Hepatitis B and C
An action plan for saving lives in Europe
The experts’ recommendation summary
Content and editorial team
Margaret Walker (CEO, ELPA)
Achim Kautz (Policy Consultant, ELPA)
Lilyana Chavdarova (Policy Manager, ELPA)

Acknowledgements
The authors would like to thank Stacey Jackson, Managing Director, Solcroft Ltd, for providing expert research, editorial and design support in putting together this consensus paper.

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About this paper

Over the past four decades, we have seen a significant increase in people across Europe being affected by hepatitis B and C; both serious, asymptomatic, infectious diseases that kill around 120,000 people in Europe every year. In response to this, a large body of work has been produced over the past three years, giving information and recommendations on how to address the burden of the disease. These ideas help to define the problem and offer guidance on how to manage it, but they do not necessarily offer direct action points. This makes it difficult for those making decisions on policy to determine the best route to take.

Last year, leading experts, institutions, patient organisations and pharmaceutical industry representatives met and agreed that the major recommendations produced between 2011 and 2014 should be compiled into one comprehensive document, to make it easier for policy makers, decision makers, civil society organisations and healthcare institutions to tackle viral hepatitis effectively. This is the focus of this paper.

Contributing institutions

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<tr>
<td>Correlation Network: European Network Social Inclusion &amp; Health</td>
<td>Eberhard Schatz</td>
</tr>
<tr>
<td>European Association for the Study of the Liver (EASL)</td>
<td>Alessio Aghemo, Fiona Godfrey</td>
</tr>
<tr>
<td>European Liver Patients’ Association (ELPA)</td>
<td>Lilyana Chavdarova, Achim Kautz, Tatjana Reic, Margaret Walker</td>
</tr>
<tr>
<td>Scotland’s Hepatitis C Action Plan Government Board</td>
<td>David Goldberg</td>
</tr>
<tr>
<td>US Centers for Disease Control and Prevention (US CDC)</td>
<td>Deborah Holtzman</td>
</tr>
<tr>
<td>Viral Hepatitis Prevention Board</td>
<td>Tinne Lernout</td>
</tr>
<tr>
<td>World Health Organization (WHO)</td>
<td>Stefan Wiktor</td>
</tr>
<tr>
<td>World Hepatitis Alliance (WHA)</td>
<td>Charles Gore</td>
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ELPA wishes to acknowledge the useful input and comments from Dr Andrew J Amato-Gauci and colleagues, from ECDC’s Hepatitis Programme.

1 Ulmer T, Hughes S et al (2014), page 3
Viral hepatitis affects millions of people every year, causing disability and death, yet most people infected with hepatitis B or C are unaware of their infection.\(^2\) As a result of these high infection levels, the loss of productivity\(^3\) and the financial costs of treatment place a heavy burden on societies across the world. However, the problem of this ‘silent pandemic’ has not yet been addressed by the global community in a systematic and decisive manner.

**The situation in the US**

Viral hepatitis also constitutes a major public health challenge in the US, where they are currently developing and implementing key recommendations to address this burden. In addition to an ongoing hepatitis B vaccination programme, efforts have been made to improve care and treatment for those living with viral hepatitis and national recommendations have focused on prevention activities, such as baby boomer testing\(^4\). The US has also benefited from major advances in hepatitis C treatment by licensing new Direct Acting Agents (DAAs) to improve outcomes.\(^5\)

The EU-28 Member States and the European Commission must take the opportunity to learn from these developments and put in place appropriate action plans.

**The European situation (EU-28)**

The EU has islands of good practice in terms of intervention provision, uptake and impact,\(^6\) but most countries face major challenges in delivering high-quality, effective hepatitis services. The World Health Organization (WHO) has recommended that the EU and its Member States develop and implement a hepatitis action plan\(^7\) that encompasses awareness, prevention and treatment across all relevant policy areas.

Europe’s investment in basic health research, including health outcomes research, needs to increase significantly, and the findings of such research will also need to be applied and implemented.\(^8\) Education and awareness raising among policy makers, the general public and healthcare professionals is pivotal to improve the prevention and management of hepatitis C.\(^9\) The links between hepatitis C and liver cancer should also be highlighted, and better links between oncology and gastroenterology/hepatology experts promoted.\(^10\)

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\(^1\) Goldberg D and Hutchinson S (2014), page 4
\(^2\) Ibid, page 7
\(^3\) Centers for Disease Control and Prevention (1998)
\(^4\) Centers for Disease Control and Prevention (2012a)
\(^5\) Goldberg D and Hutchinson S (2014), page 4
\(^6\) Ulmer T, Hughes S et al (2012), page 6
\(^7\) European Liver Patients Association (2014), page 4
\(^8\) Ulmer T, Hughes S et al (2012), page 6
\(^9\) Ibid, page 7
National-level policy recommendations

Across Europe, approaches to viral hepatitis vary widely but most countries are yet to develop targeted, locally relevant policies and the tools to implement them.\(^{11}\) It appears that effective action on hepatitis C is not seen as a high priority by EU-28 governments and barriers to treatment vary widely, reinforcing the need for country-specific national strategies, resource allocation and implementation of management policies.\(^{12}\)

Key recommendations

The key recommendations, relevant across all EU-28 Member States, are grouped as follows:

Monitoring and data collection

1. Harmonise national monitoring systems for viral hepatitis across all Member States
2. Create central registries at national level for acute and chronic viral hepatitis, and for hepatocellular carcinoma (HCC)
3. Share results with civil society stakeholders

Awareness

1. Secure government funding for awareness campaigns
2. Use mass media campaigns to raise awareness amongst the general population, including highlighting the impact of risk factors such as alcohol on people infected with viral hepatitis
3. Provide stigmatized groups, such as injecting drug users, migrants, the homeless and men who have sex with men, with appropriate knowledge and support upon diagnosis in order to help them overcome stigma
4. Improve awareness of healthcare professionals working in areas of high prevalence
5. Raise awareness amongst the prison population
6. Involve civil organisations at a national level
7. Involve civil society in World Hepatitis Day

\(^{11}\) Ulmer T, Hughes S et al (2014), page 10
\(^{12}\) Papatheodoridis G, Tsochatzis E, Hardke S and Wedemeyer H (2014), page 3
Prevention
1. Develop collaborative approaches between prevention and control measures for viral hepatitis and other diseases, including cancer
2. Involve civil society organisations and community in prevention and implementation programmes
3. Improve infection control in healthcare settings
4. Implement a strategy for people who inject drugs
5. Implement strategies for non-injection drug users
6. Prevent the spread of hepatitis B and C in prisons
7. Strengthen blood, tissue and organ donation screening
8. Implement prevention programmes targeting high-risk groups
9. Implement a hepatitis B vaccination programme
10. Promote safe sex practices

Testing and diagnosis
1. Set up local screening, referral and treatment facilities for the general population, and specifically for high-risk groups
2. Ensure early identification of chronically infected pregnant women
3. Implement routine testing for blood donors, with referral to a specialist for those testing positive
4. Provide free-of-charge, anonymous testing for all
5. Deliver targeted, low-barrier testing activities for high-risk groups
6. Develop standard protocols
7. Include liver enzyme testing in routine medical check ups

Assessment
1. Ensure that all adults and children with chronic viral hepatitis infection, including people who inject drugs, migrants and vulnerable groups, are assessed for antiviral treatment
2. Ensure diagnosed patients are referred directly to the appropriate specialist and that the available treatment options are explained, upon diagnosis
3. Ensure patients have access to appropriate treatment options for hepatitis B and C, as per the latest clinical guidelines
4. Closely monitor patients infected with either hepatitis B or C to prevent liver cirrhosis and liver cancer
5. Assess alcohol use in patients diagnosed with viral hepatitis and offer counselling where appropriate
6. Ensure community hepatitis services are free of charge for the user and integrated with other healthcare services
7. Enable health departments and prison services to collaborate effectively on prisoners’ treatment
8. Ensure waiting time for specialist appointments is no longer than six weeks

Treatment
1. Ensure an open dialogue between patients and healthcare professionals
2. Ensure treatment is publicly funded
3. Include hepatitis B and C drugs in the national essential medicines list
4. Offer unrestricted access to antiviral therapy
5. Treat infected children in specialist units
6. Provide all patients with access to new and improved drugs
7. Deliver treatments under the care of specialists, and in community settings wherever this is possible and safe to do so
8. Mandate that all European healthcare professionals follow the guidelines issued by the European Association for the Study of the Liver (EASL)

Conclusion
This summary paper highlights the key recommendations in order to illustrate the need for a high-quality, consistent approach to combating the spread of hepatitis B and C through improved monitoring, increased public awareness, effective prevention strategies, earlier diagnosis and accessible treatment provision across EU-28. This document provides a strong foundation for decision makers across EU-28 to create effective policies and targets for diagnosis and treatment at national level, giving every institution, body and government the opportunity to relieve the burden of viral hepatitis.
Hepatitis B and hepatitis C: the global situation

Viral hepatitis is a global public health problem that affects millions of people every year, causing disability and death:

• Around 400 million people are chronically infected with hepatitis B or C.\(^ {13}\)
• Together, hepatitis B and C caused 1.4 million deaths in 2010, including deaths from acute infection, liver cancer and cirrhosis.\(^ {14}\)
• An estimated 57 per cent of cases of liver cirrhosis and 78 per cent of cases of primary liver cancer result from hepatitis B or C infection.\(^ {15}\)

Why should we be concerned?

Millions of people around the world are living with viral hepatitis and millions more are at risk. Most people infected with hepatitis B or C are unaware of their infection, yet are at high risk of developing severe chronic liver diseases such as cirrhosis and liver cancer, and can unknowingly transmit the infection to other people. Because of this, viral hepatitis is often referred to as the ‘silent pandemic’.

In addition to the loss of productivity associated with chronic viral hepatitis,\(^ {16}\) the financial costs of treating liver failure and chronic liver disease place a heavy burden on healthcare systems across the world. In many countries, viral hepatitis is the leading cause of liver transplants, and such end-stage treatments are very expensive.\(^ {17}\) Some groups have an increased risk of contracting viral hepatitis; particularly recipients of organs, blood, blood products and tissue, people working or receiving care in health settings, and those in vulnerable groups.

In recent decades, viral hepatitis has not received the attention it deserves from the global community. Although the burden of disease is very high, the problem has not been addressed in a serious way for many reasons, including the relatively recent discovery of the causative viruses, the mostly silent or asymptomatic nature of the disease in its early stages, and the insidious way in which it causes chronic liver disease. The long delay – sometimes decades – between infection with the hepatitis B or C virus and the development of chronic liver disease or liver cancer made it difficult to link these diseases to the earlier infection.

\(^ {13}\) World Health Organization (2014a), page 1
\(^ {14}\) World Health Organization (2013), page 1
\(^ {15}\) Ibid, page ii
\(^ {16}\) Goldberg D and Hutchinson S (2014), page 7
\(^ {17}\) World Health Organization (2012), page 2
Can viral hepatitis be eliminated?
Measures such as vaccination for hepatitis B, harm reduction through safe blood supply and safe injection use (especially for IV drug users), and protection against infection during activities that present risk (such as sexual intercourse or cosmetic procedures), can reduce the transmission of viral hepatitis infections. The current therapies for hepatitis B and C also give healthcare providers effective tools to combat mortality and morbidity. New therapies continue to be developed, and with effective monitoring and prevention programmes in place, the future appears promising.
In the US, viral hepatitis constitutes a major public health challenge. Although there are differences between the US and the EU with regard to the burden of hepatitis, there are sufficient similarities to warrant close scrutiny of US developments. In particular, similarities in infection prevalence, morbidity/mortality trend observations and the growth in hepatitis C infections among injection drug users mean that the two regions could expect to experience similar patterns of disease and death in the future.\textsuperscript{18}

In 2012, around 1.4 million people in the US were chronically infected with hepatitis B and 3.2 million with hepatitis C,\textsuperscript{19} making hepatitis C the country’s most common blood-borne chronic infection.\textsuperscript{20}

Hepatitis B infections are a major cause of morbidity and mortality in the US. Acute hepatitis B is one of the country’s most commonly reported vaccine-preventable diseases, although effective vaccination strategies have reduced the number of cases since 1990. However, chronic infection remains a significant problem. Around half of all reported chronic cases are either people born in Asia or Asian-Americans born to hepatitis B-infected mothers in the US. Identifying these chronically infected people and providing them with appropriate care remains a challenge.\textsuperscript{21,22}

Acute hepatitis C is most prevalent in the US among those aged between 20 and 39 years old. The Hispanic population displays higher rates of acute disease, while African-Americans and whites have similar, slightly lower, incidence rates. Chronic infection rates appear to be declining, however this is partly due to increasing mortality rates among people infected with hepatitis C – particularly adults aged 45 to 65 years old. In the US, deaths from hepatitis C have exceeded those from HIV/AIDS since 2007.\textsuperscript{23,24} The challenge here is to increase the proportion of people tested and the proportion of those referred for care and treatment, if positive.\textsuperscript{25,26}

\textsuperscript{18} Goldberg D and Hutchinson S (2014), page 8
\textsuperscript{19} Centers for Disease Control and Prevention (2012a)
\textsuperscript{20} Centers for Disease Control and Prevention (2005)
\textsuperscript{21} Centers for Disease Control and Prevention (2012a)
\textsuperscript{22} Ibid
\textsuperscript{23} Ibid
\textsuperscript{24} Ibid
\textsuperscript{25} Ibid
\textsuperscript{26} Ibid
Modelling studies project that, during the next 40 to 50 years, 1.76 million people with untreated hepatitis C infection will develop cirrhosis and around 400,000 will go on to develop hepatocellular carcinoma (HCC) – the fastest growing cause of cancer-related mortality. Overall, of those infected with hepatitis C who do not receive the treatment and care they need, around 1 million will die from related complications.27

The US Institute of Medicine has identified the following key issues in the US fight against viral hepatitis:28

• Inadequate disease surveillance systems under-report acute and chronic infections, leaving the full extent of the problem unknown.
• Many people do not know that they are at risk or how to prevent infection.
• Those at risk may not have access to preventive services.
• Chronically infected people may not know that they are infected.
• Many healthcare providers do not screen people for risk factors, or do not know how to manage infected people.
• Infected people often have inadequate access to testing, social support and medical management services.

In particular, there are considered to be three major underlying factors currently impeding efforts to prevent and control infection:29

• There is a lack of knowledge and awareness about chronic viral hepatitis on the part of healthcare and social service providers.
• There is a lack of knowledge and awareness about chronic viral hepatitis among at-risk populations, members of the public and policy makers.
• There is insufficient understanding about the extent and seriousness of the public health problem, so inadequate public resources are being allocated to prevention, control and surveillance programmes.

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27 Goldberg D and Hutchinson S (2014), page 8
28 Institute of Medicine (2010), page 3
29 Ibid, page 2
The US is currently developing key recommendations to address the burden of viral hepatitis, and has started to implement these. In addition to the ongoing hepatitis B vaccination programme, efforts have been made to improve care and treatment for those living with viral hepatitis. The US Centers for Disease Control and Prevention (US CDC) issued national hepatitis B recommendations in 2008 that included engaging and testing high-risk groups, educating patients and administering treatment therapies approved by the US Food and Drug Administration (FDA).30

Because of the high burden of chronic hepatitis C infection in the US, and because no vaccine is available for preventing infection, national recommendations have focused on other primary prevention activities such as screening and testing blood donors, inactivating the hepatitis C virus in plasma-derived products, testing high-risk groups and providing them with risk-reduction counselling, and consistently implementing and practising infection control in healthcare settings.31

In 2010, the FDA approved point-of-care tests for hepatitis C infection, which meant that patients could receive test results within the same visit and would see a faster referral to care.32 In 2012, the US CDC increased their testing recommendations to include hepatitis C screening among those born between 1945 and 1965.33 About 75 per cent of those living with hepatitis C were born during this period, making this age group five times more likely to have the infection.34 A similar percentage of deaths associated with hepatitis C can also be attributed to this birth cohort.35 This additional screening programme aims to identify undiagnosed infections among this high-risk group, thus increasing their opportunities to benefit from appropriate care and treatment.

30 Centers for Disease Control and Prevention (2008)
31 Centers for Disease Control and Prevention (1998)
32 US Food and Drug Administration (2010)
33 Centers for Disease Control and Prevention (2012b)
34 Centers for Disease Control and Prevention (2013)
35 Centers for Disease Control and Prevention (2012b)
The US has also benefited from major advancements in treatments for hepatitis C. Previously, treatment for infected patients consisted of pegylated interferon combined with oral doses of ribavirin. Treatment was required for at least 48 weeks, and patients experienced a number of side effects and decreased quality of life. Of those patients receiving this therapy, around 40 per cent successfully cleared their infection. In 2011, the FDA licensed new Direct Acting Agents (DAAs) – telaprevir and boceprevir – which, when given in combination with current therapy, can increase virologic cure rates to 80 per cent while decreasing duration of therapy.\(^{36}\) The treatment duration is shorter, and patients experience better tolerability and a very high sustained virological response (SVR), even for seriously ill patients and those with cirrhosis. These DDAs are now available as standard. Since 2014, several drugs have been administered orally, representing major progression in the way treatments are administered for this infection and leading to cure for 90 per cent of patients taking one of these new oral medications.\(^{37,38}\)

It is clear that the US has understood the need for significant investment in order to reduce the burden of hepatitis, and is taking action. The EU-28 Member States and the European Commission must take the opportunity to learn from the US developments and use the resulting information to develop appropriate action plans.

\(^{36}\) Centers for Disease Control and Prevention (2012a)
\(^{37}\) Ibid
\(^{38}\) Ibid
European situation (EU-28)

An estimated 23 million people across EU-28 live with chronic hepatitis, but even with Europe’s generally good tracking of epidemics, viral hepatitis continues to develop undetected as a silent pandemic. Even in countries with high disease awareness and active prevention policies, such as Austria or Belgium, less than one in five infected people know they carry the infection. In most other countries the detection rate is dramatically lower.\(^{39}\)

There are islands of good practice within the EU (for example, France), in terms of intervention provision, uptake and impact, and European and global agencies have worked hard to raise the profile of this infection.\(^{40}\) However, most, if not all, countries face major challenges in delivering high-quality, effective services for those infected with, or at risk of acquiring, hepatitis B and C.\(^ {41}\)

Over the last 20 years, researchers, clinicians and other interested parties have developed a significant body of guidelines, recommendations, strategies and policies relating to hepatitis C within specific Member States. These ideas are crucial in helping to define the problem and how to manage it, but they do not necessarily offer direct action points. It is clear that the EU is currently lacking effective cross-border initiatives that translate evidence and strategy into direct action aimed at halting the spread of hepatitis C.\(^ {42}\)

Epidemiological data

There is a lack of reliable and official epidemiological data on hepatitis B and C across EU-28, with regard to prevalence, incidence and mortality. From the country-specific data available, the general population prevalence of chronic infection appears to vary widely between European countries, with those in the south and east of the European Union and in Turkey having a much higher prevalence than those in northwestern Europe. For the minority of countries where data do exist, prevalence ranges between 0.4 and 4 per cent of the general population.\(^ {43}\)

Among countries collecting data for both infections, Romania stands out with high prevalence for both with more than 5 per cent.\(^ {44}\) In contrast, Belgium, Sweden, Germany and the Netherlands have prevalence lower than 0.5 per cent for both infections.\(^ {45}\)

\(^{39}\) Euro Hepatitis Index 2012, page 3
\(^{40}\) Goldberg D and Hutchinson S (2014), page 4
\(^{41}\) Papatheodoridis G, Tsochatzis E, Hardke S and Wedemeyer H (2014), page 3
\(^{42}\) Ibid
\(^{43}\) Lavanchy D (2011)
\(^{44}\) European Liver Patients Association (2013), page 7
\(^{45}\) Hahné et al (2013)
Figure 1: Hepatitis B and hepatitis C prevalence (%) in the general population by country, Europe, 2000–2009

A. Hepatitis B surface antigen (HBsAg) prevalence (%)
- <0.5
- 0.5 - <1.0
- 1.0 - <2.0
- 2.0 - <4.0
- 4.0 - <6.0
- 6.0 - <8.0
- ≥8.0
- No recent data
- Not included in review

B. Hepatitis C (anti-HCV-antibody) prevalence (%)
- <0.5
- 0.5 - <1.0
- 1.0 - <2.0
- 2.0 - <4.0
- 4.0 - <6.0
- 6.0 - <8.0
- ≥8.0
- No recent data
- Not included in review

Source: Hahné et al (2013)
According to 2010 data, mortality rates related to hepatitis B and C were significantly higher than those of HIV: 1,624 for HIV, compared to 31,000 for hepatitis B and 57,000 for hepatitis C.

The data clearly show that only a minority of those infected with hepatitis C within EU-28 are currently diagnosed; for example, 31 per cent in the Czech Republic, 35 per cent in England, 37 per cent in Austria, 20-30 per cent in France and Sweden, and a maximum of 10 per cent in Romania.

**Economic data**

Hepatitis B and C incur a high economic burden due to a variety of cost implications: drug costs; healthcare costs; and indirect costs such as loss of productivity. Additionally, the longer a person remains untreated, the more expensive it is to treat any subsequent hepatitis-related conditions (such as extrahepatic manifestations) that may develop.

Analysis of the hepatitis C situation in Romania has shown that the costs of increasing treatment uptake would almost completely be offset by the potential savings for the healthcare system and by regaining lost production.

Screening of high-risk groups has been shown to be a cost-effective intervention that reduces the burden of disease due to hepatitis C, however, there needs to be an assessment of the evidence for screening the general population in mid- and highly endemic countries in Europe, and of combined hepatitis B and C screening.

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46 Cowie BC et al (2014)
47 Dore GJ et al (2014)
49 Quantify Research (2015), page 39
50 Hahné et al (2013)
Policy recommendations for EU-28

The World Health Organization (WHO) has recommended that the EU and its Member States develop and implement a hepatitis action plan,\(^\text{51}\) which encompasses awareness, prevention and treatment across all relevant policy areas. However, any such initiatives must reflect the overarching EU approach towards improving health and the citizen’s right to access and treatment.\(^\text{52}\) In a written declaration to the European Parliament,\(^\text{53}\) experts have called upon the European Commission to:

- raise awareness on hepatitis C as an urgent public health issue
- cooperate with the Member States in promoting equal access to quality care
- coordinate initiatives aimed at early diagnosis and wider access to treatment and care.

The same declaration called upon the European Council to recognise hepatitis C as an urgent public health issue and to identify priority actions to be taken. The WHO has gone further than this to include hepatitis B as well, viewing this as a similar burden.\(^\text{54}\)

By using a Right to Health framework\(^\text{55}\) to address the spread of hepatitis C, Member States will be able to adopt and use established human rights approaches that link with public health principles and health benefits, and ensure that those living with hepatitis C are aware of their rights.

Europe’s investment in basic health research, including health outcomes research, needs to increase significantly, and the findings of such research will also need to be applied and implemented.\(^\text{56}\) It is vital to build dedicated inter-country research capacities in order to:

- promote and fund research on epidemiology and factors affecting hepatitis B and C
- promote and fund research on ways of preventing and managing hepatitis B and C
- promote and fund collaborative inter-country research using common protocols.

Regulatory frameworks must also address the need for clinical trials, as innovations in drug development continue to progress. Patients should be able to offer input into the design of these trials at an early stage, to ensure that new drugs are appropriate for a real-life setting as well as passing the normal safety and efficacy tests.\(^\text{57}\)

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\(^{51}\) Ulmer T, Hughes S et al (2012), page 6
\(^{52}\) Goldberg D and Hutchinson S (2014), page 11
\(^{53}\) European Parliament (2013)
\(^{54}\) World Health Organization (2012), page 3
\(^{55}\) Hepatitis B and C Public Policy Association (2012), page 1
\(^{56}\) European Liver Patients Association (2014), page 4
\(^{57}\) Ibid
Education and awareness raising among policy makers, the general public and healthcare professionals is pivotal to improve the prevention and management of hepatitis B and C.\textsuperscript{58} The creation of online communication tools will allow experts, healthcare professionals and policy makers to pool expertise,\textsuperscript{59} while EU policy makers should support initiatives that create better public awareness of viral hepatitis risk factors. These risk factors should include transmission risks such as unsterilised tattoo equipment, needle-sharing and untested blood transfusions, as well as a lack of universal access to hepatitis B vaccination programmes.\textsuperscript{60}

The links between both hepatitis B and C and liver cancer should also be highlighted,\textsuperscript{61} and better links between oncology and gastroenterology/hepatology experts promoted.\textsuperscript{62} It is hoped that cancer organisations such as the European Cancer League (ECL), and the European Code Against Cancer, will actively encourage optimal hepatitis management as a way to prevent liver cancer.\textsuperscript{63} Similarly, the EU should support its Member States to prioritise action on liver cancer and its causes in their national cancer plans,\textsuperscript{64} while the European Commission and the EC Expert Group on Rare Diseases should include liver cancer in their work.\textsuperscript{65} The European Commission should also support stakeholders in developing medical guidelines that address the causes of liver cancer through the third EU health programme and the Horizon 2020 programme.\textsuperscript{66}

\begin{itemize}
  \item \textsuperscript{58} Ulmer T, Hughes S et al (2012), page 6
  \item \textsuperscript{59} Ibid, page 7
  \item \textsuperscript{60} European Liver Patients Association (2014), page 3
  \item \textsuperscript{61} European Association for the Study of the Liver (2013), page 5
  \item \textsuperscript{62} Ulmer T, Hughes S et al (2012), page 7
  \item \textsuperscript{63} Ibid, page 6
  \item \textsuperscript{64} Ibid
  \item \textsuperscript{65} Ibid
  \item \textsuperscript{66} Ibid, page 16
\end{itemize}
National-level policy recommendations

Across Europe, approaches to viral hepatitis vary widely. Some countries, such as England and France, have specific viral hepatitis plans while others, such as Scotland and Austria, include viral hepatitis considerations in their wider policies on sexually transmitted diseases. However, most countries in Europe are yet to develop targeted, locally relevant policies and the tools to implement them. 67

It appears that effective action on hepatitis B and C is not seen as a high priority by EU-28 governments. In addition to low or almost non-existent detection rates, less than 20 per cent of diagnosed patients will receive treatment. 68 The barriers to treatment vary widely across Europe, reinforcing the need for country-specific national strategies, resource allocation and implementation of management policies. 69

This lack of political focus may be due to the stigma attached to many of the high-risk groups affected by viral hepatitis, such as injecting drug users, children of infected mothers, sex workers, prison inmates, migrant populations and men that have sex with men. These groups carry low political weight, however, it should be noted that healthcare workers and patients on dialysis are at high risk of viral hepatitis. These and other sections of the general population are being placed at risk by a lack of political awareness and focus on the part of policy makers. 70

It is important to establish common standards for the development, coordination and implementation of EU Member State Action Plans in order to provide optimal hepatitis B and C services across Europe. In doing so, policy makers should consider the following elements:

- identify high-risk groups within their country 71
- issue evidence-based guidance on hepatitis prevention; establishing national priorities 72 and addressing underlying problems such as drug use 73
- introduce or improve national screening systems 74
- provide rapid treatment for patients at risk of disease progression 75
- monitor patients with and without disease progression 76

67 Ulmer T, Hughes S et al (2014), page 10
68 Euro Hepatitis Index 2012, page 3
70 Euro Hepatitis Index 2012, page 3
71 Ulmer T, Hughes S et al (2014), page 10
72 World Hepatitis Alliance (2014), page 7
73 Ulmer T, Hughes S et al (2014), page 10
74 World Hepatitis Alliance (2014), page 7
75 Ulmer T, Hughes S et al (2014), page 10
76 Ibid
• ensure access to appropriate treatment that takes into account disease progression and also genotype\textsuperscript{77}
• implement national policies on safety in healthcare settings\textsuperscript{78}
• review policies, procedures and practices associated with stigmatization of and discrimination against people living with and affected by viral hepatitis\textsuperscript{79}
• develop and implement comprehensive multisectoral national viral hepatitis strategies,\textsuperscript{80} with sufficient funding allocated to implement those strategies within national public health agendas, while at the same time monitoring specific hepatitis-related outcomes\textsuperscript{81}
• create a multidisciplinary group tasked with executing the national strategic plan and monitoring its progress\textsuperscript{82}

\textsuperscript{77} Ulmer T, Hughes S et al (2014), page 10
\textsuperscript{78} World Health Organization (2013), page 98
\textsuperscript{79} World Health Assembly (2014), page 5
\textsuperscript{80} World Hepatitis Alliance (2014), page 7
\textsuperscript{81} Ibid
\textsuperscript{82} Ulmer T, Hughes S et al (2014), page 10
Monitoring and data collection

Informed decision making on viral hepatitis policies requires robust monitoring and reporting activities across all European Member States. Furthermore, this monitoring and reporting should be consistent, with all countries collecting data in accordance with the same parameters in relation to both the extent of the disease and progress made towards agreed prevention and treatment goals.  

At a European level, there is already clear legislation in place that enables the EU to monitor acute cases of hepatitis B and C. However, the methodology used to collect this data has yet to be harmonised across the individual Member States, and does not allow for monitoring of chronic cases.

At a national level, it is clear that most Member States lack the monitoring systems needed to take informed, evidence-based policy decisions, and will need to significantly expand and strengthen their activities in this area. To provide accurate estimations of cases, all national monitoring systems should include data on risk factors and source of infection. The lack of comparable national data is currently hindering a comprehensive evaluation of the burden of hepatitis B and C across Europe, and how this compares with other diseases. The creation of specific, national patient registries for hepatitis would enable the collection of comparable data to facilitate monitoring, research and overall management of this condition. Detailed analysis of the disease patterns would allow optimum allocation of available resources, thus improving detection rates and highlighting areas for improvement. To maximise impact, the subsequent monitoring outputs should be shared widely, and particularly with civil society stakeholders, as recommended by the World Hepatitis Alliance in response to the quantitative and qualitative findings from the 2014 Global Community Hepatitis Policy Report.

83 World Hepatitis Alliance (2014), page 8
84 Ulmer T, Hughes S et al (2014), page 9
85 World Health Assembly (2014), page 3
86 Ibid, page 4
87 Ulmer T, Hughes S et al (2012), page 6
88 Euro Hepatitis Index 2012, page 5
89 World Hepatitis Alliance (2014), page 7
The US CDC have taken broadly similar steps in recent years to improve their national monitoring and data collection procedures, namely:

- conducted a comprehensive evaluation of the national monitoring systems for hepatitis B and C
- developed specific cooperative agreements with all state and territorial health departments to support core monitoring for acute and chronic hepatitis B and C
- conducted targeted active monitoring of levels of hepatitis B and C infections in populations not fully captured by core monitoring.\(^9\)

Transposing these US principles to the situation within European Member States, and considering them in conjunction with the key recommendations below, will facilitate consistent and informed decision making with regard to viral hepatitis policies.

### Key recommendations

1. **Harmonise national monitoring systems for viral hepatitis across all Member States**
2. **Create central registries at national level for acute and chronic viral hepatitis, and for HCC**
3. **Share results with civil society stakeholders**

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\(^9\) Institute of Medicine (2010), page 4
Awareness

Experts agree that diagnosing those infected as early as possible, and before they have progressed to severe disease, will reduce mortality and the spread of hepatitis B and C. Raising awareness is a vital step towards achieving this and should utilise a variety of methods to reach as many people as possible.

Within areas showing a high prevalence of hepatitis B and C, local literature and media channels should be used to deliver tailored awareness campaigns to high-risk groups, telling them where they can get tested. In addition to targeting those at risk, more general awareness campaigns should also be directed to the general public and healthcare workers, especially medical doctors (GPs). Incorporating hepatitis B and C into the education of healthcare professionals and creating ‘managed care networks’, where a group of healthcare providers work together to deliver a holistic programme of care, will help to promote awareness and prevention among high-risk populations. Any European and national strategy to raise awareness of hepatitis B and C should address the points below.

Key recommendations

1. Secure government funding for awareness campaigns
2. Use mass media campaigns to raise awareness amongst the general population, including highlighting the impact of risk factors such as alcohol on people infected with viral hepatitis
3. Provide stigmatized groups such as injecting drug users, migrants, the homeless and men who have sex with men, with appropriate knowledge and support upon diagnosis in order to help them overcome stigma
4. Improve awareness of healthcare professionals working in areas of high prevalence
5. Raise awareness amongst the prison population
6. Involve civil organisations at a national level
7. Involve civil society in World Hepatitis Day

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91 World Health Organization (2012), page 12
92 Ulmer T, Hughes S et al (2014), page 6
93 Goldberg D and Hutchinson S (2014), page 16
94 Ulmer T, Hughes S et al (2014), page 6
95 World Health Organization (2012), page 14
96 World Health Organization (2012), page 15
97 Ulmer T, Hughes S et al (2014), page 6
98 Euro Hepatitis Index 2012, page 11
99 Ibid, page 5
100 Ibid, page 4
101 Ibid, page 5
102 Ibid, page 12
103 World Hepatitis Alliance (2014), page 6
104 Hepatitis B and C Public Policy Association (2012), page 1
Prevention

Even though there is a vaccination for hepatitis B, and hepatitis C is a preventable disease, transmission levels remain high. While work continues to develop a vaccine against hepatitis C, there remain many ways to interrupt routes of transmission and reduce the spread of the virus. Prevention strategies within EU-28 must take a long-term view in order to have sufficient opportunity to be effective.

The WHA has recognised the need to strengthen collaborative approaches and synergies between the prevention and control measures used for viral hepatitis, and those used for other infectious diseases such as HIV as well as cancer and non-communicable diseases. 106

In response to the WHO’s 2013 global hepatitis survey, the majority of European respondents claimed to involve civil organisations in their hepatitis prevention and control programmes, and this is to be encouraged in future strategies. In healthcare settings, where staff and patients are at high risk, appropriate cleaning and usage measures are known to prevent transmission of viral hepatitis; occupational safety measures in particular will prevent transmission to healthcare workers. Strengthening the screening process and safety strategies for blood, tissue and organ donation will also help to avoid transmission of hepatitis C within healthcare settings.

Drug users are another high-risk group, particularly injection drug users, and experts agree that sufficient harm reduction coverage for prevention and treatment of those who inject drugs is essential to reduce transmission within this group. This should include a multi-intervention approach combining information and advice, opioid substitution therapy (OST) and the provision of sterile injection equipment. Hepatitis C antiviral treatment may also prove successful in preventing transmission among injection drug users, particularly where infection rates are low.

105 Institute of Medicine (2010), page 136
106 World Health Assembly (2014), page 2
107 World Health Organization (2013), page 95
108 World Health Assembly (2014), page 4
109 World Health Organization (2012), page 11
110 Ibid
112 World Health Assembly (2014), page 4
113 World Health Organization (2012), page 11
114 Goldberg D and Hutchinson S (2014), page 14
115 European Initiative for Hepatitis C and Drug Use (2014)
116 Ibid
Within the prison population, which has high levels of hepatitis B and C, strategies such as free condom distribution, needle exchange programmes, availability of OSTs and provision of bleach for cleaning syringes should all be considered. Needle exchange programmes rarely exist and, according to the Euro Hepatitis Index 2012, less than half of the 30 European countries surveyed provide prisoners with bleach for cleaning syringes. Providing optimal levels of OSTs without injection equipment provision may be sufficient to prevent appreciable transmission of hepatitis C among those inmates who inject drugs.

In terms of targeting high-risk groups, a free-of-charge hepatitis B vaccination programme that includes main risk groups as well as newborns should be part of that targeting, and it is well demonstrated that this improves coverage. Other groups that should be targeted include travellers to regions with high hepatitis B prevalence and young children – the US Institute of Medicine recommends mandatory hepatitis B vaccination before starting school.

In terms of delivering a hepatitis B vaccination programme, vaccinations should begin within 24 hours of birth, and sufficient EU and national resources should be devoted to ensuring an adequate, accessible and sustainable hepatitis vaccine supply, increasing hepatitis B vaccination of at-risk adults, and raising awareness within the general adult and adolescent population. Private and public insurance coverage for hepatitis B vaccination should also be expanded.

There is little information about existing vaccination levels for men who have sex with men or sex workers; it is important that these high-risk groups are reached, but it is hard to do so. Prisons represent a good opportunity to vaccinate some hard-to-reach groups, such as injection drug users, who may have poor access to community healthcare. Adults in prison are exposed to viral hepatitis through sex with infected persons, injection drug use and sharing close living quarters with other infected inmates. The transient nature of prison populations mean the benefits of a hepatitis B vaccination programme extend beyond the

117 Euro Hepatitis Index 2012, page 12
118 Goldberg D and Hutchinson S (2014), page 14
119 Institute of Medicine (2010), page 93
120 Euro Hepatitis Index 2012, page 11
121 Ibid, page 4
122 World Hepatitis Alliance (2014), page 22
123 Institute of Medicine (2010), page 116
124 Ibid, page 136
125 Ibid, page 125
126 Ibid, page 9
127 Ibid, page 135
128 Euro Hepatitis Index 2012, page 11
129 Ibid
130 Ibid, page 30
prisoners themselves into the wider community. However, less than half the countries surveyed by the Euro Hepatitis Index 2012 have a programme for vaccination in prisons.

The availability of post-exposure immunisation (PEP) for hepatitis B – medication given after a suspected or actual hepatitis B exposure to decrease the likelihood of infection – is another aspect to consider. This procedure is beneficial to prevent not only the infection after occupational exposure, but also after injection drug use or unprotected sex. Experts believe access to this should be free upon recommendation by a physician.

Promoting safer sex practices, including minimizing the number of partners and using barrier protective measures (condoms), will protect against hepatitis B and hepatitis C transmission. However, free condom distribution for high-risk groups only exists in just over half the countries included in the Euro Hepatitis Index, and even then it is not seen in all prisons.

**Key recommendations**

1. Develop collaborative approaches between prevention and control measures for viral hepatitis and other infectious diseases, as well as cancer and NCDs
2. Involve civil society organisations and community in prevention and implementation programmes
3. Improve infection control in healthcare settings
4. Implement a strategy for people who inject drugs
5. Implement strategies for non-injection drug users
6. Prevent the spread of hepatitis B and C in prisons
7. Strengthen blood, tissue and organ donation screening
8. Implement prevention programmes targeting high-risk groups
9. Implement a hepatitis B vaccination programme
10. Promote safe sex practices

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131 Euro Hepatitis Index 2012, page 30
132 Ibid
133 Euro Hepatitis Index 2012, page 42
134 World Health Organization (2012), page 11
135 Euro Hepatitis Index 2012, page 32
Testing and diagnosis

Testing for viral hepatitis is not only advantageous for patients, but also benefits national healthcare systems, the economy and society. Detection and treatment at an early stage can reduce the spread of the virus and both the cost and duration of treatment, as well as increasing the chances of recovery. Indeed, most liver cancer cases could be prevented with appropriate management of viral hepatitis B and C. Diagnosed patients also have the opportunity to reduce their risk behaviours, such as drinking alcohol, smoking and an unhealthy diet, in order to slow down inflammation and the natural process of fibrosis and cirrhosis. Specific policy measures to ensure early detection of viral hepatitis will therefore improve health outcomes,136 and improved diagnosis would save significant financial resources.

The numbers of undiagnosed people carrying the hepatitis virus in Europe are high; on average, around 90 per cent of people with liver disease are unaware of their condition, and viral hepatitis, particularly hepatitis B, is much more infectious during needlestick exposure than HIV.137 General awareness about hepatitis and the way it is transmitted is low, therefore easy access to testing or counselling will improve public knowledge about the disease and help to prevent further infection. Increased testing would also provide a better picture of the real burden of the disease.

To increase testing, it is necessary for governments to invest in better detection and treatment programmes within primary healthcare.138 These should incorporate standardised national protocols (ultimately leading to standardised European protocols), with immediate referral to a specialist for those testing positive. A liver enzyme test should be mandatory in routine medical check ups for all people between 20 and 60 years old, as should a review of the patient’s medical history, and patients with elevated liver enzyme levels should be tested for possible causes, including viral hepatitis.139

Outreach programmes will help to ensure more voluntary counselling and testing,140 and should identify ways of encouraging or incentivising high-risk individuals to be tested, as well as ensuring that such policies for hepatitis B and C include access to and retention in treatment.

136 Ulmer T, Hughes S et al (2012), page 15
137 European Liver Patients Association (2014), page 3
138 Hepatitis B and C Public Policy Association (2012), page 1
139 European Liver Patients Association (2014), page 3
140 Hepatitis B and C Public Policy Association (2012), page 1

Hepatitis B and C – an action plan for saving lives in Europe
In order to increase testing in high-risk groups as well as in the general population, it is important to make these services as convenient and accessible as possible. This means exploring innovative ways of reaching all vulnerable groups and ensuring universal access to testing and treatment, by overcoming barriers such as transportation, language, lack of anonymity or cost. Screening programmes should be supported by counselling before and after the test, and in particular, stigmatized groups such as injection drug users, the homeless and men who have sex with men should be provided with appropriate knowledge and support upon diagnosis. A positive diagnosis for any healthcare staff member working with these groups should also be supported by such counselling.

It is recommended that individuals who are part of a high-risk population, or who have a history of hepatitis B and C risk exposure/behaviour, should be offered testing. For all healthcare workers, including cleaning staff, regular testing should be mandatory. In general, screening is free for risk groups in the majority of the countries covered in the Euro Hepatitis Index 2012, but it is very disappointing to see that, overall, Europe has a lack of free, anonymous, hepatitis testing and counselling walk-in facilities.

Most European screening programmes in risk populations include pregnant women and donors of blood or organs, and some countries also include injection drug users and migrant populations from high prevalence areas. However, testing in risk group populations needs to be improved in all countries. Certain groups tend to be repeatedly forgotten, such as sex workers, men who have sex with men, prison inmates or migrants from high prevalence areas. It is also recommended to test people with HIV for hepatitis C on an annual basis. Currently, hepatitis C is normally tested for during the first visit after HIV detection, and the test may be repeated if risk behaviour prevails or if there is any reason to fear infection, but this does not happen annually.

141 Hepatitis B and C Public Policy Association (2012), page 1
142 Euro Hepatitis Index 2012, page 4
143 Ulmer T, Hughes S et al (2014), page 6
144 World Health Organization (2014b), page 14
145 Euro Hepatitis Index 2012, page 33
146 Ibid
147 Ibid
148 Ibid, page 43
It is recommended that all pregnant women receive prenatal testing for hepatitis B during each pregnancy, regardless of risk factors or immunisation history, to prevent mother-to-child transmission.\textsuperscript{149} Appropriate resources and guidance should be made available to primary healthcare staff to deliver such testing programmes. In addition to first-trimester screening, testing should be repeated later in pregnancy for those women who tested negative if they have clinical and laboratory evidence of hepatitis or have an ongoing risk of acquiring hepatitis B infection.\textsuperscript{150}

Introducing screening of donated blood and the subsequent notification and counselling of donors testing positive will provide unique opportunities for early diagnosis and timely medical support to asymptomatic individuals who come to donate blood.\textsuperscript{151} This will also prevent further spread of the infection.

Annual screening for infectious diseases in injection drug users is recommended,\textsuperscript{152} as they are more likely than non-users to contract viral hepatitis, and to experience more severe outcomes following infection.

It is vital that these accessible screening programmes be free of charge for everyone and maintain anonymity.\textsuperscript{153} Around half of the 44 European countries responding to the WHO 2013 global hepatitis survey did not operate a national screening and referral policy for hepatitis B and C, although the majority of those that do have such a policy keep the names of those tested confidential. Just over half (24) of the responding European countries reported charging people for the hepatitis C test, although the majority of those do offer the test free of charge to members of specific high-risk groups. Half of the responding European countries have made the hepatitis C test compulsory for members of specific groups, including blood donors, healthcare workers, pregnant women and patients on haemodialysis.\textsuperscript{154}

\textsuperscript{149} Institute of Medicine (2010), page 82
\textsuperscript{150} Euro Hepatitis Index 2012, page 42
\textsuperscript{151} World Health Organization (2012), page 12
\textsuperscript{152} Euro Hepatitis Index 2012, page 43
\textsuperscript{153} Ibid, page 12
\textsuperscript{154} World Health Organization (2013), page 99
Introducing and investing in standardised testing protocols for hepatitis B and C across whole populations, while ensuring universal access and anonymity, will improve overall health outcomes for all groups and ease the financial burden of viral hepatitis currently facing European governments.

**Key recommendations**

1. Set up local screening, referral and treatment facilities for the general population and specifically for high-risk groups\(^{138}\)
2. Ensure early identification of chronically infected pregnant women
3. Implement routine testing for blood donors, with referral to a specialist for those testing positive
4. Provide free-of-charge, anonymous testing for all
5. Deliver targeted low-barrier testing activities for high-risk groups
6. Develop standard protocols
7. Include liver enzyme testing in routine medical check ups

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\(^{135}\) Ulmer T, Hughes S et al (2014), page 12
Assessment

Clearly, following a viral hepatitis diagnosis, the next step is for the patient to access assessment for treatment. However, a substantial proportion of those diagnosed with chronic hepatitis B and the majority of those diagnosed with hepatitis C remain untreated. The reasons for this, and the numbers of people affected, vary widely among European countries. Certain groups, such as drug users, the homeless, migrants and prisoners, are often unable to access the treatment they require. There is also a lack of consistent guidelines, limited access to the latest medication and a lack of capacity within treatment centres. This strongly supports the need for country-specific national strategies, resource allocation and implementation of global management policies.\textsuperscript{156}

The WHA has noted with concern that equitable access to quality, effective, affordable and safe treatment for both hepatitis B and C is lacking in many parts of the world, particularly in developing countries. It recommends that governments include special provision in their policies addressing hepatitis to ensure that all populations affected by viral hepatitis, particularly people who inject drugs, indigenous people, migrants and vulnerable groups, have equitable access to prevention, diagnosis and treatment.\textsuperscript{157}

Ideally, everyone infected with viral hepatitis should have immediate access to a healthcare specialist and be offered the most appropriate treatment options, as per the latest clinical guidelines.\textsuperscript{158} This includes directly referring patients to the appropriate specialist and explaining the available treatment options, upon diagnosis.\textsuperscript{159} All individuals diagnosed with chronic hepatitis C should be referred to a specialist for assessment.\textsuperscript{160}

Once patients receive a diagnosis of hepatitis B or C, it is recommended that they are immediately and closely monitored to prevent the development of liver cirrhosis and liver cancer, as well as to build transmission models.\textsuperscript{161} Their alcohol use should also be assessed and counselling offered to those displaying moderate to high levels of alcohol intake.\textsuperscript{162}

One of the most critical barriers to treatment for hepatitis B is a lack of patient knowledge and awareness.\textsuperscript{163} Although there are several barriers to treatment for chronic hepatitis C, lack of funding appears to be the predominant barrier in Eastern European countries such

\textsuperscript{156} Papatheodoridis G, Tsachatzis E, Hardke S and Wedemeyer H (2014), page 3
\textsuperscript{157} World Health Assembly (2014), page 4
\textsuperscript{158} Ulmer T, Hughes S et al (2014), page 6
\textsuperscript{159} Ibid
\textsuperscript{160} Goldberg D and Hutchinson S (2014), page 20
\textsuperscript{161} Ulmer T, Hughes S et al (2014), page 6
\textsuperscript{162} World Health Organization (2014b), page 15
\textsuperscript{163} Papatheodoridis G, Tsachatzis E, Hardke S and Wedemeyer H (2014), page 15
as Romania,\textsuperscript{164} where the majority of patients are not reimbursed for their treatment. In some countries, treatment funding is less of a problem than clinical examinations having to be privately paid for by the patient, which can prevent proper management of the disease.\textsuperscript{165} The importance of cost and funds has recently increased with the introduction of the latest generation of DAAs.

In contrast to Romania, barriers to treatment in non-Eastern European countries do not usually include the lack of funds but instead relate to medical barriers – either the limitations of interferon-alfa-based regimens or non-hepatic comorbidities, including parenteral drug use (PDU) and alcohol abuse, in the majority of patients.\textsuperscript{166}

Moving forward, community hepatitis services should be free for the user and integrated with other healthcare services; adequate resources should be made available to achieve this.\textsuperscript{167} In particular, comprehensive viral hepatitis services should be integrated into settings that serve high-risk populations,\textsuperscript{168} such as STD clinics, sites for HIV services and care, homeless shelters and mobile health units.

Barriers to therapy may also arise from healthcare providers, including limited knowledge and awareness among primary care physicians and even difficulties in access and communication with specialists.\textsuperscript{169}

For patients with healthcare insurance, access to therapy is often relatively easy and costs to patients are either fully reimbursed or require a small co-payment. But even with insurance, for patients in some countries (for example, Romania), the amount of time taken to receive treatment can also be a barrier. Because of the way the insurance companies allocate the money, it can sometimes take up to two years for patients to get their medication.\textsuperscript{170} When it comes to waiting for specialist appointments, the expert panel involved in the Euro Hepatitis Index 2012 recommends that patients should wait no longer than six weeks between appointments.\textsuperscript{171}

With regard to prisoners – a high-risk group – health departments should follow the recommendation of the US Institute of Medicine to collaborate effectively with prison

\textsuperscript{164} Papatheodoridis G, Tsolakis E, Hardke S and Wedemeyer H (2014), page 16
\textsuperscript{165} Euro Hepatitis Index 2012, page 44
\textsuperscript{166} Papatheodoridis G, Tsolakis E, Hardke S and Wedemeyer H (2014), page 16
\textsuperscript{167} Institute of Medicine (2010), page 16
\textsuperscript{168} Ibid, page 86
\textsuperscript{169} Papatheodoridis G, Tsolakis E, Hardke S and Wedemeyer H (2014), page 15
\textsuperscript{170} Euro Hepatitis Index 2012, page 37
\textsuperscript{171} Ibid, page 36
services, working together to ensure the availability of comprehensive viral hepatitis services for prisoners.\textsuperscript{172}

Despite the increasing efficacy of hepatitis treatments, it is frustrating that only a relatively small proportion of diagnosed patients are receiving and benefiting from these. It is vital that all diagnosed patients have equitable access to treatment, in order to significantly reduce the burden of hepatitis across Europe.

**Key recommendations**

1. Ensure that all adults and children with chronic viral hepatitis infection, including people who inject drugs, migrants and vulnerable groups, are assessed for antiviral treatment

2. Ensure diagnosed patients are referred directly to the appropriate specialist and that the available treatment options are explained, upon diagnosis

3. Ensure patients have access to appropriate treatment options for hepatitis B and C, as per the latest clinical guidelines

4. Closely monitor patients infected with either hepatitis B or C to prevent liver cirrhosis and liver cancer

5. Assess alcohol use in patients diagnosed with viral hepatitis and offer counselling where appropriate

6. Ensure community hepatitis services are free of charge for the user and integrated with other healthcare services

7. Enable health departments and prison services to collaborate effectively on prisoners’ treatment

8. Ensure waiting time for specialist appointments is no longer than six weeks

\textsuperscript{172} Institute of Medicine (2010), page 100
Treatment

Over recent years, the development of antiviral drugs for hepatitis B and C has improved outcomes for all types of patients with viral hepatitis prior to the cirrhotic stage.

The treatment regimens and strategies for each type of viral hepatitis are quite different. Hepatitis B treatment aims to control the virus and to reduce the viral load under the most sensitive detection level. This dramatically reduces the risk of progression to fibrosis and cirrhosis, as well as reducing the risk of transmission and the development of liver cancer. In some cases, hepatitis B patients develop antibodies so that drugs to suppress the virus are no longer needed.

Hepatitis C treatment is defined as successful when viral load is undetectable in tests performed three months after completion of treatment. This is called a sustained virological response (SVR). People who achieve an SVR are generally considered to be ‘cured’, virologically. Recent years have seen huge advances in this area and with the latest innovative medication, such a response can be achieved in over 90 per cent of cases.

International agencies and experts, including the WHO and those attending the 2012 Conference on Hepatitis B and C in Mediterranean and Balkan Countries, have called for national action plans to incorporate community-based treatment programmes. These should include assessments of needs, particularly for vulnerable groups, along with training and support. Given the complexities of viral hepatitis and the highly personalised nature of the treatment regimes, it is important to establish an open, two-way communication between healthcare professionals and patients that leads to a collaborative approach to treatment.

Decisions over who should receive hepatitis C treatment are complicated, as healthcare providers must consider the health of the patient, in particular the degree of fibrosis or cirrhosis, as well as the cost, safety, and efficacy of the required medicines. Based on these considerations, patients with more advanced fibrosis and cirrhosis should be prioritised for treatment. However, there are no population-based data to indicate how many patients meet these criteria. Furthermore, this prioritisation may change, as safer and more effective medicines become available, assuming that they are affordable.

173 Hepatitis B and C Public Policy Association (2012), page 1
174 Ulmer T, Hughes S et al (2014), page 12
175 World Health Organization (2014b), page 21
With regard to funding, it is disappointing that nearly a fifth of the WHO Member States in the European region do not offer publicly funded treatment for hepatitis B, and this rises to nearly a quarter for hepatitis C treatment.\textsuperscript{176} Over 88 per cent reported that at least one available drug for treating hepatitis C is on their national essential medicines list or subsidised by the government, however the drugs most commonly reported were interferon alpha, pegylated interferon and ribavirin, which have now been superseded by new and improved drug developments.\textsuperscript{177}

All individuals with moderate or severe hepatitis C-related liver disease should have unrestricted access to antiviral therapy.\textsuperscript{178} Antiviral treatments, which will successfully clear the virus in the majority of patients, are available in most countries. However, providing optimal treatment and care requires effective strategies to increase the share of infected people admitted into medical care, subsidised/reimbursed treatment and appropriate patient education to optimise treatment results.\textsuperscript{179}

With regard to treating infected children, ideally this should be managed by a specialist unit with experienced paediatric specialists.\textsuperscript{180} In all cases, treatments should be under the care of qualified healthcare specialists to optimise the processes and management of the disease according to best practice. Currently, hepatitis C therapy is provided in specialised centres by hepatologists/gastroenterologists or other subspecialists, and this is partly due to the current complexity of treatment. The latest developments enable certain treatments to be administered by suitably trained GPs and other primary care staff, extending availability to greater numbers of patients. To accomplish this, clinics will need to be properly equipped and healthcare workers will need training in the clinical management of hepatitis C infection.\textsuperscript{181} This includes professionals, such as specialist nurses, dedicated to providing patient education.\textsuperscript{182}

\begin{thebibliography}{99}
\bibitem{176} World Health Organization (2013), page 99
\bibitem{177} Ibid
\bibitem{178} Goldberg D and Hutchinson S (2014), page 20
\bibitem{179} Euro Hepatitis Index 2012, page 4
\bibitem{180} Ibid, page 44
\bibitem{181} Ibid, page 44
\bibitem{182} World Health Organization (2014b), page 21
\end{thebibliography}
The role of nurses is often underestimated; well-trained specialist hepatitis nurses, just as for other chronic diseases, are extremely beneficial. They guide the patient through treatment and educate them about their disease, demonstrably improving treatment outcomes. It is disappointing to see that specialist hepatitis nurses are only available in one third of countries responding to the Euro Hepatitis Index 2012.\textsuperscript{183}

It is vital that all patients should have access to the latest improved medication. Many countries have been very slow to introduce the first phase of DAAs such as telaprevir and boceprevir to treat hepatitis C, and patients still face limitations. This is also the case with the latest medication approved by the European Medicines Agency in 2014, with an efficacy of more than 90 per cent. Sometimes, only selected patients suggested by physicians, or in certain regions, will receive the new medication. Indeed, one third of the countries responding to the Euro Hepatitis Index 2012 do not provide the new drug class of DAAs at all. Although it has not been measured, the situation for hepatitis B is said to be even worse: many countries only provide the old and ineffective medication. Hepatitis B can be very well controlled with the new compounds, however, this is only the case for a quarter of patients using the older drugs.\textsuperscript{184}

Continuing success of hepatitis B and C treatment across Europe will be dependent on provision of updated guidelines that adopt the latest scientific developments. Across EU-28, all healthcare professionals should follow the guidelines presented by the European Association for the Study of the Liver (EASL), which aim to standardise the actions of European physicians in order to improve performance.\textsuperscript{185}

\textsuperscript{183} Euro Hepatitis Index 2012, page 37
\textsuperscript{184} Ibid
\textsuperscript{185} Ibid, page 44
Key recommendations

1. Ensure an open dialogue between patients and healthcare professionals
2. Ensure treatment is publicly funded
3. Include hepatitis B and C drugs in the national essential medicines list
4. Offer unrestricted access to antiviral therapy
5. Treat infected children in specialist units
6. Provide all patients with access to new and improved drugs
7. Deliver treatments under the care of specialists, and in community settings wherever this is possible and safe to do so
8. Mandate that all European healthcare professionals follow the guidelines issued by EASL
Conclusion

Despite the significant and growing burden of hepatitis B and C across EU-28, we are still in a position where only a very small minority of those infected are diagnosed or receive treatment for these preventable, treatable and curable conditions. Indeed, most EU-28 countries are failing to implement any preventative activities, even those that will clearly deliver solutions.

It is vital that all EU-28 countries work together to develop a consistent, evidence-based approach to address this silent pandemic. The situation in the US provides a learning opportunity that can and should inform policy developments at both European and national level.

This summary paper highlights the key recommendations of leading organisations in the field of liver disease in order to illustrate the need for a high-quality, consistent approach to tackling viral hepatitis through improved monitoring, increased public awareness, effective prevention strategies, earlier diagnosis and accessible treatment provision across EU-28. If significant progress can be made in these areas, alongside continuing therapeutic advancements, then the prospect of eradicating both the infection and related disease becomes possible.

This document provides a strong foundation for decision makers across EU-28 to create effective policies and targets for diagnosis and treatment at national level, giving every institution, body and government the opportunity to relieve the burden of viral hepatitis.
Bibliography


