC work on HBV/HCV morbidity and mortality surveillance [15] are difficult due to the different wording of the questions that were asked between the two surveys. The lack of available data on HBV/HCV-specific liver morbidity and mortality means that many Member States will be unable to report on the WHO core indicators on HBV/HCV mortality [15]. Of the three types of HBV/HCV liver death specified by WHO (liver cancer, liver cirrhosis, and chronic liver disease), only four Member States are currently able to monitor all three (See Annex 2).

4.4 Testing needs and priorities

Just over half of responding countries agreed that there is a need for European-level testing guidance, in particular guidance covering who to test, how to target those at risk, and monitoring and evaluation of testing initiatives. Many respondents cited the need for practical/toolkit-type guidance that would be readily available, e.g. on the ECDC website. It was considered that this guidance could support the development of national guidance documents, add value to existing guidance, and would be timely, given the increasing movement of populations across national borders.

4.5 Limitations

There were some important limitations that may affect the validity of the findings. Firstly, respondents found that the survey was difficult to complete: considering that many of the questions were open to different interpretations and that active engagement with a broad team of colleagues was needed in order to answer the questions. Furthermore, respondents reported it to be challenging to provide simple universal answers, which could not accurately represent the diversity in practices (and policy) across a country. This was particularly relevant for countries such as Germany and Ireland. The difference between terms such as policy, guidance and practice may have been subject to different interpretations by different respondents. Also, there may be situations where no explicit policy exist in a country, but a fairly uniform practice is implemented. More than a third of EU/EEA countries did not respond to the survey, thus affecting the generalisability of the findings to the whole region. Finally, the questionnaire was in English only and no translation was available.

4.6 Conclusion

The results suggest a wide variation in existing testing policy and practice, and a public health added value in having Europe-wide practical guidance on how testing initiatives should be conducted, evaluated, and monitored. There is a lack of monitoring of all aspects of HBV/HCV testing, diagnosis, treatment, morbidity, and mortality, and further work is likely to be required to meet the requirements of the WHO HBV/HCV core indicators.

References

1. European Association for the Study of Disease of the Liver. EASL Clinical Practice Guidelines: Management of chronic hepatitis B virus infection. *Journal of Hepatology*, 2012, 57; 167-185
2. Nelson PK, Mathers BM, Cowie B, Hagan H, Des Jarlais D, Horyniak D, et al. Global epidemiology of hepatitis B and hepatitis C in people who inject drugs: results of systematic reviews. *Lancet*. 2011; 378: 571–83.
3. Alter MJ, Hadler SC, Judson FN, Mares A, Alexander J, Hu PY, et al. Risk factors for acute non-A, non-B hepatitis in the United States and association with hepatitis C virus infection. *J Am Med Assoc*. 1990; 264: 2231–5.
4. Villano SA, Vlahov D, Nelson KE, Lyles CM, Cohn S, Thomas DL. Incidence and risk factors for hepatitis C among injection drug users in Baltimore, Maryland. *J Clin Microbiol*. 1997; 35: 3274–7.
5. European Centre for Disease Prevention and Control, 2010. Hepatitis B and C in the EU Neighbourhood: prevalence, burden of disease and screening policies. Stockholm: ECDC; 2010a. Cited 10 July 2015. Available from: http://ecdc.europa.eu/en/publications/Publications/TER_100914_Hep_B_C%20_EU_neighbourhood.pdf
6. Healthcare Improvement Scotland. Quality Indicators for Hepatitis C, April 2012. Cited 13 July 2015. Available from: http://www.healthcareimprovementscotland.org/our_work/long_term_conditions/hepatitis_c/hepatitis_c_quality_indicators.aspx
7. Consensus Conference report. French consensus conference on hepatitis C: screening and treatment. *Gut* 1998, 42: 892-898
8. Cornberg M, Razavi HA, Alberti A, Bernasconi E, Buti M, Cooper C, et al. A systematic review of hepatitis C virus epidemiology in Europe, Canada, and Israel. *Liver International*, 2011; 31: s2; 30-60
9. Wiessing L, Ferri M, Grady B, Kantzanou M, Sperle I, Cullen KJ, et al. Hepatitis C virus infection epidemiology among people who inject drugs in Europe: A systematic review of data for scaling up treatment and prevention. *PLoS One*, 2014; 9 (7): e103345
10. Martin NK, Hickman M, Miners A, Hutchinson SJ, Taylor A, Vickerman P. Cost-effectiveness of HCV case-finding for people who inject drugs via dried blood spot testing in specialist addiction services and prisons. *BMJ Open*, Aug 2013; 3(8)
11. Martin NK, Vickerman P, Brew IF, Williamson J, Miners A, Irving WL, et al. Is increased hepatitis C virus case-finding combined with current or 8-week to 12-week direct-acting antiviral therapy cost-effective in UK prisons? A prevention benefit analysis. *Hepatology*, 2016; 63: 1796-1808
12. Coats JT, Dillon JF. The effect of introducing point-of-care or dried blood spot analysis on the uptake of hepatitis C virus testing in high-risk populations: A systematic review of the literature. *International Journal of Drug Policy*, 2015; 26: 1050-1055.
13. World Health Organization. Global Policy report on the prevention and control of viral hepatitis in WHO member states. WHO, Geneva, 2013. Cited 6 September 2016. Available from: http://apps.who.int/iris/bitstream/10665/85397/1/9789241564632_eng.pdf
14. World Health Organization. Monitoring and evaluation for viral hepatitis B and C: recommended indicators and framework. WHO, Geneva, 2016. Cited 24 June 2016. Available from: http://apps.who.int/iris/bitstream/10665/204790/1/9789241510288_eng.pdf
15. European Centre for Disease Prevention and Control, 2010. Surveillance and prevention of hepatitis B and C in Europe. Stockholm: ECDC; 2010b. Cited 27 June 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/101012_TER_HepBandC_survey.pdf

Appendix 1. Web links to EU/EEA Member State guidance that covers HBV/HCV testing

Member State	Virus	Web link to guidance
Denmark	HBV/HCV	https://sundhedsstyrelsen.dk/~media/AD9E0753B12546B8AEA323BF02AC3D2C.ashx
Estonia	HBV	https://www.riigiteataja.ee/akt/640871 https://www.riigiteataja.ee/akt/127102015008
	HCV	http://www.eusti.ee/Ravijuhis_2015.pdf
France	HBV/HCV	http://www.has-sante.fr/portail/jcms/c_1050355/fr/strategies-de-depistage-biologique-des-hepatites-virales-b-et-c http://social-sante.gouv.fr/IMG/pdf/Rapport_Prise_en_charge_Hepatitis_2014.pdf
	HCV	http://social-sante.gouv.fr/IMG/pdf/rapport_.pdf
Germany	HBV/HCV	http://www.awmf.org/uploads/tx_szleitlinien/021-011l_S3_Hepatitis_B_Virusinfektionen_Prophylaxe_Diagnostik_Therapie_2011-07.pdf www.rki.de/DE/Content/Infekt/Blut/Blutsicherheit/FAQ_node
Hungary	HBV/HCV	http://njt.hu/cgi_bin/njt_doc.cgi?docid=131312.317640 http://njt.hu/cgi_bin/njt_doc.cgi?docid=34341.314410
Ireland	HBV/HCV	http://www.hpsc.ie/A-Z/SpecificPopulations/Migrants/MigrantToolkit/ http://www.hse.ie/eng/services/publications/HealthProtection/HepCstrategy.pdf http://www.hpsc.ie/AZ/Hepatitis/BloodborneVirus/File.4352.en.pdf https://www.giveblood.ie/Become_a_Donor/Keeping_Blood_Safe/ http://www.hpsc.ie/A-Z/Hepatitis/BloodborneVirus/File.4374.en.pdf http://www.irishprisons.ie/images/pdf/hc_standards_2011.pdf
Italy	HBV/HCV	http://www.salute.gov.it/imgs/c_17_normativa_1653_allegato.pdf http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=53728&articolo=39
Latvia	HBV/HCV	http://likumi.lv/doc.php?id=140695 http://likumi.lv/doc.php?id=125683 http://likumi.lv/doc.php?id=144279 http://likumi.lv/doc.php?id=11215 http://likumi.lv/doc.php?id=56050 http://likumi.lv/ta/id/274511 http://polsis.mk.gov.lv/documents/4965
Lithuania	HBV/HCV	https://www.e-tar.lt/portal/lt/legalAct/9fdfab0581911e487f9801bbd787a9f https://www.e-tar.lt/portal/lt/legalAct/TAR.A8DBA9F5457B https://www.e-tar.lt/portal/lt/legalAct/TAR.ECA3E41BD530/TzxkqSZTxE https://www.e-tar.lt/portal/lt/legalAct/TAR.ABA07177DB7F/MwKxNvdLki https://www.e-tar.lt/portal/lt/legalAct/0e618d901cc811e69446a4bedc730fe6
Romania	HBV	http://www.ms.ro/documente/Anexa%202%20la%20norme%20BTS_14877_17043.pdf http://www.ms.ro/documente/Anexa%204%20la%20norme%20securit_14877_17045.pdf http://www.transfuzia.ro/Legislatie%20Romania/LEGE_Nr_282.pdf http://www.ms.ro/documente/Anexa%207%20la%20norme%20Mama%20si%20copii_14877_17049.pdf http://lege5.ro/Gratuit/geydcnbssha/ordinul-nr-916-2006-privind-aprobarea-normelor-de-supraveghere-prevenire-si-control-al-infectiilor-nosocomiale-in-unitatile-sanitare
Spain	HBV/HCV	http://www.msssi.gob.es/profesionales/saludPublica/medicinaTransfusional/legislacion/legislacion.htm http://www.msssi.gob.es/ciudadanos/enfLesiones/enfTransmisibles/sida/publicaciones/recomendaciones.htm http://www.institucionpenitenciaria.es/web/portal/laVidaEnPrision/atencionSanitaria/epidemiologia.html http://www.institucionpenitenciaria.es/web/portal/laVidaEnPrision/atencionSanitaria/psiquiatria.html http://www.institucionpenitenciaria.es/web/portal/laVidaEnPrision/atencionSanitaria/programasSalud.html https://www.msssi.gob.es/organizacion/sns/planCalidadSNS/pdf/Guia_practica_AEP.pdf
	HCV	http://www.msssi.gob.es/organizacion/sns/planCalidadSNS/pdf/Guia_practica_AEP.pdf http://www.institucionpenitenciaria.es/web/portal/laVidaEnPrision/atencionSanitaria/programasSalud.html
England and Wales	HBV/HCV	http://publications.nice.org.uk/hepatitis-b-and-c-ways-to-promote-and-offer-testing-to-people-at-increased-risk-of-infection-ph43/considerations
Scotland	HBV	https://www.gov.uk/guidance/infectious-diseases-in-pregnancy-screening-programme-overview http://www.bhiva.org/SRH-guidelines.aspx https://www.gov.uk/government/publications/new-healthcare-workers-clearance-for-hepatitis-b-and-c-tb-hiv
	HCV	www.sign.ac.uk/guidelines/fulltext/133/index.html

Appendix 2. Member States able to report on WHO core HBV/HCV indicators

Table A2.1: Number of Member States able to report on WHO core HBV/HCV indicators, based on information obtained from the survey

World Health Organization Indicator [WHO 2016]	Number (%) of EU/EEA Member States with data available to monitor this indicator, N=22	
	HBV	HCV
C.6: Proportion of people living with chronic HBV/HCV who have been diagnosed	3 (14%)	5 (23%)
C.7.a: Proportion of HBV-infected persons who are currently on treatment	7 (32%)	
C.7.b: Proportion of persons diagnosed with chronic HCV started on treatment during a specified time frame		12 (55%)
C.10: Deaths attributable to HBV/HCV infection:		
Due to liver cancer	6 (27%)	6 (27%)
Due to cirrhosis	5 (23%)	5 (23%)
Due to chronic liver disease	6 (27%)	6 (27%)
Data available on all three causes of HBV/HCV liver death	5 (23%)	5 (23%)

**European Centre for Disease
Prevention and Control (ECDC)**

Postal address:
Granits väg 8, SE-171 65 Solna, Sweden

Visiting address:
Tomtebodavägen 11A, SE-171 65 Solna, Sweden

Tel. +46 858601000
Fax +46 858601001
www.ecdc.europa.eu

An agency of the European Union
www.europa.eu

Subscribe to our monthly email
www.ecdc.europa.eu/en/publications

Contact us
publications@ecdc.europa.eu

Follow us on Twitter
[@ECDC_EU](https://twitter.com/ECDC_EU)

Like our Facebook page
www.facebook.com/ECDC.EU

ECDC is committed to ensuring the transparency and independence of its work

In accordance with the Staff Regulations for Officials and Conditions of Employment of Other Servants of the European Union and the ECDC Independence Policy, ECDC staff members shall not, in the performance of their duties, deal with a matter in which, directly or indirectly, they have any personal interest such as to impair their independence. Declarations of interest must be received from any prospective contractor(s) before any contract can be awarded.
www.ecdc.europa.eu/en/aboutus/transparency

HOW TO OBTAIN EU PUBLICATIONS

Free publications:

- one copy:
via EU Bookshop (<http://bookshop.europa.eu>);
- more than one copy or posters/maps:
from the European Union's representations (http://ec.europa.eu/represent_en.htm);
from the delegations in non-EU countries (http://eeas.europa.eu/delegations/index_en.htm);
by contacting the Europe Direct service (http://europa.eu/europedirect/index_en.htm) or
calling 00 800 6 7 8 9 10 11 (freephone number from anywhere in the EU) (*).

(* The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Priced publications:

- via EU Bookshop (<http://bookshop.europa.eu>).



■ Publications Office