

# Hepatitis C: The beginning of the end—key elements for successful European and national strategies to eliminate HCV in Europe

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**Abbreviations:** CDA, Center for Disease Analysis; DAAs, direct acting antivirals; EASL, European Association for the Study of the Liver; ECDC, European Center for Disease Control; EC, the European Commission; ELPA, European Liver Patients' Association; EMCDDA, European Monitoring Centre for Drugs and Drug Addiction; EU, European Union; GHSS, Global Health Sector Strategy on Hepatitis; HCV, hepatitis C virus; ICMHD, International Centre for Migration, Health and Development; MSM, Men who have sex with men; NCDs, noncommunicable diseases; NGOs, nongovernmental organizations; PWID, People who inject drugs; VHPB, Viral Hepatitis Prevention Board; WHA, World Hepatitis Alliance; WHO, World Health Organization.

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**Summary**

Hepatitis C virus (HCV) infection is a major public health problem in the European Union (EU). An estimated 5.6 million Europeans are chronically infected with a wide range of variation in prevalence across European Union countries. Although HCV continues to spread as a largely “silent pandemic,” its elimination is made possible through the availability of the new antiviral drugs and the implementation of prevention practices. On 17 February 2016, the Hepatitis B & C Public Policy Association held the first EU HCV Policy Summit in Brussels. This summit was an historic event as it was the first high-level conference focusing on the elimination of HCV at the European Union level. The meeting brought together the main stakeholders in the field of HCV: clinicians, patient advocacy groups, representatives of key institutions and regional bodies from across European Union; it served as a platform for one of the most significant disease elimination campaigns in Europe and culminated in the presentation of the HCV Elimination Manifesto, calling for the elimination of HCV in Europe by 2030. The launch of the Elimination Manifesto provides a starting point for action in order to make HCV and its elimination in Europe an explicit public health priority, to ensure that patients, civil society groups and other relevant stakeholders will be directly involved in developing and implementing HCV elimination strategies, to pay particular attention to the links between hepatitis C and social marginalization and to introduce a European Hepatitis Awareness Week.

**KEYWORDS**

barriers to prevention, burden, care, elimination, high-risk populations, surveillance, treatment, viral hepatitis

**1 | INTRODUCTION**

On 17 February 2016, the Hepatitis B and C Public Policy Association (HBCPPA)\* held the hepatitis C (HCV) Policy Summit Hepatitis C: The Beginning of the End—Key elements for successful European and national strategies to eliminate HCV in Europe. The aim of the meeting was to bring together high-level policy makers and academics, patient advocates, health organizations and other stakeholders. The event served as a platform to support the hepatitis elimination campaigns in Europe and culminated in the presentation of the HCV Elimination Manifesto, endorsing elimination of HCV in Europe by 2030.

The summit was held in collaboration with the European Association for the Study of the Liver (EASL), European Liver Patients Association (ELPA), European Parliament Friends of the Liver Group, the Viral Hepatitis Prevention Board (VHPB), the

Correlation Network, International Center for Migration Health and Development (ICMHD), the World Hepatitis Alliance (WHA) and other international stakeholders and advocacy organizations. The following organizations were represented: the World Health Organization (WHO), the European Commission (EC), the European Center for Disease Control (ECDC) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

**2 | OVERVIEW AND BACKGROUND: TACKLING THE CHALLENGES OF THE GLOBAL HCV BURDEN<sup>1-6</sup>**

Chronic infection with HCV has a high prevalence and is the seventh leading cause of death worldwide. It was initially estimated that up to 180 million people have chronic HCV infection worldwide, but the most recent estimations report approximately 70 million people with chronic HCV infection.<sup>7</sup> This decrease in the prevalence over time has primarily been driven by the rising number of HCV-associated deaths and the ageing of HCV-infected population. It is now estimated that there are 5.6 million chronically affected in Europe. The estimated prevalence of HCV in the European Union (EU) and Economic Area (EEA) is 1.1% (95% CI: 0.9-1.4),<sup>8</sup> but varied

\*HBCPPA is a non-profit organization that aims to inform national and international policy on issues related to awareness, epidemiology, prevention and management of viral hepatitis B and C. The Association carries out its work through partnerships with relevant stakeholders including government representatives, health providers, patients, public health and civil society advocates and the private sector. Since its inception in 2009, the Association has held four high-level Summit meetings to move forward policy on Hepatitis B and C with national and international stakeholders, the most recent of which is detailed in this report.

widely among European countries and certain groups were at higher risk of infection. It is estimated that among people who inject drugs (PWID), men who have sex with men (MSM) and sex workers, the prevalence of HCV is 44%, 4% and 11%, respectively.<sup>9</sup> Up to one-third of all chronically infected patients will develop liver problems, such as cirrhosis or hepatocellular carcinoma (HCC) leading to significant burden for productivity and, most importantly, individual quality of life. HCV is the leading cause of liver transplantation, and treatment of liver-related diseases represents a significant cost to health systems.<sup>10</sup> Without treatment, most patients die from liver-related complications.

Due to recent advances in treatment strategies and medications, the majority of those treated recover and HCV cure rates are presently over 95%.<sup>11</sup> This is the first time that the elimination of HCV infection at the population level has become a possibility. Treatment of HCV infection reduces the progression of cirrhosis, decompensation of cirrhosis and the development of HCC, while it will reverse severe symptoms associated with HCV, improving quality of life as well as serious associated diseases, such as lymphomas.<sup>10</sup> Therefore, although new antiviral treatments with direct acting antivirals (DAAs) are expensive, they will be cost-effective in the long term by reducing the costs of treating decompensated cirrhosis, hepatocellular cancers and the number of liver transplantations.

However, HCV infection presents specific challenges that require holistic, patient-centred and health system-wide approaches that address awareness, prevention, care and treatment through the joint collaboration of health providers, patients and stakeholders. In the current context faced by many European countries, with threats to the fiscal security of health systems and neglect of marginalized populations, putting HCV on the health policy agenda is even more crucial.<sup>12</sup>

A question that often arises is why HCV infection continues to be a major public health problem in Europe, with a prevalence seven times greater than that of HIV.<sup>13</sup> The answer lies in the facts that HCV patients often have no symptoms for the first 20-30 years of infection, and surveillance of HCV is weak across many EU countries.<sup>14</sup> Also, the burden of HCV is disproportionately present in marginalized populations including PWID, prisoners, migrants and the homeless. Systematic screening policies are lacking, and it is not clear which are the most cost-effective methods for recruiting these hard-to-reach populations into testing, care and treatment programmes.<sup>15</sup>

The key issues for addressing HCV in Europe are the following.

## 2.1 | A “silent” epidemic

The undetected spread of HCV is one of the most important challenges to address, as the disease is often only detected in the late stages, if at all. Fewer than 40% of all cases are detected, even in high-income countries.<sup>3</sup> As a silent epidemic, HCV rates are increasing in Europe,<sup>16</sup> mainly among PWID, who are disproportionately affected by HIV, tuberculosis and who face stigmatization and social exclusion.

## 2.2 | Improving HCV surveillance

Collectively, European countries must improve surveillance. However, the rates of reported HCV cases in EU from 2006 to 2013 are roughly stable, although there is a great geographical variation with the highest number of reported cases in northern countries. Currently, EU countries with good surveillance systems present high HCV prevalence rates, but true prevalence rates are unknown.<sup>8</sup>

## 2.3 | Funding on the EU level

Meeting this challenge requires action on prevention, treatment (eg, medical products, agreements on joint procurement and pricing of drugs) and health technology assessment. The involvement of EU agencies, including the ECDC, is also necessary. The EC has invested over €30 million to date in scientific cooperation on HCV at the EU level and should guide the process.<sup>17</sup>

## 2.4 | Focus on high-risk populations

In Europe, HCV is now transmitted primarily among PWID. Globally, 67% of PWID are infected with HCV, whereas PWID account for the majority of HCV/HIV co-infections worldwide.<sup>18</sup> In high-income countries, PWID account for 50-80% of HCV infection.<sup>18</sup> In Europe, recent increases in HCV prevalence reflect poor treatment access and uptake among this group. Historically, HCV treatment guidelines have excluded PWID, due to concerns about effectiveness, adherence and risk of re-infection. However, a growing body of literature shows that treatment is highly effective and there is no difference in treatment adherence between PWID and others.<sup>19,20</sup> Therefore, several recent international guidelines recommend HCV treatment in PWID.<sup>21,22</sup> Nevertheless, PWID face various barriers to treatment, including access to testing for HCV, lack of awareness of HCV infection and discrimination, which are strongly linked with the criminalization of drug use, memories of painful interferon-based treatments, police brutality, lack of awareness of the existence of DAAs, all of which delay entry into effective treatment.<sup>23</sup> In addition, although referral and treatment pathways are unclear in many cases, PWIDs are often denied treatment because of the potentially high risk of re-infection. To overcome these limitations, community programmes and meaningful involvement of affected communities are critically important. It is also necessary to improve the knowledge of staff working and facilitate collaboration between clinical hepatology and addiction services. It should be emphasized that HCV cannot be eliminated without a concerted focus on raising awareness and coordinating prevention, testing, care and treatment of the PWID population.

## 2.5 | Burden on health systems

The cost of HCV to European health systems is significant. Costs to health systems include ongoing treatment of cirrhosis, HCC and end-stage renal disease, among others, which amount to an

enormous expenditure by European countries.<sup>10</sup> In a survey including five European countries, the estimated direct and indirect costs in patients with chronic hepatitis C were 76% and 65%, respectively, higher than people without hepatitis C in 2010.<sup>24</sup> HCV is also related to a loss of productivity among those infected, when patients are unable to fully participate at their workplaces and in society.

## 2.6 | Unnecessary burden on quality of life

Eliminating HCV is not just an urgent financial matter, it is a question of human rights, as living with HCV greatly impacts quality of life for families and communities. Aside from being a practical possibility, for the patient a cure is not only possibly life-saving, but also life-changing.<sup>4</sup> Although the majority of cases have not yet been identified, risk groups are well-known and the tools and means for eliminating the disease are available with appropriate commitment from governments, the pharmaceutical industry, patients, health providers and others stakeholders.

## 2.7 | Improving coordination among member states

Although there has been a call to action among member states, including ongoing discussions and initiatives among stakeholders in conjunction with patient associations like ELPA, there is still a general lack of coordination among member states. Coordination must happen at the EU and national levels with the wider involvement of stakeholders including policy makers, nongovernmental organizations, patients, the health sector and others.

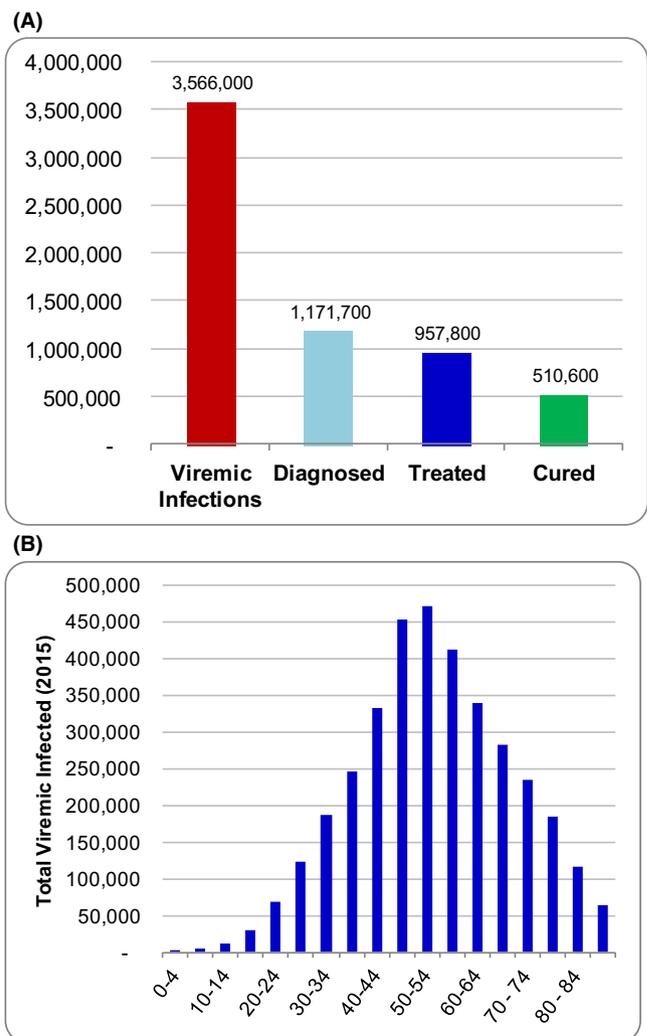
## 2.8 | Engaging stakeholders

It is widely believed that the current opportunity to eliminate HCV will require the engagement of partners around Europe to link research, services, health providers and policy makers. Key focus areas for stakeholder engagement include: (i) access to affordable/free treatment and care (ii) scale-up of harm reduction by connecting marginalized groups to needed services and addressing barriers like stigma and discrimination, as well as laws that criminalize drug use and (iii) the full involvement of the affected communities in these processes.<sup>25</sup> Indeed, advocacy groups and associations are working with stakeholders to advance elimination by creating and disseminating HCV management guidelines, raising awareness, collaborating with ECDC, WHO, EMCDDA and other groups but an integral approach on national and local level often is missing. In particular, EASL has created, updated and disseminated guidelines for the management of hepatitis C, and also organizes the annual International Liver Congress, gathering more than ten thousand attendees each year. In addition, EASL has emphasized the need for future research regarding better clarification of: (i) epidemiological data for HCV infection in the general population and specific patients groups in the EU; (ii) reinfection rates following effective antiviral therapy in PWID; (iii) ideal access to anti-HCV treatments at the national levels; and d) the public health impact of anti-HCV therapy on specific group of patients.

## 3 | HCV BURDEN IN EUROPE—ELIMINATING HCV IN EUROPE: CURRENT CHALLENGES AND CRITERIA FOR SUCCESS<sup>26–31</sup>

A key challenge to HCV elimination in Europe is the lack of reliable estimates of the burden of disease. Knowing the true burden of disease and the profile of those infected is necessary in order to design programmes and policies to scale-up prevention and treatment. The burden of disease estimates is also necessary for estimating the cost that these efforts entail for European health systems.

In an effort to produce more reliable prevalence estimates, the Center for Disease Analysis (CDA) has been visiting nearly every EU country in order to assess the HCV disease burden through expert consultation and modelling. CDA estimates show 3.6 million viremic infections in European Union, with only 1.2 million cases diagnosed (Figure 1A), 1 million treated and 500 000 cured. Overall,



**FIGURE 1** A, Numbers of viremic, diagnosed, treated and cured hepatitis C patients in European Union in 2015. B, Numbers of viremic hepatitis C patients in different age groups across the European Union in 2015. Source: Polaris Observatory ([www.centerforda.com/polaris](http://www.centerforda.com/polaris))

there is a viremic prevalence of around 0.7% (with one-third of infections already diagnosed), which was less than expected. However, it should be emphasized that there is a great geographical variation regarding prevalence (range: 0.1%-2.6%) and diagnosis rates (from 10% to almost 90%; Figure 2). Interestingly, most of the patients infected in Europe are between 45 and 60 years old (with a median age of 54 years), indicating a possible target birth-cohort group for screening programmes (Figure 1B).<sup>32,33</sup> Similarly, HCV treatment rates vary dramatically across the EU (ranging from 0.6% to 10.2%) and unfortunately in many countries there is a great discordance between prevalence rates and treatment rates (Figure 2). Characteristically, it is estimated that only 21 of European countries account for 80% of viremic HCV infections (including France, Germany, Greece, Italy, Poland, Romania, Spain and United Kingdom) and 28% of countries account for more than 80% of the treated patients (including France, Germany, Italy, Portugal, Spain and United Kingdom). On the other hand, there was a significant increase in the number of patients who received antiviral therapy in 2015 (nearly 130 000 patients or 3.7% of those infected) after a long period of almost steady rates of patients under therapy (60 000-80 000/year) during the last decade, partly due to the availability of the new DAAs.

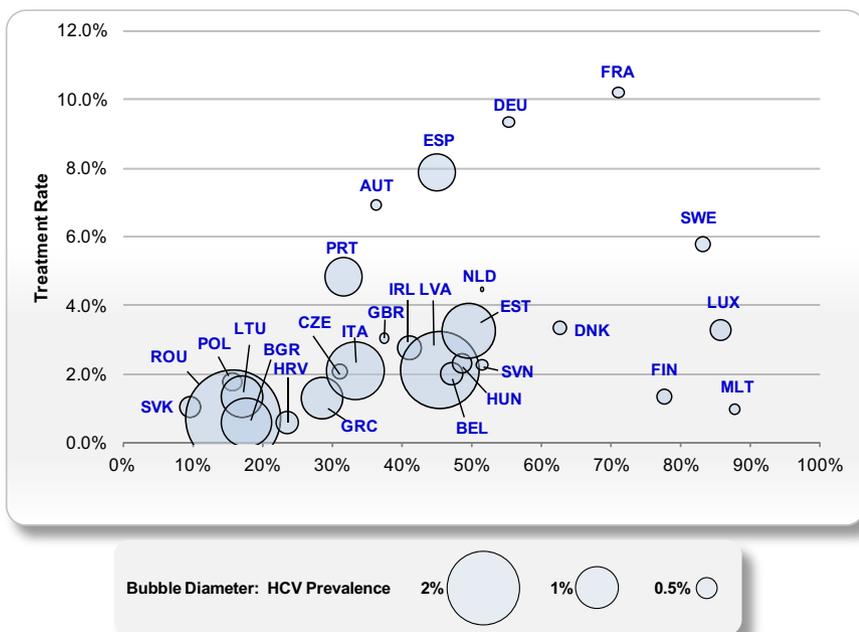
It is estimated that if we would continue to treat all patients with Peg-IFN irrespectively of fibrosis stage, HCV would decline by 40%, while liver-related deaths, HCC and decompensated cirrhosis would increase by 30%, 15% and 25%, respectively (Figure 3A). However, if we use the more effective new DAAs in those with more than moderate (>F2) fibrosis, HCV infections will decline by 70%, while HCV-related morbidity and mortality will decrease by 45%-55% (Figure 3B). Finally, based on the elimination scenario (ie, expand screening to find infected individuals to treat all patients up to age of 70 years with DAAs irrespectively of fibrosis stage, starting in 2017),

HCV infections will decline 90% by 2030 and 95% by 2035, while liver-related diseases will decline 55% by 2030 and 70% by 2035 (Figure 3C). Interestingly, this policy seems to be more cost-effective than the status quo and this is common to all countries irrespectively of their average incomes. Nevertheless, although negotiation of drug prices is important, the central issue for HCV elimination is how to pay for it now in order to ensure cost saving in the long run.

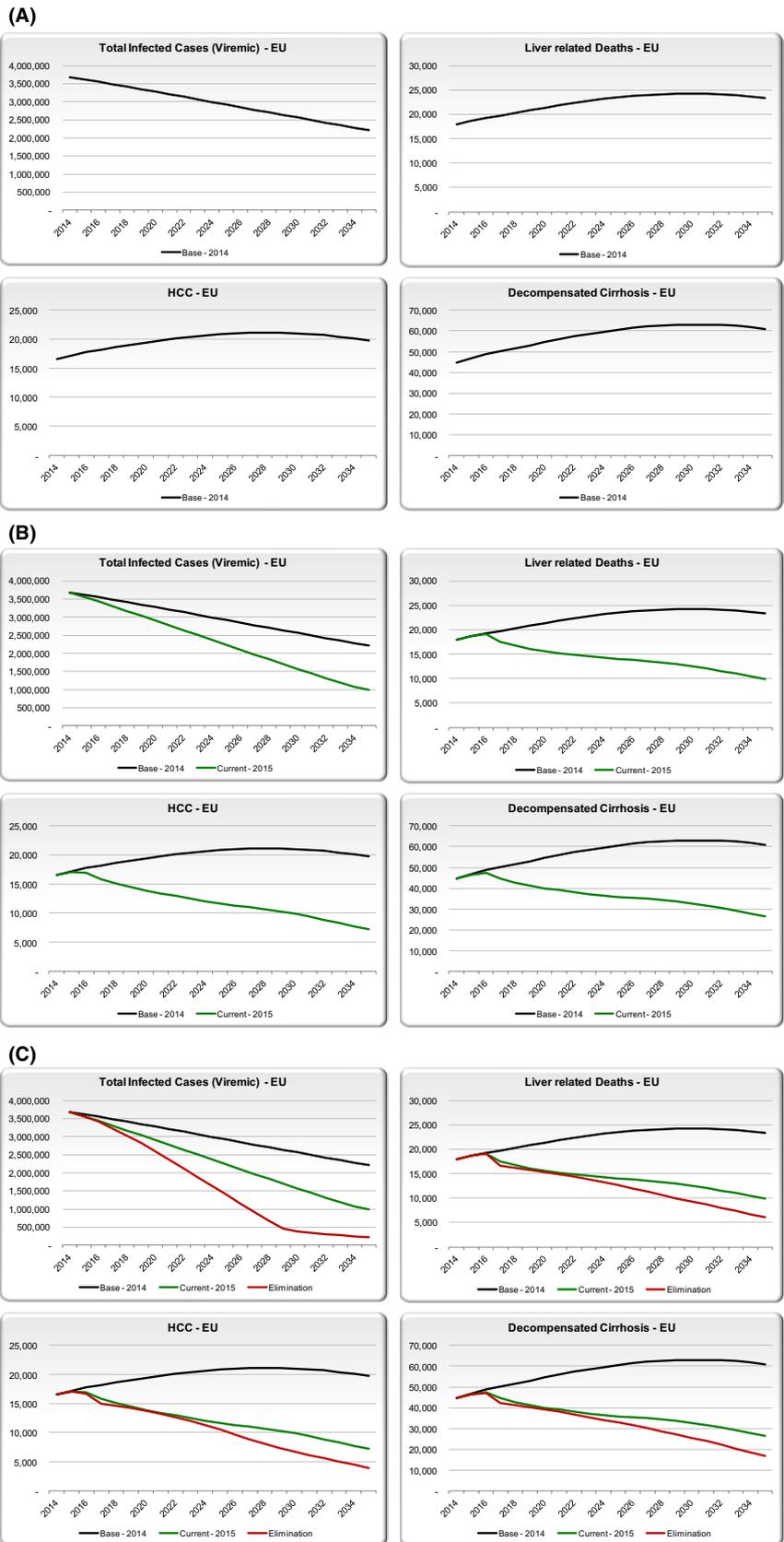
Thus, it is feasible to eliminate HCV infection in the EU but treatment has to be increased to 6%-10% of total infections (coupled with active screening), to reduce new infections, while screening and treatment have to encompass all HCV-infected individuals irrespectively of fibrosis stage, as most new infections occur among younger individuals who have mild to no fibrosis (F0 or F1). In addition, in order to reduce liver-related deaths, eligibility has to increase to older patients (currently, the median age in the EU is 54 years, and half of the HCV-infected population will be above 65 years in 11 years). However, it should be emphasized that because treatments are curative, the number of treated patients and the associated costs is finite. Thus, treatment of HCV is cost saving, but a mechanism is needed to help countries manage the initial increase in spending to achieve HCV elimination.

#### 4 | THE FIRST GLOBAL HEPATITIS STRATEGY

Elimination requires EU and regional leadership, according to WHO. Efforts are currently underway globally, evidenced by the explicit inclusion of hepatitis in Goal 3 of the Sustainable Development Goals and the forthcoming WHO Global Health Sector Strategy on Hepatitis (GHSS)—the Global Hepatitis Strategy 2016-2021. The overall goal of the GHSS is to eliminate hepatitis as a public health



**FIGURE 2** Rates of prevalence, diagnosis and treatment across the European Union countries. Source: Polaris Observatory ([www.centerforda.com/polaris](http://www.centerforda.com/polaris))



**FIGURE 3** Estimated total number of viremic hepatitis C patients, with liver-related deaths, hepatocellular carcinoma, and decompensated cirrhosis from 2014 to 2034 if all patients are treated with pegylated interferon-alfa and ribavirin combinations (A), or patients with more than moderate (>F2) fibrosis are treated with direct acting antivirals (DAAs) (B), or all patients up to age of 70 years are treated with DAAs (C)

threat within the framework of universal coverage rather than as a specific disease intervention. To this end, the Hepatitis Strategy focuses on stronger prevention and health system efforts with five strategic directions including the following:

- (i) information for focus and accountability, (ii) interventions, (iii) quality and equitable delivery, (iv) financing and (v) innovation.

While reducing hepatitis as a health threat does not necessarily imply eradication, elimination is achievable through a scale-up

of treatment and prevention services. In order to eliminate hepatitis as a health threat, the Strategy sets the targets of a 90% reduction in new cases of chronic HBV and HCV in addition to a 65% reduction in deaths. Some Strategy interventions have already made significant progress, but others represent challenges. For example, to reach these targets, 90% of those living with hepatitis B and C need to be diagnosed and 90% of those put on treatment, which requires an enormous scale-up in testing and treatment.

Given the current European political and social contexts, this scale-up is only possible through the adoption of a public health approach, focusing on innovation and committed partnerships with government, civil society and the private sector, in addition to concrete and tailored actions by European national governments. All of this needs to be translated into national action plans, which will be discussed at the next World Health Assembly.

## 5 | THE COST OF HCV ELIMINATION

The cost of treating the disease is a serious obstacle to the elimination of HCV. Modelling techniques show that by taking estimates of the true cost of the disease into account, HCV can become a rare disease in the next 20-25 years, with a significant budget commitment. However, one that pales in comparison with the amount spent on treatment of HIV and many noncommunicable diseases (NCDs), for example, and the cost of doing nothing. European countries, where public health systems assume the majority of the cost burden, must consider the cost savings as well as the value of the health benefits gained. Modelling studies show that the cumulative disease burden over the next 35 years will decrease dramatically with the implementation of new therapies, and a sharp decline can be expected in the number of deaths.<sup>26</sup>

Thus, resources spent on HCV provide good value for money, given that high initial annual spending will give way to decreased costs in the medium term.<sup>34,35</sup> One potential option suggested for obtaining funds needed to expand HCV treatment is the creation of a European Hepatitis Fund.<sup>26</sup> Such a fund would receive money from donors and serve as a platform for negotiating prices with drug companies and managing cash flow.

The Hepatitis Fund would serve to help countries manage the initial increase in health spending needed to combat the disease, with the benefit that later costs can be recouped through health savings.

## 6 | CURRENT ACTION ON HCV AT THE EU LEVEL

At the EU level, action on HCV is underway by the EC, which coordinates the response of member states to public health threats. Action includes engaging the EU Health Program, where some viral hepatitis activities are financed, particularly with regard to improving access to testing and access to care.

Another European action includes the EU HIV/AIDS Action Plan 2014-2016, which treats viral hepatitis as a co-infection, and the work of EU agencies that provide independent scientific advice. The EC has organized country visits to member states, and agencies such as ECDC and EMCDDA play a role in surveillance.

At the same time, the European Medicines Agency approved nine new medicinal products through accelerated approval processes in 2014-2017.<sup>31</sup> The agency is also initiating a new mechanism whereby member states can purchase together to obtain better prices and conditions (joint procurement). Health and technology assessment can also benefit from being carried out in a common way among member states.

## 7 | EU HEALTH SYSTEMS SUSTAINABILITY

With European health systems under financial stress, efforts aimed at key ministers and decision makers that come from nongovernmental organizations (NGOs), patient organizations, health professionals and civil society are key to raising awareness of the disease and ensuring it has a place on the policy agenda. From the perspective of patients and advocacy groups, there is the sense that there has been more focus in Europe on producing abundant recommendations than on using or implementing them, as evidenced by the European Liver Patients' Association action plan on key recommendations at the EU and national levels. The plan highlights the well-documented recommended focus areas for HCV and HBV, which can be classified in terms of:

1. Monitoring and data collection. It is necessary to harmonize national monitoring systems for viral hepatitis across all member states, to create central registries at national level for acute and chronic viral hepatitis and for HCC and to share results with civil society stakeholders.
2. Awareness. It is important to secure government funding for awareness campaigns and to use mass media campaigns to raise awareness among the general population. In addition, it would be useful to highlight the impact of risk factors, such as alcohol consumption, on people infected with viral hepatitis or to involve civil organizations at a national level and civil society in World Hepatitis Day. Furthermore, it would be useful to provide stigmatized groups, such as injecting drug users, migrants, the homeless, MSM and prisoners, with appropriate knowledge and support upon diagnosis. Actions to help patients and the society to overcome stigma are also required. Finally, awareness should include healthcare professionals working in areas of high prevalence.
3. Prevention. This could be achieved by involving civil society organizations and community members in prevention, harm reduction and implementation programmes. Several other measures could be useful such as improvement of infection control in healthcare settings, implementation of prevention programmes targeting high-risk groups, such as PWID and noninjection drug

users, prisoners and sex workers, as well as enhancement of blood, tissue and organ donation screening.

4. Testing and diagnosis. These could be improved by community testing, referral and treatment facilities for the general population and specifically for high-risk groups. Further measures could be early identification of chronically infected pregnant women, implementation of routine testing for blood donors and low-barrier testing activities for high-risk groups (HBsAg, anti-HCV), as well as free-of-charge liver enzymes testing in routine medical check-ups with referral to a specialist for further evaluation in case of any abnormal test.
5. Assessment could be achieved by ensuring that all adults and children with chronic viral hepatitis, including PWID, migrants, prisoners and vulnerable groups, are evaluated for antiviral treatment. In addition, they are referred directly to a specialist with appointments no longer than six weeks for appropriate treatment options in line with the latest clinical guidelines. Finally, it is important to monitor infected patients in order to prevent the development of cirrhosis and HCC.
6. Treatment. It is important to ensure open dialogue between patients and healthcare professionals including about the new HCV drugs.<sup>36,37</sup> The latter should be offered without restrictions in all infected patients under the care of specialists, and in community settings wherever this is possible and safe according to the EASL guidelines.<sup>11</sup> In addition, any HCV strategy should include prevention, diagnosis and treatment and should place patients at its core.

## 8 | GOOD PRACTICES IN HCV—ELIMINATION AT THE NATIONAL AND LOCAL LEVELS<sup>38–44</sup>

There are many cases of good practices in HCV strategies for policies, prevention, screening and treatment across Europe, including France, Germany, Netherlands, Portugal and Scotland. Several countries have developed successful practices through political engagement, a commitment to research and the use of evidence to inform policies and programmes, and a concerted focus on the most marginalized groups at increased risk for HCV, including drug users and prison populations.

### 8.1 | France

In France, a country with an estimated viremic prevalence, diagnosis rate and treatment rate were 0.3%, 69% and 5.2%, respectively, in 2013.<sup>45</sup> In addition, in 2014, of an estimated 74 000 undiagnosed HCV and HBV patients aged 18–80 years, 37% were 70–80 years old (ages 60–80 years were mostly women) and the majority of those 18–59 years old were men.<sup>38,40</sup> Thus, the undiagnosed HCV population in France is mostly men under 70 years old. New French guidelines from 2016 emphasize a risk factor-based, targeted screening strategy in addition to population-based testing for HIV, HBV and HCV, focused on all 18–59 years old.

### 8.2 | Germany

The German Action Plan on Hepatitis, developed in 2013, includes recommendations for (i) better information for drug users, (ii) sterile or hygienic drug use and paraphernalia, (iii) recruiting more addicts into therapy and (iv) employing specially trained HCV nurses for patient monitoring. The plan is informed by research including the DRUCK study, a multi-site sero-behavioural survey which showed that the prevalence of HCV infection among drug users ranged between 42.3% and 75% and of HIV infection between 0% and 9.1%, 6% of HCV infected were HIV positive, while 83% of HIV infected were also HCV positive.<sup>46,47</sup> Interestingly, only 19.4% had been ever successfully treated. The study showed frequent unsafe drug use, unknown infection status, gaps in knowledge about the means of transmission, low rates of HBV vaccination and imprisonment as an element of the risk profile, among others. In providing information on the hidden population of drug users, this study and others have helped to generate better knowledge of the population affected in order to inform hepatitis prevention efforts among drug users in Germany.

### 8.3 | Italy

In 2015, a survey based on testing and treatment claims identified 350 000 individuals with chronic hepatitis C listed in the NHS registries with the understanding that a similar number of unidentified carriers of HCV might be hidden in the general population, as well. (EPA C Newsletter 2015). Starting 2014, >93 000 infected patients, mostly with advanced HCV, have been treated with interferon-free regimens in selected hospital facilities, leading to greater than 95% SVR rates (AIFA Newsletter, 29 September 2017).

### 8.4 | Scotland

Scotland's Hepatitis C Action Plan (2006–) has led to concrete gains in its five focus areas of prevention, diagnosis, treatment, coordination and evaluation/research. The plan has coincided with an appreciable reduction in incident infection and has led to an increase in the proportion of people diagnosed, greater numbers initiating treatment and a reduction in the overall prevalence of infection. In 2015, in alignment with the inaugural World Hepatitis Summit Declaration on the elimination of Hepatitis (The Glasgow declaration), the Scottish Government launched its policy to eliminate hepatitis C as a serious public health concern. A target to cut new presentations of HCV-related liver failure and HCC (later to be confined to just liver failure) by 75% during 2015–2020 was approved as was the prioritization of therapy for those with moderate to severe liver disease; this approach was agreed in the context of the need to achieve optimal benefit from highly effective but costly drugs.

As the action plan had invested in robust monitoring systems, it has been possible to gauge the impact of this approach. Preliminary data indicate that the incidence of HCV-related decompensated

cirrhosis is now on the decline and that Scotland is cautiously optimistic that the 2020 target will be reached. Subject to reductions in the cost of therapy, it is likely that a target to reduce the prevalence of HCV infection in Scotland from around 35 000 to 5000 or less over the next 10 years, will be approved by the Scottish Government. Accordingly, Scotland is truly embracing the concept of elimination and, because of its action plan investment, will be in an outstanding position to deliver.

## 8.5 | Portugal

The success of Portugal in effectively advancing its national agenda on HCV treatment illustrates many of the fiscal, political and social challenges faced by European countries in developing HCV policies. In 2011, Portugal faced many difficulties in addressing HCV, including low investment in public health, low number of identified chronic HCV patients as compared to estimated prevalence, outdated guidelines on diagnosis and treatment, no clear hospital referral network for HCV and the high costs of new, innovative treatments. Moreover, the context of the economic crisis and cuts in services amid the pressures of interest groups and activists created a highly charged political environment in which patients suffered without access to treatment. Since then, thanks to the efforts of civil society and academia, a group of stakeholders including physicians, patients, managers and healthcare system representatives prepared a literature review and consensus paper on the need for an overall focus on HCV elimination and new prevention policies, new financing and access models, lower prices from drug companies, a national action plan and a central patient registry.

As a part of the resulting National Action Plan for Hepatitis C, the Ministry of Health announced a new risk-sharing model for patient treatment, full funding for patients and the creation of the registry. As a result, all of the identified HCV patients<sup>14,16</sup> were included in the new programme, resulting in a decrease in the time from treatment request to authorization. In January 2016, over 8000 HCV patients had been authorized for treatment, two-thirds had been initiated in treatment and 1230 patients had been cured. This effort has been associated with a 73% reduction in the incidence of HCC, a 92.5% reduction in the need for liver transplantation due to hepatitis C and a 93.2% reduction in development of cirrhosis. Thus, it is estimated that the lifelong healthcare costs was reduced by >270 million euros in total, or >30 000 euros per patient.

## 8.6 | The Netherlands

The Netherlands demonstrated the effectiveness of harm reduction strategies towards PWID. The Dutch harm reduction approach builds on programmes that started in the late 1970s with providing methadone in combination with social-medical care and needle-exchange facilities aiming to reduce drug users' risk to get infected with blood borne viruses. The approach, probably in combination

with demographic changes in the PWID population led to an impressive reduction of blood-borne infection diseases in this population.<sup>48</sup> According to the Amsterdam Cohort Studies among people who use drugs, the incidence of HCV among PWID has decreased dramatically since 1986 to nearly zero.<sup>49</sup> However, studies in the Netherlands show an increase in HCV incidence among HIV-positive MSM.<sup>50,51</sup> Current policy in the Netherlands is to provide prevention, screening, linkage to care, treatment, social welfare and participation for all groups affected by HCV and HBV.

## 9 | CONCLUSIONS: EUROPEAN UNION AND NATIONAL SUPPORT FOR THE ELIMINATION OF VIRAL HEPATITIS IN EUROPE<sup>52-59</sup>

Despite the well-documented need, HBV and HCV have struggled to become recognized as public health priorities in Europe. In contrast, HIV has been significantly reduced in terms of incidence in Europe and serves as a model for promoting access, cooperation and partnership when faced with an outbreak of infectious disease. Increasingly, EU member states are developing national plans on viral hepatitis. In addition, surveillance is being scaled up with successes in prevention of all infections related to the healthcare setting and, in some member states, successes in access to treatment. However, there is still a lack of reliable data on the disease burden and on accessibility to DAAs in many member states. There is an urgent need to raise awareness and promote a better understanding of the epidemic to facilitate tailored policies, collaboration and sharing of best practices. Improving EU national policies related to HBV and HCV is a priority for treating and eventually eliminating these diseases.

In facing this challenge, member states count on the support of the ECDC. The ECDC works with member states to provide information, share good practices, help build capacity and provide scientific advice. The organization coordinates HBV and HCV surveillance programmes across EU/European Economic Area countries, maintains a network of European scientific experts, supports countries in prevalence estimates and provides risk estimates taking into account the characteristics of European populations. As noted, an elimination strategy can only be successful with a focus on PWID as a key risk group.<sup>55</sup> The ECDC directly provides evidence-based guidance and technical support with a focus on key populations. As with any other policy area, the active participation of affected individuals and communities in the development of responses in design, implementation and evaluation is the most effective way to ensure that responses fit the needs of patients. In addition to the difficulty in prevention and screening, the cost of treatment of HCV continues to be a major obstacle to European efforts to eliminate the disease. Countries will spend a considerable proportion of their health budgets on costs related to HCV, whether treating the disease or treating liver-related associated diseases, which are costs that already accrue to the

health system. Thus, HCV treatment is an investment that can be recovered in future through health savings. However, the issue of political viability of making such an investment is still present in EU countries.

Currently scientific breakthroughs have made eliminating HCV a possibility, with the potential to save lives and lead to a significant savings in societal and economic costs. The specific challenges of HCV require holistic, people-centred, health system-wide approaches to disease awareness, prevention and integrated care and treatment with all stakeholders combining their diverse skills and resources in a unified response.

## 10 | PRESENTATION OF THE HCV ELIMINATION MANIFESTO

On 17 February 2016, government representatives, policy makers, patients, medical associations and committed individuals gathered in Brussels at the EU HCV Policy Summit to express commitment to the elimination of HCV in Europe by 2030. The commitment to elimination was based on a public health and a human rights approach, given that HCV is a life-threatening disease that affects millions in Europe. The HCV Elimination Manifesto (Annex S1) was the result of work and collaboration from several of the stakeholder groups that attended the meeting. It set the direction for a focus on needed future action to eliminate hepatitis C in Europe by 2030 advocating for recognition of hepatitis C as a public health priority, gaining the involvement of all stakeholders, developing integrated care and treatment pathways, prioritising the link between hepatitis C and socially marginalized groups, harmonising and improving surveillance, holding a European Hepatitis week.

## AUTHORS' DECLARATION OF PERSONAL INTERESTS

George V. Papatheodoridis has served as advisor/lecturer for Abbvie, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Janssen, Merck Sharp & Dohme, Novartis and Roche; has received research grants from Abbvie, Bristol-Myers Squibb, Gilead, Janssen and Roche; has participated in clinical trials of Abbvie, Bristol-Myers Squibb, Gilead, Janssen, Merck Sharp & Dohme, Novo Nordisc, Regulus Therapeutics and Tiziana Pharmaceuticals; was in the Data Safety Management Board for Gilead.

Angelos Hatzakis has received research grants from AbbVie, Gilead, MSD and unrestricted grants from AbbVie, BMS; has participated in advisory boards of BMS, Gilead; Gilead, MSD, Novartis; has been Co-Chair of Hepatitis B and C Public Policy Association funded by AbbVie, BMS, Gilead, MSD.

Evangelos Cholongitas has served as advisor/lecturer and/or has received research grants for Abbvie, Bristol-Myers Squibb, Gilead, Merck Sharp & Dohme, Novartis and Regulus Therapeutics and Tiziana Pharmaceuticals.

Ricardo Baptista Leite, Ioannis Baskozos, David Goldberg, Achim Kautz have no conflict of interests.

Jagpreet Chhatwal has received research grants from Merck and Gilead and served on the scientific advisory board of Merck and Gilead.

Massimo Colombo has served as advisor for Abbott/Abbvie, Achillion, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GenSpera, Glaxo Smith-Kleine, Janssen, Lundbeck, Merck, Novartis, Roche, Tibotec, Vertex; has been speaking and teaching for Bayer, Bristol-Myers Squibb, Gilead, Novartis, Roche, Tibotec, Vertex; has received grant and research support from Bristol-Myers Squibb, Gilead Merck, Roche.

Helena Cortez-Pinto has served as an advisor/lecturer for Intercept Genfit and Gilead.

Antonio Craxi has served as an advisor/lecturer for Abbvie, Alfasigma, Bayer, Bristol-Myers Squibb, Gilead, Janssen, Merck Sharp & Dohme, Novartis and Roche; has received research grants from Abbvie, Bristol-Myers Squibb, Gilead, Merck Sharp & Dohme and Roche; has participated in clinical trials of Abbvie, Bristol-Myers Squibb, Gilead, Janssen, Merck Sharp & Dohme; has been in the Data Safety Management Board for Abbvie and Novartis.

Charles Gore has no personal financial or other interests of relevance.

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## SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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