Road to Elimination: Barriers and Best Practices in Hepatitis C Management

Overview of the status of HCV care in Europe and Australia

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FOREWORD

In 2013, the introduction of a new class of medicines (direct-acting antivirals, or DAAs) dramatically transformed the treatment of the hepatitis C virus (HCV), allowing us to face this disease with renewed hope.

For the first time there is a global common goal: the elimination of viral hepatitis as a public health threat. But even though we have the tools to eliminate it, we are still not fully leveraging them to assure universal access to prevention, care, and treatment. Countries are advancing at very different speeds and most do not have a strategy to address viral hepatitis, in spite of the World Health Organization's recommendation to develop one. The longer the process takes, the more patients will suffer, and the higher the costs to the health system and society will be due to ongoing transmission and the costs of care, particularly for those who present late.

In 2017 and beyond, we need to turn our attention to how to operationalize the global elimination goal, and how countries can increase their efforts. This report addresses the barriers that are impeding progress toward eliminating hepatitis C, and provides suggestions to overcome them based on the best practices identified in different countries. It aims to support policy-makers and other stakeholders around the world to develop and adopt effective solutions to eliminate HCV.

We firmly believe that the knowledge of what works and what does not will enable health systems and key stakeholders to reduce human suffering and accelerate their progress so that we can declare HCV eliminated as a public health threat by 2030.

Charles Gore
Jeffrey Lazarus
Ricardo Baptista Leite

CONTENTS

EXECUTIVE SUMMARY

Viral hepatitis is a global health threat and a leading cause of mortality from which no country, rich or poor, is spared. An estimated 400,000 people die every year as result of HCV infection, with 66,700 of these deaths occurring in Europe (WHO, 2017). Until recently, hepatitis C treatment was poorly tolerated, complicated to deliver, and not broadly effective across all patient types. Today, better tolerated and highly effective treatment options for HCV infection are available in the form of direct-acting antivirals (DAAs) and result in cure rates of well over 90% across the disease spectrum. According to clinical recommendations, all patients willing to be treated and who have no contraindications to treatment should be considered for therapy.

In May 2016, the World Health Organization (WHO) developed a strategy with the goal of eliminating hepatitis B and C as public health threats by 2030. The strategy aims to achieve a 90% reduction in incidence and a 65% reduction in mortality from 2015 levels. In pursuing this global strategy, the WHO Regional Office for Europe proposed a more ambitious framework which sets regional milestones and targets to be achieved by 2020. For example, it proposes that 50% of people living with chronic HCV infections are diagnosed and aware of their condition; and 75% of eligible individuals diagnosed with HCV have treatment coverage. In this context, scaling-up access to prevention, treatment, and care is a top priority. Nevertheless, the translation of global and regional strategies into national action plans with measurable targets is still often missing.

Through literature review and country experts' consultation conducted between November 2016 and March 2017, this report analyzes the status of 11 countries, identifying and comparing key success factors and main barriers for each step of the HCV care cascade: (1) awareness and prevention; (2) testing and diagnosis; (3) linkage to care and access to qualified health services; (4) access to medication; and (5) monitoring and evaluation. Accordingly, specific recommendations on best practices are defined, aiming to inform policy-makers on how to act on their decision to eliminate HCV.

A comprehensive HCV strategy has been seen in countries that perform better across the different steps of the HCV health care cascade. Attention needs to be paid to all steps, starting with raising awareness in the general population, high prevalence groups and primary care physicians (PCPs), and defining a clear testing and diagnosis strategy. Furthermore, better integration between diagnosis and treatment or support services is needed, including good referral systems from PCPs to specialized care, providing universal coverage of DAAs and developing good HCV patient registries. Finally, experts agreed that in order to better target strategies to countries' specific needs, better epidemiological data is needed in all countries.

In all countries, there are barriers to HCV elimination that need to be overcome, as well as best practices in HCV management that can be adopted. Widespread adoption on the national level of the best practices identified in this report is essential to eliminate HCV by 2030.

INTRODUCTION

Epidemiology and burden of hepatitis C

Viral hepatitis is a global health threat and a leading cause of mortality from which no country, rich or poor, is spared (WHO, 2016d). Given its essentially asymptomatic nature, viral hepatitis is a silent epidemic. In other words, most people are unaware they are infected. Untreated chronic hepatitis C infection naturally progresses to liver cirrhosis and liver cancer. About 71 million people are estimated to have chronic HCV infections, representing a global prevalence of 1%. In the WHO European Region (53 countries), the estimated prevalence is higher, at 1.5%, meaning that 14 million people live with HCV chronic infection in the region (WHO, 2017).

The most common transmission route is injecting drugs with shared, unsterilized equipment. Medical and dental procedures in settings with inadequate infection control (dialysis centers, for example), tattooing with reused paraphernalia, infected donor blood, blood products, and organs are other transmission pathways. HCV can also be transmitted from mother to infant and during unprotected sex, especially among HIV-positive men who have sex with men (MSM). Sixty to eighty percent of people exposed to the virus develop chronic infections, while the remaining clear the virus (Hajarizadeh, Grebely, & Dore, 2013; WHO, 2016d).

Until 2014, hepatitis C treatment was toxic, complicated to deliver, and not broadly effective across all patient types. The overall cure rates were lower than 50%, in particular for people with cirrhosis (Manns, Wedemeyer, & Cornberg, 2006). Nowadays, safer and highly effective treatment options for HCV infection are available. Regardless of a patient's HIV status, stage of liver disease, or HCV treatment history, 12 weeks of treatment results in cure rates of at least 90% (Pawlotsky, 2014). According to recommendations from the European Association for the Study of the Liver (2017), all patients (both treatment-naive and treatment-experienced) with compensated or decompensated chronic liver disease related to HCV, who are willing to be treated, and who have no contraindications for treatment, must be considered for therapy. Annually, an estimated 400,000 people with chronic HCV infection die as result of HCV infection, from cirrhosis (65%), and hepatocellular carcinoma (34%); 66,700 of these deaths occur in Europe (WHO, 2016b).

WHO OBJECTIVES WORLDWIDE AND FOR EUROPE

The 69th World Health Assembly adopted its first-ever "Global Health Sector Strategy on Viral Hepatitis for 2016–2021" in May 2016, with the goal of eliminating hepatitis B and C as public health threats by 2030 (WHO, 2016c). WHO has defined elimination of viral hepatitis as a public health threat as achieving a 90% reduction in new chronic infections and a 65% reduction in mortality from 2015 levels. To attain these targets, it is essential that effective prevention services are expanded, and 80% of eligible patients are treated.

Figure 1 ǀ WHO Global targets for eliminating HCV by 2030 – an integrated strategy across HCV care cascade is required

Awareness and prevention	Testing and diagnosis	Link to care and access to qualified health services	Access to medication

90% of all persons with chronic HCV diagnosed and aware of their condition

90% reduction in new cases of chronic HCV

90% of injections administered with safety-engineered devices in and out of health facilities

Harm reduction services that provide at least 300 sterile injection kits per person per year for PWID

100% blood donations screened in a quality-assured manner

80% of eligible persons with chronic hepatitis C virus infection treated

65% reduction in viral hepatitis C deaths

Source: WHO, 2016c

Following the global strategy, in September 2016, the WHO European Regional Committee adopted an action plan for the health sector response to viral hepatitis. The action plan highlights the need for equity and for focusing on those most at risk of viral hepatitis infection. It provides the framework for a comprehensive health sector response to viral hepatitis and sets regional milestones and targets under five strategic directions: information for focused action, interventions for impact, delivering for equity, financing for sustainability and innovation for acceleration. In regard to hepatitis C, five targets are set to be achieved by 2020 (WHO, 2016a):

Figure 2 ǀ WHO European targets by 2020

Awareness and prevention	Testing and diagnosis	Link to care and access to qualified health services	Access to medication

50% of all persons with chronic HCV diagnosed and aware of their condition

50% of injections administered with safety-engineered devices in and out of health facilities

Harm reduction services that provide at least 200 sterile injection kits per person per year for PWID

100% blood donations screened in a quality-assured manner

75% treatment coverage of people diagnosed with HCV infections who are eligible for treatment

Source: WHO, 2016a

PROJECT RATIONAL AND SCOPE

There is an urgent need to scale up access to integrated care. Several relevant international reports on viral hepatitis have been published, and particularly on hepatitis C (European Liver Patients Association, 2017; The European Union HCV Collaborators, 2017; WHO, 2016d). Most of the reports focus on testing and treatment, and global and regional strategies have not yet been broadly translated into national measurable action plans. The European Liver Patients Association (ELPA) recently conducted a survey of its representatives in 27 countries (26 of which were in the European Region) in which it identified numerous gaps and setbacks for the implementation of hepatitis B and C policy in Europe (European Liver Patients Association, 2017). In our report, we reviewed 11 different high-income countries in order to identify key success factors and main barriers to the implementation of an effective health sector response.
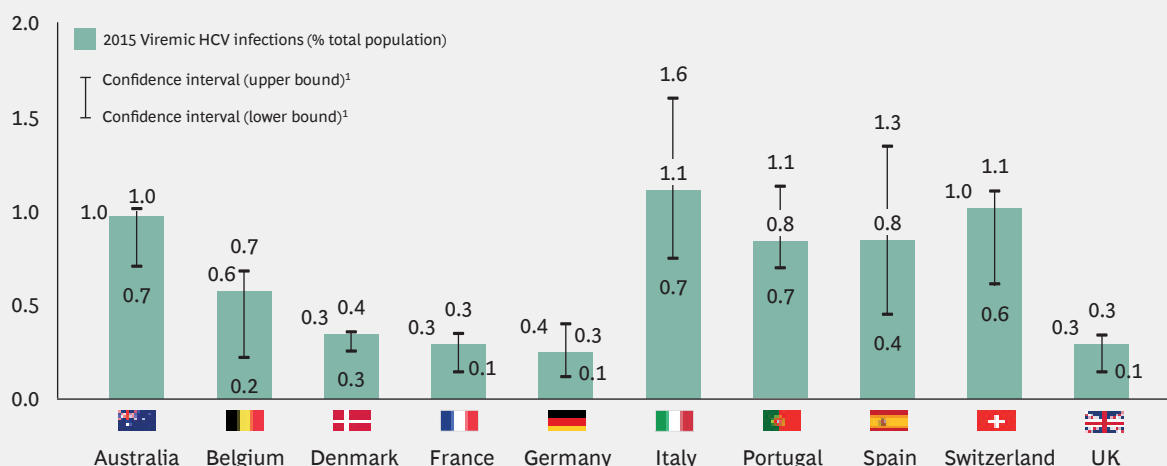
COUNTRY SELECTION AND BRIEF CHARACTERIZATION

For the country review, Australia has been used as a global benchmark because it is widely considered a model country in terms of its hepatitis strategy. We have also included the five European countries with the largest populations: England[1], France, Germany, Italy, and Spain. Scotland[1] was added as an example of a country that has had a plan in place for many years, and Belgium, Denmark, Portugal, and Switzerland serve as samples of mid-sized European countries with varying diagnosis and treatment rates.

Estimated HCV prevalence varies among the countries reviewed (See Figure 3.) Higher prevalence levels can be observed in Mediterranean countries (Italy and Spain), as well as in Portugal, Switzerland, and Australia. Despite the decrease in the estimated prevalence in recent years across all countries, the differences between countries show that there is still room for improvement. It is worth mentioning that the absence of reliable data on prevalence for most, if not all, of the countries was a recurring issue during our research. For example, recent estimates in Switzerland suggest a lower prevalence of around 0.7% (Zahnd, Brezzi, Bertisch, Giudici, & Keiser, 2017).

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1. England and Scotland data are shown as UK, according to individual data availability. Data on prevalence and diagnosis rates from Scotland are higher than the average for the UK - (Hutchinson et al., 2015)

Figure 3 | Estimated HCV prevalence in selected countries (% of total population) in 2015

Legend:
- 2015 Viremic HCV infections (% total population)
- Confidence interval (upper bound)[1]
- Confidence interval (lower bound)[1]

Country	Value	Upper	Lower
Australia	1.0	1.0	0.7
Belgium	0.6	0.7	0.2
Denmark	0.3	0.4	0.3
France	0.3	0.3	0.1
Germany	0.4	0.3	0.1
Italy	1.1	1.6	0.7
Portugal	0.8	1.1	0.7
Spain	0.8	1.3	0.4
Switzerland	1.0	1.1	0.6
UK	0.3	0.3	0.1

1. 95% Uncertainty Interval
Source: Razavi and al. (2017); The Polaris Observatory HCV Collaborators (2016)[2]

HCV NATIONAL PLANS

Most of the countries reviewed (7 of 11) have established national plans or strategies to improve HCV care. In countries without a specific plan (Denmark, England, Portugal, and Switzerland), some initiatives were identified. Denmark and England had plans, but they were outdated (2007 and 2004, respectively) and not comprehensive, given advances in care standards. In the case of Portugal, a decision to create a plan has been announced and is currently under development. In Switzerland, an independent organization (Swiss Experts in Viral Hepatitis) is collaborating with recognized experts, NGOs, and private companies, in the development of the Swiss Hepatitis Strategy (as of the time of this research, this plan is not supported by the government).
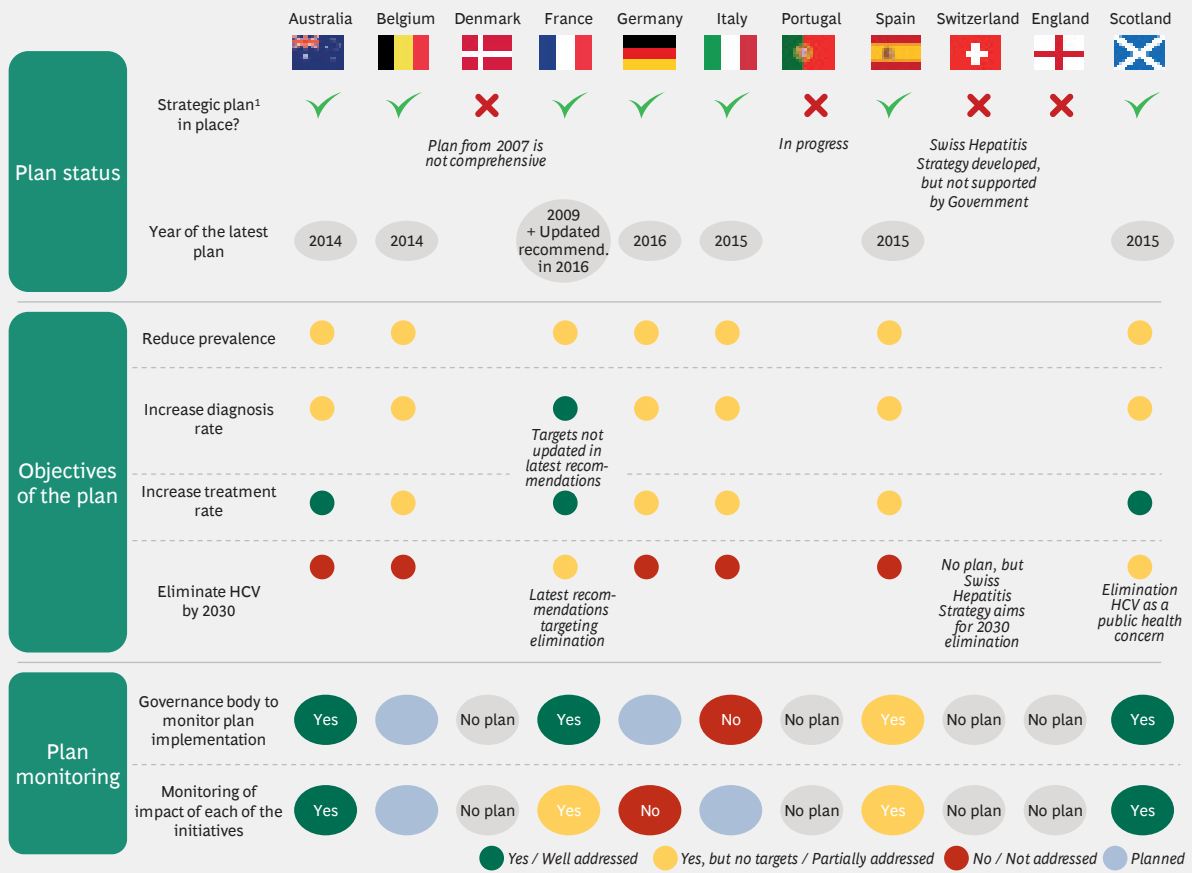
Some countries include HCV initiatives within a broader disease plan or strategy. Only Australia, Belgium, and Spain have HCV-specific plans in place. Other countries have included HCV along with HBV (for example France and Italy) and/or other blood-borne viruses (for example, Scotland's most recent plan) and/or STI's (Germany).

Although most countries are aware of WHO targets, few plans have specific targets for the reduction of prevalence levels or the increase of diagnosis and treatment rates. In addition, current plans in the countries in question do not contain explicit commitments to eliminate HCV by 2030 since most of the plans were elaborated prior to WHO's Action Plan. Elimination commitments have recently been announced by some governments (France). Scotland's plan includes a goal to eliminate HCV, however, no specific deadline has been set.

Developing monitoring and evaluation tools is critical to ensuring successful implementation of the initiatives in the plan. However, while some countries have established well-defined governance models and monitoring plans (Australia, Scotland, and France), not all have done so. It is essential for actions to be well-defined and include clear accountabilities, timelines, budgets, and key performance indicators.

2. Data from Razavi and al. (2017) except for Australia and Switzerland (The Polaris Observatory HCV Collaborators (2016))

Figure 4 | Description of the availability of HCV elimination plans, objectives, and implementation in the selected countries

		Australia	Belgium	Denmark	France	Germany	Italy	Portugal	Spain	Switzerland	England	Scotland
Plan status	Strategic plan[1] in place?	✓	✓	✗	✓	✓	✓	✗	✓	✗	✗	✓
			Plan from 2007 is not comprehensive					*In progress*		*Swiss Hepatitis Strategy developed, but not supported by Government*		
	Year of the latest plan	2014	2014		2009 + Updated recommend. in 2016	2016	2015		2015			2015
Objectives of the plan	Reduce prevalence	🟡	🟡		🟡	🟡	🟡		🟡			🟡
	Increase diagnosis rate	🟡	🟡		🟢	🟡	🟡		🟡			🟡
					Targets not updated in latest recommendations							
	Increase treatment rate	🟢	🟡		🟢	🟡	🟡		🟡			🟢
	Eliminate HCV by 2030	🔴	🔴		🟡	🔴	🔴		🔴	*No plan, but Swiss Hepatitis Strategy aims for 2030 elimination*		🟡
					Latest recommendations targeting elimination							*Elimination HCV as a public health concern*
Plan monitoring	Governance body to monitor plan implementation	Yes	Planned	No plan	Yes	Planned	No	No plan	Yes	No plan	No plan	Yes
	Monitoring of impact of each of the initiatives	Yes	Planned	No plan	Yes	No	Planned	No plan	Yes	No plan	No plan	Yes

🟢 Yes / Well addressed   🟡 Yes, but no targets / Partially addressed   🔴 No / Not addressed   🔵 Planned

1. Strategic plan refers to government supported strategies to tackle HCV

METHODOLOGY

This report consists of a cross-country comparison to identify the key success factors and main barriers across the HCV health care cascade. While the report is structured in accordance with the different steps of the HCV health care cascade, it should be noted that the steps cannot be addressed in isolation because they are interdependent. In order to eliminate HCV, a comprehensive strategy addressing all steps of the health care cascade is required (for example, poor access to treatment may prevent physicians from screening patients who do not have serious symptoms -- but offering good access to treatment without a good screening plan will not result in the elimination of HCV).

For the purposes of this report, the health care treatment cascade is as follows:

(1) **Awareness and prevention:** this includes awareness among the general population, high prevalence groups and care providers, and development of primary prevention.

(2) **Testing and diagnosis:** this includes screening and targeted interventions to increase the number of patients diagnosed and aware of their condition.

(3) **Linkage to care and access to qualified health services:** this includes referral of patients to receive adequate care, considering different settings where patients may get diagnosed (e.g. primary care services, addiction clinics, prisons), and access to qualified health care professionals.

(4) **Access to medication:** this includes access to state-of-the-art care, primarily direct-acting antivirals (DAAs).

(5) **Evaluation and monitoring:** this includes availability of well-developed databases or registries which are critical to track patients through the health care cascade process and to measure the impact of different initiatives and treatment options.
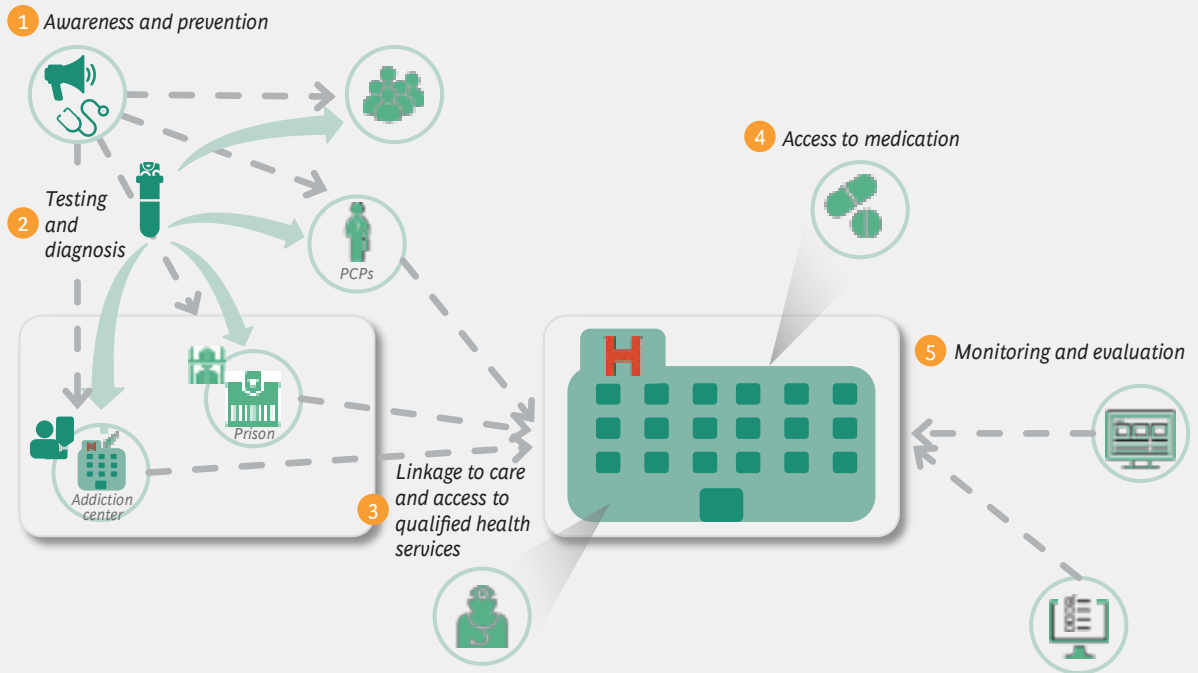
Figure 5 | HCV continuum of care

1 Awareness and prevention

2 Testing and diagnosis

PCPs

Prison

Addiction center

3 Linkage to care and access to qualified health services

H

4 Access to medication

5 Monitoring and evaluation

Figure 6 | Review framework and main drivers across the HCV healthcare cascade

Awareness and prevention	Testing and diagnosis	Linkage to care and access to qualified health services		Access to medication	Monitoring and evaluation
Burden of the disease in the country	HCV diagnosis rates	Integration of primary and specialist care	PCP role as a gatekeeper	Coverage of HCV treatment and dedicated funding	Existence of HCV patient registry
General population awareness	Screening programs in place	Integration of prison facilities and health care system	Range of doctors able to prescribe DAAs	Funding agreements	Reporting of new cases
Awareness of risk groups		Integration of addiction centers and health care system	Access to care for diagnosed patients	Access to DAAs	Evaluation of outcomes
Primary care physicians' awareness		Inclusion of HCV diagnosis within EHR			
Prevention campaigns					

For each of the countries reviewed, a country profile was developed using input from the available literature followed by validation interviews. Common sources of information were national plans, media, scientific papers, and previous reports on hepatitis C. When country examples are mentioned in the report they reflect the overall perception in the country, but may not apply to all regions within the country in question.

Over 50 experts from the different countries, including clinicians, academics, regulators, payers, scientists, and patient association representatives, were interviewed or provided information to complete and validate each country profile. Interviews usually lasted one hour, and the questions covered varied according to the information required to complete the review of the country and the expertise of the interviewee. Opinions expressed may not always reflect opinion of the organizations to which the experts belong. All interviewees and experts agreed to participate on a pro-bono basis. While some wish to remain anonymous, we have taken the opportunity to acknowledge some in this report (see Appendix).

The main barriers and best practices identified were validated with experts from the different countries through an online survey in which they were asked to select barriers and best practices that are present in their countries from a long list identified through desk research and expert interviews, and a webinar during which preliminary results from the analysis were presented and discussed.

The Expert Review Panel, consisting of Charles Gore, Jeffrey Lazarus, and Ricardo Baptista Leite, was formed to discuss the main findings and help define the report's key messages.

AWARENESS AND PREVENTION

In order to ensure that HCV is eliminated, it is not sufficient to focus only on diagnosing and treating current HCV patients. Prevention of transmission and reinfection, through awareness and primary prevention initiatives, must also be addressed.

Regarding health service infection-control measures, all the countries reviewed met the 2020 WHO target for screening 100% of blood donations. Moreover, standard precautions and other infection control practices are consistently employed by health care providers and do not pose a risk for the spread of HCV.

Making the general population, high prevalence groups, and health care personnel aware of the disease and its risks is important not only to ensure that high risk populations are tested and infected individuals get diagnosed and treated, but also to prevent transmission. As a 2018 milestone, WHO/Europe proposed that all Member

Figure 7 | Main barriers and success factors to increase HCV awareness and prevention

Flags are examples of representative countries

Main barriers

- ✗ Lack of good prevalence data by groups
  - Including no definition of risk groups by age cohorts which could make targeting of awareness and screening campaigns easier
- ✗ Lack of government support to develop awareness campaigns
- ✗ Awareness campaigns not delivered in communities' usual settings
- ✗ Awareness levels of general population, high prevalence groups and PCPs not measured
- ✗ HCV not regarded as a priority for education programs for physicians
- ✗ Low PCPs awareness about current treatment effectiveness
- ✗ Lack of harm reduction policies adapted to prisons
- ✗ Drug and alcohol consumption restrictions to access treatment set by doctors might lead to higher transmission and reinfection rates, hindering prevention efforts

Key Success Factors

- ✓ "Network-based approach" to increase awareness and reach out through educating and training peers of those at risk
- ✓ Awareness campaigns targeting common settings of high prevalence groups (e.g. included within harm-reduction programs)
- ✓ Strong government support of campaigns targeting high prevalence groups' awareness
- ✓ Strong third-sector support of campaigns targeting high prevalence groups' awareness
- ✓ HCV trainings provided to support professionals in contact with HCV patients
- ✓ Promotion of campaigns with prevention as a priority message
- ✓ Strong harm-reduction programs

States mark World Hepatitis Day (adopted during the 63rd World Health Assembly in 2010). In 2020, the goal is for most Member States to adopt a national viral hepatitis communication and awareness strategy.

Countries with high diagnosis rates, such as Australia and France, enjoy reasonable awareness levels among the general population and high awareness levels both among high prevalence groups and primary care physicians.

Even though the awareness levels are not measured in the countries reviewed, the level of consciousness in the general population is assumed to be quite low in most. Raising awareness is regarded as one of the best ways to identify and diagnose the large pools of "hidden" patients who need to be engaged and treated in order to eliminate HCV. The absence of clear symptoms, the time taken for the disease to progress, the strong associated stigma, and the disease's transmission routes are among the main drivers of this lack of awareness. Strong support for awareness campaigns from governments or from the third sector (voluntary sector, non-governmental organizations, non-profit organizations) is needed.

France implemented TV and radio awareness campaigns with prevention as a priority message for the general population. Other countries also implemented campaigns that reached a broader population but conveyed more targeted messages. For example, Australia focused on a "network-based approach" for people who inject drugs (PWID). This consists on giving appropriate training and support to people with or at risk of HCV, so that they communicate prevention messages to their peers, who view them as a credible, trusted sources of information.

In general, countries have focused their campaigns on high prevalence groups whose members are more knowledgeable about HCV than the general population. Initiatives targeting high prevalence groups are highly diverse and widely used. Most of the countries implemented well-developed harm-reduction programs for PWID which in some cases, such as France and Australia, combine awareness and prevention measures (for example needle and syringe exchange programs). In some cases, these programs still do not reach all the population at risk (for example, people in prisons/ correctional facilities).

One of the key barriers to targeting certain high prevalence groups in many European countries is the lack of good epidemiological data that would help to better tailor strategies. For example, it is not possible to clearly define high prevalence groups by age cohort, as is the case, for instance, in the US, where baby boomers are clearly defined. If it were possible, this would allow for easier identification and targeting of certain segments, particularly ex-PWID and blood transfusion recipients, that could inform systematic screening of blood samples.

Finally, primary care physicians (PCPs) are considered one of the cornerstones to increasing awareness among the general population and to identifying, diagnosing, and referring patients to specialists for treatment. PCP awareness of transmission routes, high prevalence groups, and available treatment options is essential to ensure effective HCV screening and linkage to care. This is especially relevant for countries in which screening programs are not well developed, as it might be completely up to the judgment of PCPs to identify and test patients. Being familiar with new treatment options has also been seen to improve the rate of referrals to specialists.

The level of awareness among PCPs varies across countries (and, in some cases, across regions within countries). Despite the critical role of PCPs in HCV diagnosis, developing HCV education programs for PCPs is still not considered a priority in many countries. Moreover, in many countries there are no HCV education programs for PCPs, and therefore physicians are not always aware of the new treatments with better efficacy and tolerability profile compared with previous treatment options. Australia, France, and Scotland are exceptions. In France, HCV is included as a priority topic in educational programs for health professionals, and Australia and Scotland provide HCV training courses to support professionals who are in contact with patients at risk of HCV. Public Health England with the Royal College of General Practitioners commissioned an online learning course on viral hepatitis (B and C) specifically for PCPs.

Figure 8 | Identified best practices on awareness and prevention
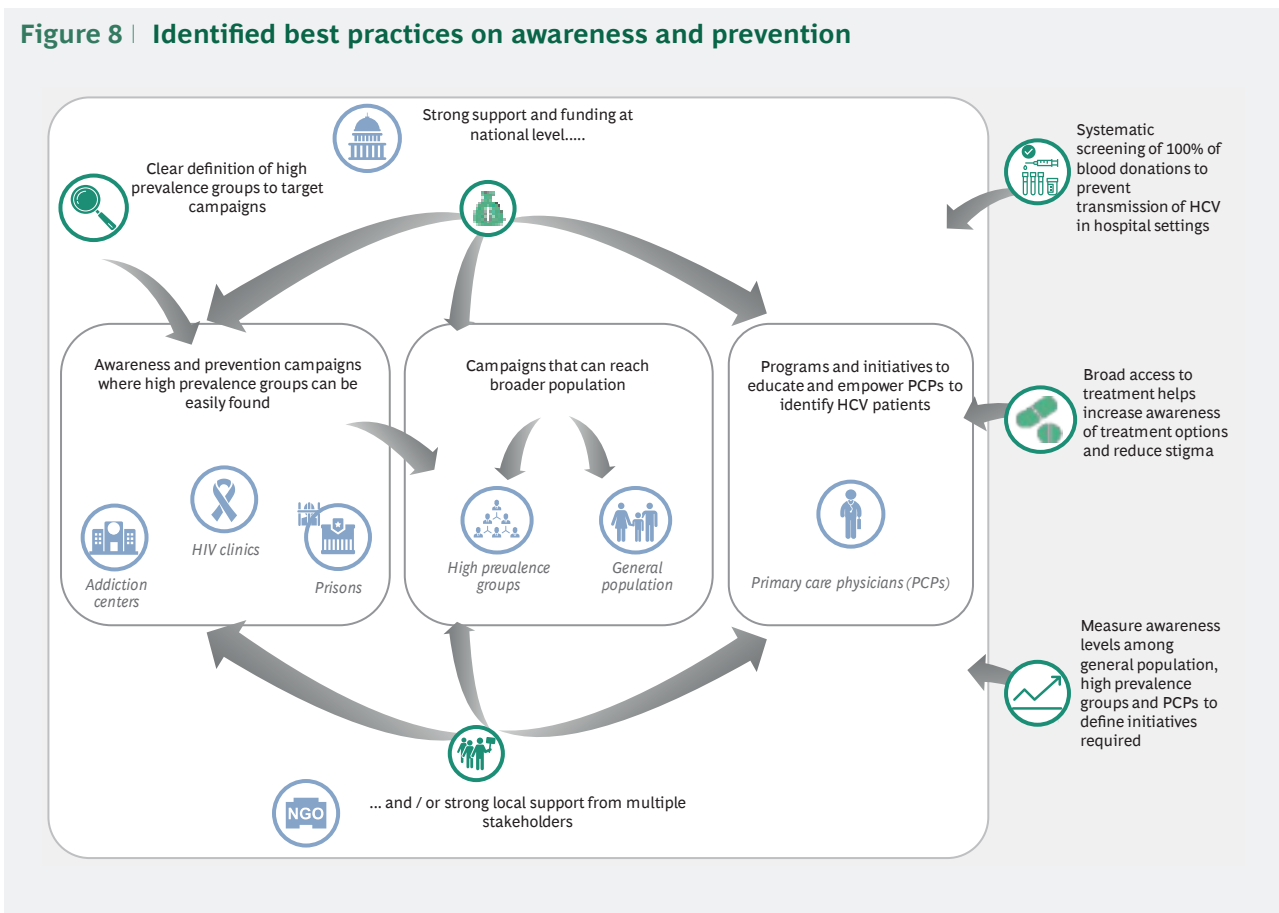
CASE STUDY FOR AWARENESS | FRANCE

Three things have been key to achieving strong awareness levels in France among high prevalence groups and PCPs, and good awareness among general population:

1. Strong government and civil society support for awareness and prevention initiatives

In its latest National Plan (2009-2012) as well as in the latest recommendations made (December 2016), the government outlined several strategies to raise awareness in the general population, such as increasing the visibility of HCV on the internet or the "Hépatites info service" telephone line. Projects that contribute to increasing HCV education and awareness are funded by the government (many through funding to scientific associations), and PR strategies leverage collaborations with key opinion leaders and journalists. There is also a collaboration of the government with pharmaceutical companies to develop and launch awareness campaigns at a national and local level.

2. Awareness and prevention campaigns targeting common settings of high prevalence groups

In order to achieve the high awareness levels observed within risk groups in France, the authorities have integrated HCV care within systems and networks commonly used by high prevalence populations. For example, the existence of strong harm-reduction programs for PWID (key high prevalence group in France) contributes to increasing the impact of initiatives integrated with them, such as sharing information about the disease, and its risks and symptoms, or screening opportunities that directly target PWID when they attend to Opioid Substitution (OPS) or Needle and Syringe Programs (NSP). Other awareness campaigns have also targeted different common settings of high prevalence group populations, such as tattoo and piercing studies, clubs, social services centers, etc.

The presence of doctors (as well as screening facilities such as screening buses) close to these patients' settings (e.g. doctors going into prisons) further contributes to increasing awareness and engagement.

### 3. HCV training provided to PCPs, and other professionals in contact with HCV patients

Primary care physicians, together with other professionals such as personnel in addiction centers, are an essential part of the health cascade given their gatekeeping role. They are normally the first point of contact with the patient, and therefore the best channel to inform them. In order to increase the awareness levels of these professionals, France has included HCV as a priority topic in educational programs, focusing on the identification of risk factors. Guidelines (for screening, treatment, and risk) are updated frequently and communicated to professionals. In addition, HCV presence in Ministry of Health and related institutions internal websites is promoted.

TESTING AND DIAGNOSIS

Most individuals living with viral hepatitis are unaware they are infected because of the absence of clear symptoms. Early diagnosis of HCV infection is critical since it reduces the risk of transmission and mitigates associated health care costs (patients in later stages of the infection are more likely to develop advanced liver disease, hepatocellular carcinoma (HCC) and/or other health problems).

WHO/Europe proposed that by 2020, 50% of all people with chronic HCV and 75% of patients at a late stage of viral hepatitis-related liver disease (cirrhosis or HCC) should have been diagnosed. As a starting point, we have observed a broad range of diagnosis rates across the countries reviewed. Although diagnosis rates have remained stable or improved in the last five years in all countries analyzed, some of the European countries reviewed are still not reaching the HCV diagnosis target of 50%[3] [4], meaning further action is required to improve in this dimension. In fact, differences show that there is still room for improvement in several countries.

Figure 9 | **Estimated percentage of diagnosed HCV patients (% of total patients)**

Diagnosis rate (2015)
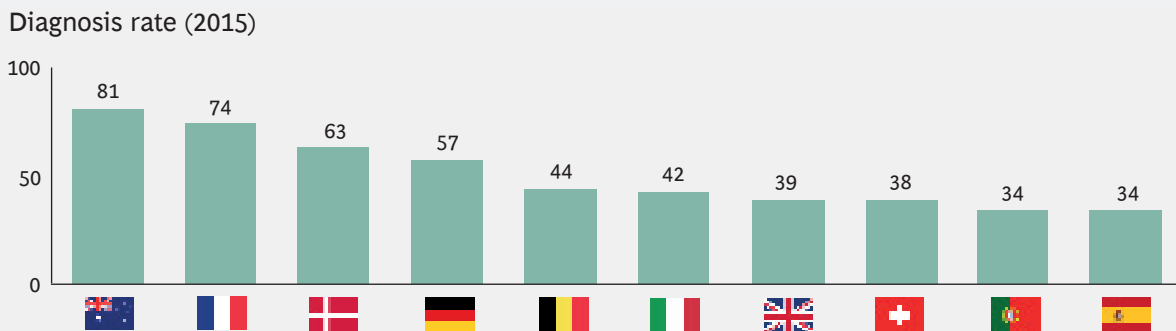
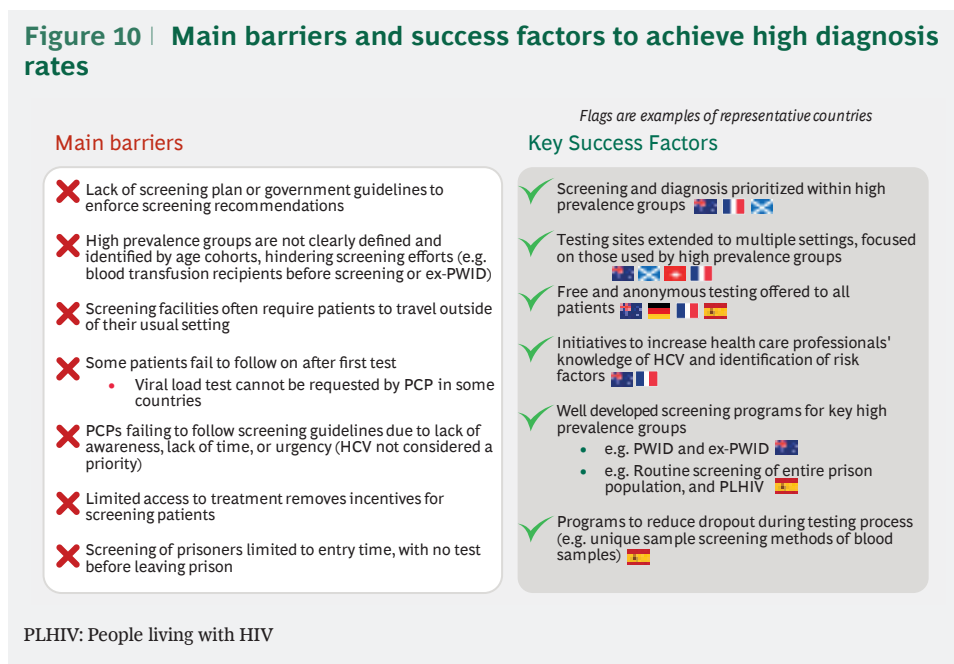Source: Razavi and al. (2017); Polaris Observatory (2017)[5]

3. England and Scotland data are shown as UK, according to individual data availability. Data on diagnosis rates from Scotland are higher than the average for the UK (55% in 2013) - (Hutchinson et al., 2015)
4. Data for Italy has varied significantly in the latest update from Polaris Observatory in April 2017, given new data available, increasing its estimates on diagnosis rates from 42% in 2015 (as reported in Razavi and al. (2017)) to 75% in 2015 and 77% in 2016
5. Data from Razavi and al. (2017) except for Australia and Switzerland (Polaris Observatory accessed in April 2017, data for 2015 – Base 2016)

Half of the countries reviewed, including countries with high diagnosis rates, such as Australia and France, have a national plan, which specifically addresses screening. According to experts, screening programs focused on high prevalence populations are more cost effective and yield good results. In fact, as of now, none of the countries analyzed has implemented a general population testing program, although it was suggested in the latest 2016 recommendations for France (Ministère des Affaires Sociales et de la Santé, 2016), and according to experts, Germany is considering including a liver assessment in the CheckUp35 program that aims to screen all people over the age of 35 annually.

Figure 10 | Main barriers and success factors to achieve high diagnosis rates

Flags are examples of representative countries

Main barriers

❌ Lack of screening plan or government guidelines to enforce screening recommendations

❌ High prevalence groups are not clearly defined and identified by age cohorts, hindering screening efforts (e.g. blood transfusion recipients before screening or ex-PWID)

❌ Screening facilities often require patients to travel outside of their usual setting

❌ Some patients fail to follow on after first test
   • Viral load test cannot be requested by PCP in some countries

❌ PCPs failing to follow screening guidelines due to lack of awareness, lack of time, or urgency (HCV not considered a priority)

❌ Limited access to treatment removes incentives for screening patients

❌ Screening of prisoners limited to entry time, with no test before leaving prison

Key Success Factors

✓ Screening and diagnosis prioritized within high prevalence groups

✓ Testing sites extended to multiple settings, focused on those used by high prevalence groups

✓ Free and anonymous testing offered to all patients

✓ Initiatives to increase health care professionals' knowledge of HCV and identification of risk factors

✓ Well developed screening programs for key high prevalence groups
   • e.g. PWID and ex-PWID
   • e.g. Routine screening of entire prison population, and PLHIV

✓ Programs to reduce dropout during testing process (e.g. unique sample screening methods of blood samples)
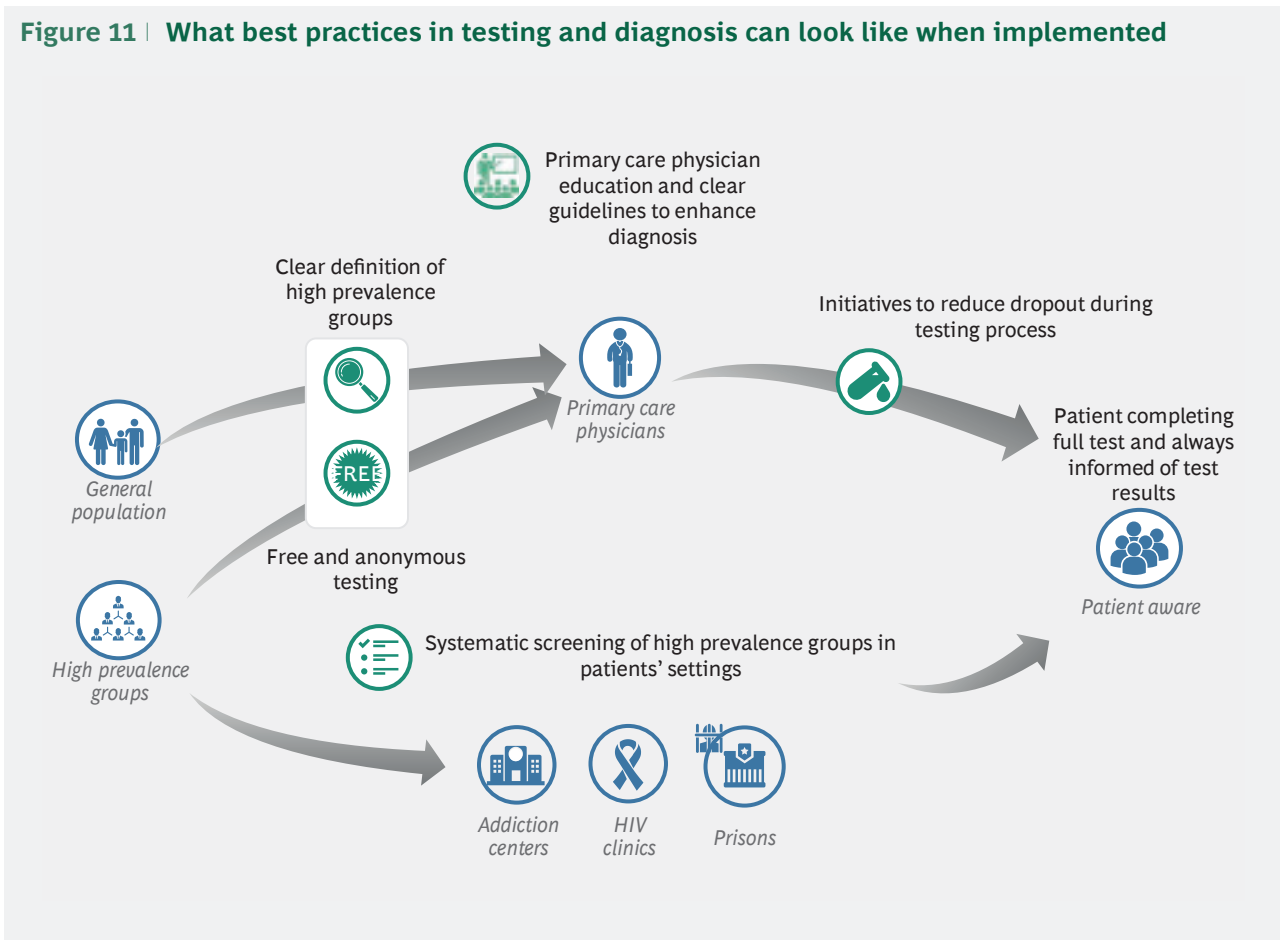
PLHIV: People living with HIV

All countries have screening guidelines and some have specific screening programs for high prevalence groups. The existence of screening programs is not necessarily a driver of high diagnosis rates, but the degree of implementation of those programs is. In some cases, high prevalence groups are poorly identified or diagnostic strategies are disliked by the target population, thereby creating strong barriers to diagnosis. One successful advanced solution is to integrate screening with harm-reduction and community initiatives (such as civil societies and NGOs) by extending testing to multiple settings where high prevalence groups can be found. Moreover, screening programs should address the high dropout rates in the testing process. As mentioned, elevated awareness levels among high prevalence groups and PCPs is also an important driver of diagnosis rates.

The role of PCPs is also considered essential for developing detection strategies by identifying high prevalence groups. In some countries, PCPs do not consider HCV to be a priority and, even if screening guidelines are in place, they do not follow them due to a lack of awareness, time or sense of urgency. In some cases, PCPs' perception is that HCV is an infection that only affects risk groups, which inhibits testing within the general population. As mentioned earlier, France and Australia initiated strategies to educate health care professionals about HCV and to better identify risk factors. There appears to be a clear need to increase education for PCPs and define clear guidelines to enhance screening.

Moreover, in some countries PCPs do not have access to confirmatory diagnoses (such as viral load) after a first-line antibody positive text. This was mentioned as a contributing factor in drop-out rates.

Experts maintain that proactive diagnosis programs are required to eliminate HCV (to find the "last mile patients") and that merely providing access to treatment is not enough to eliminate the virus. One missed opportunity that has been pointed out by some experts is the prison setting. In most countries, inmates are only screened upon admission, if they are screened at all, but not when they are released, a missed opportunity to diagnose and treat HCV.

Figure 11 | **What best practices in testing and diagnosis can look like when implemented**

Primary care physician education and clear guidelines to enhance diagnosis

Clear definition of high prevalence groups

Initiatives to reduce dropout during testing process

General population

Primary care physicians

Patient completing full test and always informed of test results

Free and anonymous testing

High prevalence groups

Patient aware

Systematic screening of high prevalence groups in patients' settings

Addiction centers

HIV clinics

Prisons

CASE STUDY FOR TESTING AND DIAGNOSIS | AUSTRALIA

One of the key areas contributing to Australia's success in fighting HCV is diagnosis. Australia has achieved world-leading diagnosis rates, with 81% of infected population diagnosed in 2015 (Polaris Observatory, 2017).

Instead of focusing efforts on the general population, Australia's screening strategy has been focused on the diagnosis of key high prevalence groups (PWID and prison population), in order to achieve high diagnosis rates in a cost-effective manner. Screening efforts are well supported by strong awareness campaigns among high prevalence groups and PCPs, as well as broad access to treatment. Free and anonymous testing is available for all patients, and government efforts contribute to increasing PCPs' ability to identify risk factors.

To screen key high prevalence groups, testing sites have been extended to multiple settings, with special focus on those frequented by high prevalence groups, such as addiction clinics, OST and harm-reduction programs, etc. Once diagnosed at those settings, patients can be directly referred to specialists (such as a PWID diagnosed in addiction center) or even treated in their usual settings (such as treatment in prison facilities).

Other high prevalence groups are also well addressed: there is systematic testing of people living with HIV (PLHIV) and good screening of the MSM population through HIV programs. Beyond specific programs for high prevalence groups in their common settings, there are recommendations for PCPs to screen annually all people with risk factors. Experts believe that the ability of primary care physicians to prescribe treatment, and broad access to care, contributes to increasing their awareness, thus driving screening rates. Furthermore, in order to improve patient engagement, HCV is included among other diseases in a plan that provides incentives for doctors who develop management care plans for patients.

LINKAGE TO CARE AND ACCESS TO QUALIFIED HEALTH SERVICES

Once a patient is diagnosed with HCV, it is indispensable to assure the continuum of care by qualified health services and access to treatment. Chronically ill patients may require care for a broad set of health problems. In addition to the possibility of developing liver cirrhosis and hepatocellular carcinoma, people living with chronic hepatitis infections may experience extrahepatic symptoms of their infection, including insulin resistance and diabetes. Other factors which increase complications, such as alcohol consumption, smoking, mental health issues, and obesity, also must be addressed. An initial assessment of alcohol intake for all people with chronic viral hepatitis infection, followed by the offer of a behavioral alcohol reduction intervention for those with moderate-to-high alcohol intake, is recommended (European Association for the Study of the Liver, 2017.)

Depending on where patients are diagnosed, access to qualified services can prove to be a challenge, and there is a risk of losing patients prior to follow-ups. Engaging HCV patients through the care pathways remains a major barrier to realizing the benefits of treatment (Christensen et al., 2012; Howes, Lattimore, Irving, & Thomson, 2016). WHO/ Europe proposes that 90% of patients diagnosed with chronic HCV infections be linked to care and adequately monitored by 2020. For this to happen, barriers to care must be reduced so patients can progress through the care pathways.

As shown in Howes et al. (2016), there are multiple reasons a patient may miss adequate access to care that are not directly due to health care systems (patient moves or is released from prison, never returns for results, leaves the practice) but that nonetheless require a proactive systemic response. Therefore, it is important not only to ensure an effective referral process, as we will discuss in this section, but also to empower patients to seek diagnostics and care through awareness initiatives focused on HCV risks and treatment options.

We have considered three main settings to review how good systems are in terms of linking to care: the general population which usually is diagnosed at primary care, patients who are diagnosed at addiction clinics or informal settings (beyond traditional health care providers), and patients who are diagnosed in prisons.

Figure 12 | Main barriers and success factors to ensure streamlined access to care

Flags are examples of representative countries

Main barriers

❌ Diagnosed patients who have not been treated because DAAs were not available, are not monitored and referred to specialists directly

❌ Patients who are diagnosed in informal settings (outside National Healthcare Service) don't get linked to care – they sometimes need to get screened again by PCP and often get lost

❌ Release of prisoners on short notice / short sentence times hampers monitoring and treatment

❌ PWID must travel to hospital facilities to access treatment

❌ Prison population needs to travel to hospital facilities outside prison to access treatment

Key Success Factors

✓ HCV treatment delivered in addiction clinics

✓ HCV treatment delivered within prison facilities

✓ Well developed and integrated programs for PWID and PLHIV, integrating HCV testing and support in clinics

✓ Good referral system in place within National Healthcare Service

✓ Direct access to specialists

✓ Wide range of doctors able to prescribe treatment, including PCPs

✓ PCPs able to provide treatment in their offices if approved by specialist

PLHIV: People living with HIV

In most of the countries reviewed, PCPs act as gatekeepers for access to specialist care. Once patients are diagnosed by PCPs, the referral process works well for HCV patients. The challenge, as mentioned, is getting PCPs to test and diagnose their patients. However, some opportunities for improvement have been identified in other countries, including improved clarity on which specialist a PCP should refer to, the introduction of electronic referral systems, better follow-up processes to check whether patients attended the specialist clinic, and better awareness among PCPs to improve low referral rates.

Experts in some countries have highlighted an additional problem regarding patients diagnosed before DAAs were available. They stress the fact that these patients are not being monitored and are not referred to specialists directly. In fact, in some countries, even if these patients are identified, they cannot be contacted directly for legal reasons. In other countries, as occurs in some of the main hospitals in Portugal, HCV status is recorded in national Electronic Health Records which allows for patients to be "recalled" by the health services.

In three countries PCPs can either prescribe treatment or provide treatment to patients in their office once it is prescribed; an identified best practice. In two of these countries (Australia and Germany[6]), a wide range of ambulatory-care doctors, including PCPs, can prescribe treatment. Authorizing PCPs to prescribe direct-acting antivirals (DAAs) is regarded as one of the key actions taken by Australia in its plan against HCV. This action offers several potential benefits:

- Reduces strain on secondary care, leaving only complex cases for the specialist
- Increases awareness levels among PCPs–if they can prescribe treatment, they will increase their knowledge of the disease and risk factors, thereby driving screening rates
- Increases patient engagement and diagnosis rates due to more convenient and people-centered care

6. In Germany, according to experts, PCPs can prescribe but usually prescriptions are done by specialists

Although allowing PCPs to prescribe can be beneficial, it was not mentioned as a priority in European countries by the experts consulted, unless the country has elevated diagnosis and treatment rates (as is the case of Australia). Otherwise, the focus should be placed on screening undiagnosed patients and ensuring that all diagnosed patients have access to treatment.

High prevalence groups face different challenges. Diagnosis typically occurs in informal settings (such as outreach harm-reduction teams), in dedicated health care facilities (addiction treatment centers, HIV clinics) or in prisons and some countries have major barriers to assuring access to qualified physicians in those cases. Integration of HCV care within harm reduction, support and community programs is regarded as a key lever to engaging patients in these high prevalence groups.
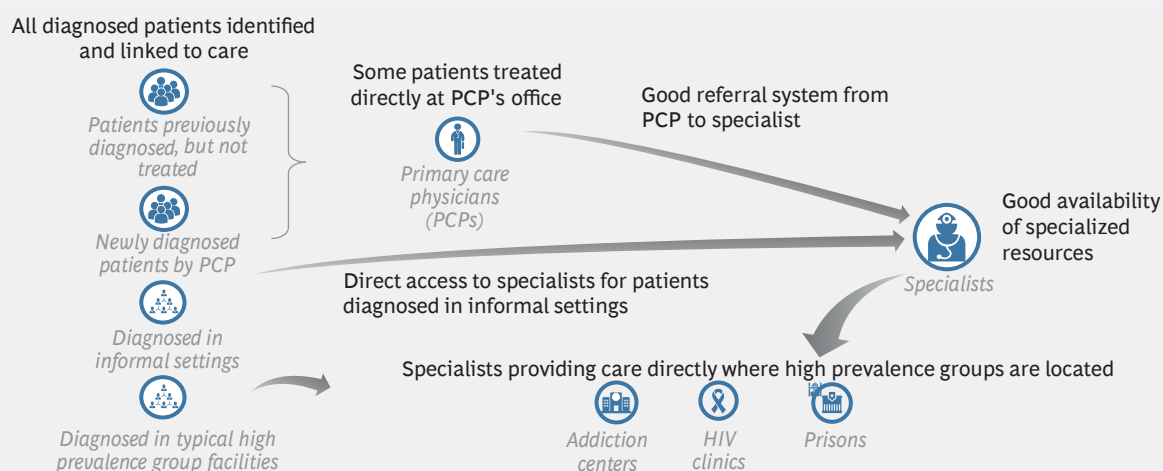
Integration of addiction centers and specialist providers varies across the countries reviewed. According to experts, integration is only adequately addressed in four of the countries analyzed, while in other countries the situation varies across centers. Patients in some countries cannot be directly referred to specialists and may require an additional diagnosis by a PCP. One of the best practices identified is the development of programs for PWID and people living with HIV (PLHIV) integrating HCV testing and support to ensure a link to specialist care in clinics (Australia, France, Switzerland, and Scotland). For example, in Australia and Switzerland, patients can directly access treatment in addiction clinics.

Coordinating prison health services and conventional health providers presents difficulties in most countries. According to experts, although some best practices exist in others, only two of the countries analyzed adequately address HCV in their prisons. Because conventional health services have limited access to prison records, prisoners with short sentences don't establish treatment continuity. Besides, in many countries treatment is not directly provided in prisons and instead, inmates need to be treated at community hospitals, thereby posing challenges due to security protocols, or transferred to prisons which do offer treatments. In other cases, uncertainty regarding funding for treatment, or prioritizing treatment for other high prevalence groups instead of prisoners, contributes to the problem commonly faced by HCV patients in penitentiary facilities. Good practices in care coordination were found in France, Italy[7], and Scotland, where prisoners are being treated directly within prison facilities. This best practice can also be found in some regions (such as Australia) or in specific prisons in other countries.

The availability of specialists to deliver HCV treatments was not considered a problem in any of the countries analyzed. Nonetheless, availability of resources should be reassessed if additional measures for screening or linkage to care are implemented, or if access to treatment is broadened, since this would result in an increase in the number of patients requiring specialist care.

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7. Patients can be treated in prison, but examinations to establish their status must be done in the corresponding hospital

Figure 13 | How best practices in linkage to care and access to qualified health services can look in practice

All diagnosed patients identified and linked to care

Patients previously diagnosed, but not treated

Newly diagnosed patients by PCP

Diagnosed in informal settings

Diagnosed in typical high prevalence group facilities

Some patients treated directly at PCP's office

Primary care physicians (PCPs)

Good referral system from PCP to specialist

Direct access to specialists for patients diagnosed in informal settings

Good availability of specialized resources

Specialists

Specialists providing care directly where high prevalence groups are located

Addiction centers *HIV clinics* *Prisons*

CASE STUDY FOR LINKAGE TO CARE | SCOTLAND

Scotland's comprehensive and integrated approach to care for HCV has been one of the key areas of its strategy. Through the Managed Care Networks, all the stakeholders involved in HCV care (NHS, Health Boards, addiction centers, penitentiary system, third sector, patient associations, etc.) are actively involved and aligned.

Managed Care Networks were launched in 1999 and are defined as "a linked group of health professionals and organizations from primary, secondary, and tertiary care, working in a coordinated way that is not constrained by existing organizational or professional boundaries to ensure equitable provision of high quality, clinically effective care" and have largely contributed to developing services that are person-centred, delivered locally where possible, but specialized where need be. Their aim is to ensure service improvement and planning (mapping services across Scotland, designing models of care), provide education to build capacity and capability in specialist care (for both professionals and caregivers), collect and report data to measure and improve quality of care, and communicate and engage with stakeholders (shaping services that meet patient and caregiver needs).

Within the NHS, referral system from PCPs to specialists is well developed, and diagnosed patients are efficiently sent to the corresponding specialists for treatment. Additionally, patients can be diagnosed in addiction centers and directly referred to specialists. Finally, inmates are diagnosed in the prison and can access treatment within the facilities.

Further efforts are under development to bring care closer to patients. For instance, there is an ongoing trial in OST patients where treatment is provided entirely by pharmacists, who diagnose, prescribe, dispense, monitor, and run tests to confirm virological outcomes themselves.

The existence of a HCV patients' registry containing information on all diagnosed patients is leveraged to track patients, ensuring that they are treated and that their progress is monitored.

CASE STUDY FOR ACCESS TO QUALIFIED HEALTH SERVICES |
GERMANY AND AUSTRALIA

Both Australia and Germany provide good access to qualified health services. In both countries, there is a wide range of doctors able to prescribe DAAs, including PCPs. In Australia, although specialists are still responsible for around 65% of the prescriptions made, PCPs are increasingly more relevant. The share of prescriptions made by PCP has increased from 4% in March 2016 (when DAAs were introduced) to 19% in September 2016 (The Kirby Institute, 2017). In Germany, not many PCPs currently prescribe, but direct appointments with specialists are available, also facilitating access to patients.

Current availability of specialized resources and system capacity is in line with demand in both countries, which is reflected in short waiting lists for specialist appointments.

ACCESS TO MEDICATION

Effective antiviral agents have the potential to dramatically reduce morbidity and mortality for those with hepatitis C. DAAs have cure rates exceeding 95%, with pan-genotypic regimens becoming available (WHO, 2016c). By 2020, WHO/Europe has set a target for 75% of the diagnosed eligible patients with chronic HCV infections to receive effective treatment and for at least 90% of them to be cured.

Strong government commitment to new treatments is necessary to ensure universal coverage. According to the European Liver Patients Association (2017), national plans must be developed and include forecasted budgeting to expedite unrestricted access to treatment, in order to succeed in eliminating HCV.

Only a few of the countries reviewed have granted universal coverage for DAAs. Australia, Portugal, Germany, and, since 2017, France and Italy, offer access to DAAs for all patients, regardless of their level of fibrosis. Scotland and England do not have fibrosis requirements, but have limits on numbers of patients who can be treated each year, so usually only patients with higher fibrosis levels receive treatment. Other countries such as Spain, Belgium, and Switzerland only provide treatment for patients with a certain fibrosis level by prioritizing severe cases. Some of these countries are already considering broadening access to additional fibrosis levels. For instance, in Spain access has been broadened to all fibrosis levels in some regions and commitment to broaden it at national level has been recently announced; and in Belgium access was extended to F2 patients in January 2017, and full access is expected by 2019.

Treatment rate is defined as the number of patients treated over total viremic infections (treated patients in 2015 and 2016 over viremic patients in 2014 in Figure 14)[8]. This figure also varies across countries. It is important to note treatment data together with diagnosis rates (see Figure 14) since some countries (like Spain) are performing very well in terms of treatment despite having low diagnosis rates.

Patients may not be accessing treatment either because they do not get linked to care or because they do not get access to treatment despite having been referred to a specialist.

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8. In the case of Scotland, treatment rate for 2015+2016 is estimated at ~8%. The estimate takes into account that prevalence was ~37,000 in 2014 (Hepatitis C in the UK, 2015 report), 1,263 patients were treated Jan-Sept 2016 (Health Boards, 2016) and 1,273 patients were treated in 2014 (Hepatitis C in the UK, 2015 report) and assumes a similar number of treated patients in 2015 and 2014 and a pro forma estimate for 2016

Figure 14 | Treatment and diagnosis rates per country, 2015 and 2016

Estimated % treated HCV patients 2015 + 2016

Estimated % diagnosed HCV patients 2015

Estimated HCV prevalence 2015 (% of total population)
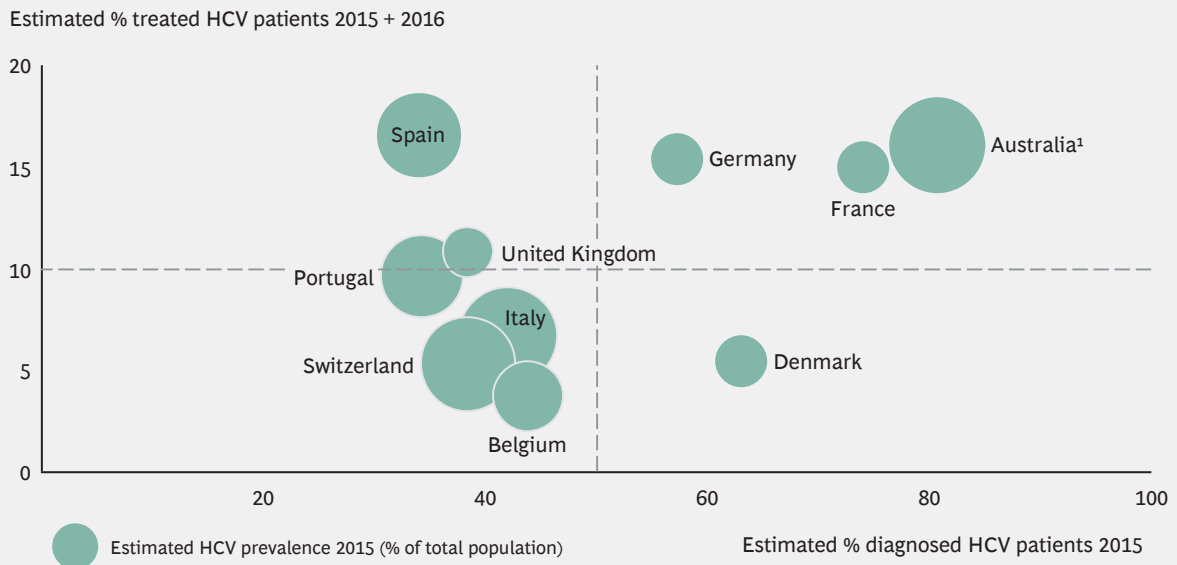
1. Note that number of patients treated increased significantly in Australia from ~7k in 2015 to ~30k in 2016. DAAs were approved early 2016
Source: Polaris Observatory (2017) Razavi and al. (2017); The Polaris Observatory HCV Collaborators (2016)[9]

Figure 15 | Main barriers and success factors to ensure access to medication

Flags are examples of representative countries

Main barriers

❌ Gap between dedicated funding and treatment costs

❌ Prisoners not always getting access to treatment
  – Funding constraints
  – Not prescribed due to lack of universal treatment within prisons (challenges faced bringing patients to all specialist visits)

❌ Drug and alcohol consumption restrictions by doctors prevent patients from accessing treatment

❌ Incentives for financial savings might prevent doctors from prescribing DAAs

Key Success Factors

✔ Although not broad access, DAA coverage for some key risk group patients regardless of their fibrosis level

✔ No drug or alcohol consumption restrictions to access treatment

✔ DAA coverage for all patients regardless of their level of fibrosis

✔ Full treatment coverage by national health care system, with no co-payment requirements

✔ Risk-sharing (e.g. funding caps) and price-volume agreements lead to significant discounts in treatment costs

✔ Availability and management of funding for DAAs at national level

9. Prevalence 2015 (%) data from Razavi and al. (2017) except for Australia and Switzerland (The Polaris Observatory HCV Collaborators (2016). Diagnosis 2015 (%) data from Razavi and al. (2017) except for Australia and Switzerland (Polaris Observatory (2017) accessed in April 2017). % treated patients estimated as treated patients in 2015 and 2016 over prevalence in 2014, using data from Polaris Observatory (2017) accessed in April 2017, data from 2015 and 2016 (Base 2016)

Among countries with high treatment rates, we have found that risk-sharing agreements (based on undetectable viral load, SVR, cure) and price-volume agreements, in combination with broad access to medication, have led to significant discounts in individual treatment costs, thereby allowing them to treat a larger number of patients with the same budget. Some of the agreements which have been mentioned in the press (not pharma press statements) include:

- Australia has committed to providing AUD 1 billion in funding between March 2016 and February 2021, and an agreement has been reached in which manufacturers will continue to supply drugs at no additional cost after a cap of about 13,000 patients per year (Alexander, 2016).
- Portugal has reached an agreement which includes performance-based payments on SVR (treatment is only paid for patients who are cured), price per cure (fixed payment, independent of the duration of the treatment) and a price-volume component (Carriço, 2015, 2017).
- Spain's health system has reached an agreement which includes price per cure and a volume-discount component ("Hepatitis C: Condiciones de financiación de los nuevos fármacos," 2016).

Although there are no formal lifestyle conditions which exclude patients from treatment, in some countries, not consuming drugs or alcohol is an informal requirement imposed by doctors which prevents some patients from accessing treatment. That being said, these measures have a greater impact on more vulnerable populations.

In Germany, it was also stated that incentives for financial savings might prevent doctors from prescribing DAAs in some cases out of fears of receiving fines.
Finally, availability and management of funding for DAAs at national level has been a best practice in countries including Portugal, Australia, Belgium, and France to ensure equitable access to treatment across regions.

Figure 16 | **How best practices in access to medication can look when implemented**
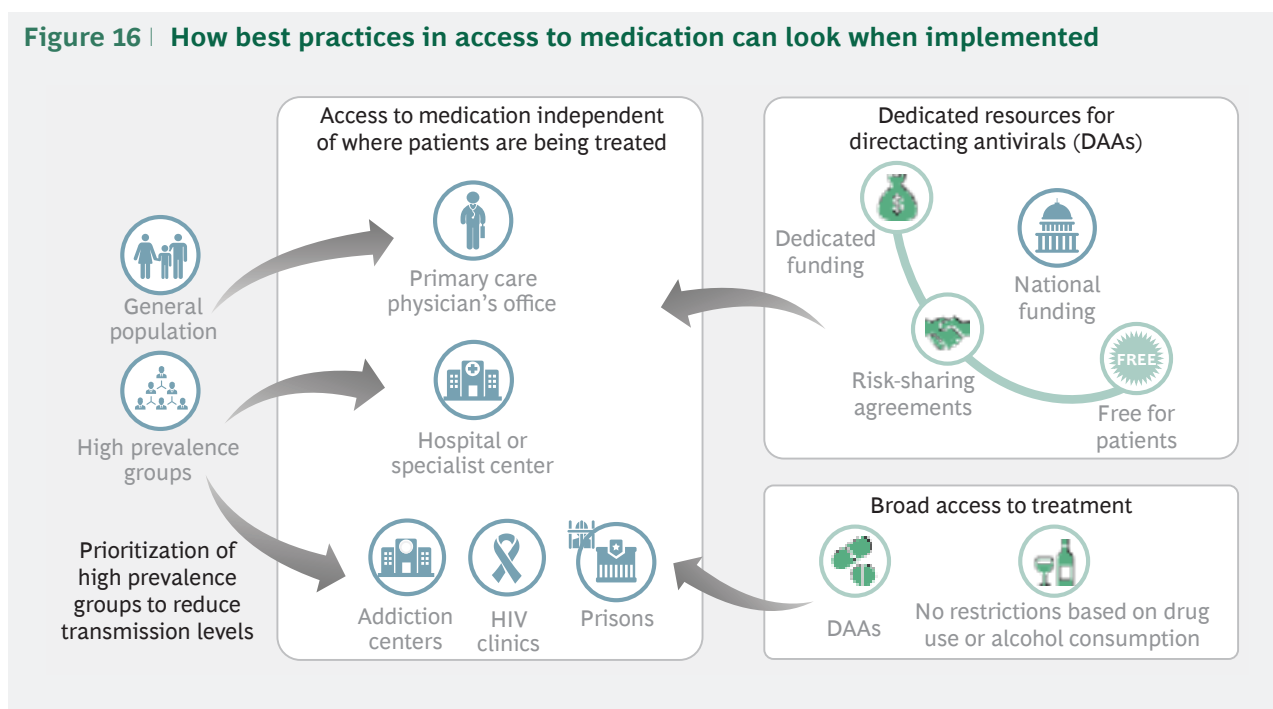
CASE STUDY FOR ACCESS TO MEDICATION ╎ PORTUGAL

Portugal is regarded as a role model in providing HCV treatment to diagnosed patients. Full access to DAAs has been granted for all HCV patients diagnosed, regardless of their level of fibrosis, since February 2015, following the introduction of DAAs in 2014.

There are no lifestyle requirements to access treatments. Only in cases of very short expected lifetime or consistent drug abuse behavior can the doctors decide to deny treatment access. Treatment costs are covered by the National Healthcare System, with no co-payment required.

Performance-based and price-volume agreements have reduced treatment costs and grant access to all patients. According to experts, although specific details of the agreement are confidential, Ministry of Health only pays for cured patients (pay per performance based on SVR measurement), there is fixed treatment cost independent of duration of the treatment, and there is a price-volume agreement. According to experts, this agreement combined with appropriate level of funding for DAAs has allowed treatment of all patients who request it. Furthermore, the fact that funding is provided at a national level has enabled access across the different regions.

Finally, good data on treated patients is available, as it is mandatory to include patients in the registry to get access to DAAs.

MONITORING AND EVALUATION

Monitoring implementation of comprehensive HCV activities and evaluating the impact is critically important. Efficient monitoring and evaluation systems are required to establish accountability mechanisms among stakeholders. Systems rely on having high-quality information, and this can only be achieved by having a systematic process to ensure that data is collected consistently both within and across different stakeholders.

Figure 17 ⏐ **Main barriers and success factors to achieve effective monitoring and evaluation**

Flags are examples of representative countries

Main barriers

✖ HCV-associated stigma and privacy protection legislation interfere with the creation of registries and follow-up after treatment (e.g. reinfection)

✖ Lack of clear legal framework on data collection at Europe level

✖ Data recorded on reported diagnoses is not leveraged to track patients or create a registry

✖ No mandatory reporting of diagnosed patients or, when there is, diagnosed patients not systematically reported due to time requirements and / or lack of reward

Key Success Factors

✓ Mandatory reporting of all HCV diagnosed patients

✓ HCV registry tracking all patients to monitor progress
  − Database with all diagnosed patients
  − Registry with all patients eligible for DAA treatment

✓ Treatment effectiveness measured from outcomes in the registry

One of the key elements in an adequate monitoring and evaluation information system is a comprehensive HCV patient database. According to experts, on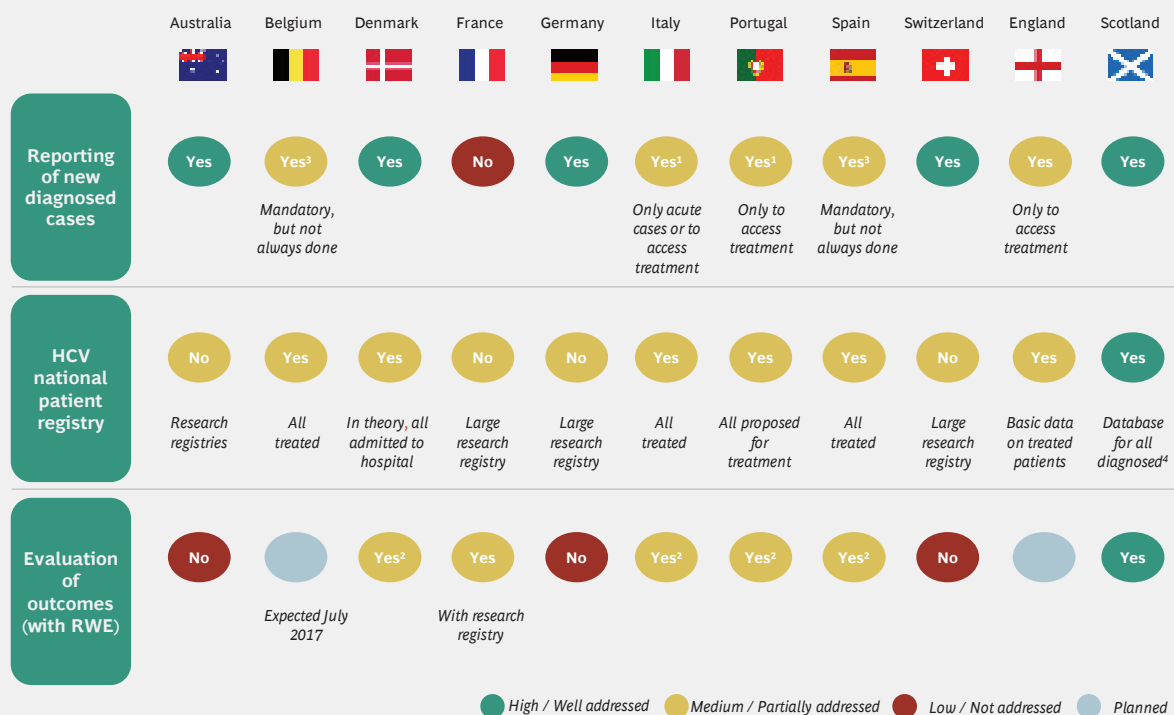ly one out of the 11 countries reviewed has a well-developed database which includes all diagnosed patients. Five countries have registries designed to include all treated patients, and one country has a registry which is designed to include all patients admitted to the hospital. All the other countries have cohort registries which vary in their volume and scope, but no national registry. Despite the fact that reporting diagnosed patients is mandatory in many countries, excessive paperwork and limited incentives are factors which limit physician adherence to registries.

Even when outcomes are tracked in registries, only SVR is usually reported. Further outcomes, such as reinfection rates or post SVR follow-up, are typically not tracked. The lack of a clear legal framework on data collection at the Europe level was mentioned by experts as a challenge to implement well-functioning registries for HCV patients.
The availability of registries is considered relevant since they can be used not only to track patients, but also to monitor and evaluate implementation of plans. Another opportunity for well-developed registries which is not fully leveraged by any of the countries analyzed consists of assessing the value (in terms of outcomes to cost) of different treatment options in order to inform decision-making and define policy.
Moreover, outcomes measurement and value procurement is only possible with a robust patient registry that allows health authorities to participate in risk-sharing contracts where only responders would incur a treatment cost.

Figure 18 | Cross-country review on monitoring and evaluation developments

	Australia	Belgium	Denmark	France	Germany	Italy	Portugal	Spain	Switzerland	England	Scotland
Reporting of new diagnosed cases	Yes	Yes[3]	Yes	No	Yes	Yes[1]	Yes[1]	Yes[3]	Yes	Yes	Yes
		Mandatory, but not always done				*Only acute cases or to access treatment*	*Only to access treatment*	*Mandatory, but not always done*		*Only to access treatment*	
HCV national patient registry	No	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes
	Research registries	*All treated*	*In theory, all admitted to hospital*	*Large research registry*	*Large research registry*	*All treated*	*All proposed for treatment*	*All treated*	*Large research registry*	*Basic data on treated patients*	*Database for all diagnosed[4]*
Evaluation of outcomes (with RWE)	No	Planned	Yes[2]	Yes	No	Yes[2]	Yes[2]	Yes[2]	No	Planned	Yes
		Expected July 2017		*With research registry*							

● High / Well addressed ● Medium / Partially addressed ● Low / Not addressed ● Planned

1. Patients need to be included in the registry to be eligible for treatment, so all treated patients tracked there; 2. Only outcome being measured is SVR; 3. Mandatory to report all diagnosed patients but not done because it is time-consuming and not rewarded. All treated patients reported in the registry; 4. Self-reported
Note: results based on desk research and qualitative assessment from expert interviews

Figure 19 │ How best practices in monitoring and evaluation can look when implemented
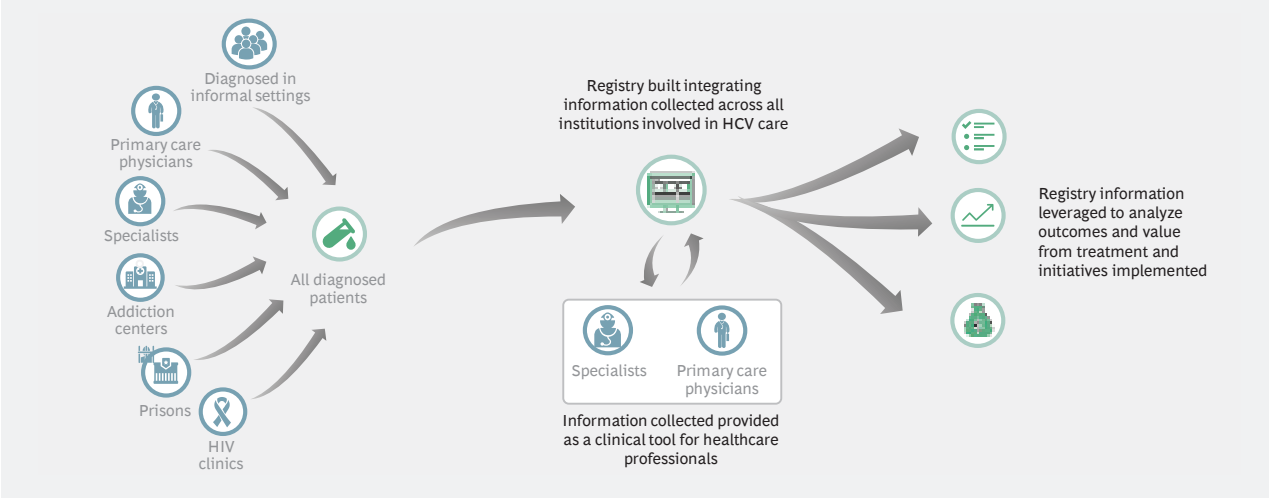
CASE STUDY FOR MONITORING AND EVALUATION │ SCOTLAND

As one of the pioneers in HCV care, Scotland has been collecting HCV patients' data for over 15 years. There is a database in place that, according to experts, contains information from all diagnosed patients in the country. The data contains information on demographics, treatment, and outcomes.

The data is fed into the database from the different Health Boards. All newly diagnosed (positive serological tests) cases must be reported (and added to the database).

The data on treatment collected in the database is reconciled by comparing with pharmacy prescribing data as well as the annual clinical audits of the Managed Care Network. Each Health Board has a Service Level Agreement (SLA) with Health Protection Scotland that sets out the requirements for collecting and providing data. The data from the database can be accessed by the Public Health Viral Hepatitis Programme Manager, as well as consultants in infectious diseases or GI and Health Protection Scotland.

According to experts, the data from the database is leveraged to monitor patients under treatment. Those with positive PCR tests who are eligible for treatment are placed on lists and tracked. In some areas (such as Tayside), the monitoring of patients continues after treatment completion, to monitor and evaluate reinfection.

The database collects information on treatment outcomes, which is evaluated during the annual clinical audits of the Managed Care Network for HCV, comparing across the different centers to identify variance and areas for improvement. This evaluation of outcomes is also used to evaluate the impact of the different initiatives. The data from the database can also be linked with other databases, such as cancer registries, to carry out further analysis. Scotland also assesses the impact of its investments in HCV infection and disease prevention through the evaluation of outcome indicators.

The database of HCV patients is also leveraged to inform other areas, such as activity and spend monitoring on HCV treatment, projection and estimates on untreated patients, identifying patients lost to follow up, mapping patients' postcodes to develop outreach services, etc.

Heatmap with HCV cases created with data from the database

There is a clearly defined governance model in place, with people responsible for reporting to the government in each of the Health Boards. A multiagency committee led by the Ministry of Health (National Sexual Health and Blood Borne Virus Advisory Committee, NSHBAC), meets twice per year to report on progress. Health Protection Scotland provides oversight of the different Managed Care Networks. Executive Leads in each Health Board are responsible for monitoring progress and reporting on the indicators, as well as ensuring implementation at a local level. Finally, a small number of national networks support the effective delivery of Framework Outcomes by providing and facilitating professional advice and sharing expertise and best practices.

Defined metrics (treatment numbers, SVR, etc.) are reported by the Health Boards every three months for evaluation. In addition, local visits to explore progress and initiatives such as the Local Authorities Single Outcomes Agreement (SOAs) are used to track progress of the initiatives taken (e.g. pilots allowing pharmacists to provide treatment).
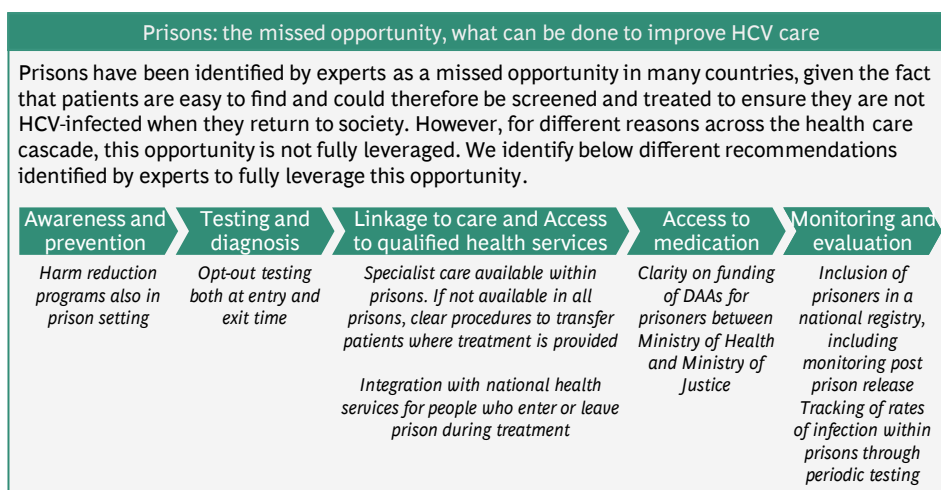
GENERAL RECOMMENDATIONS

This report reviewed the status of countries across the HCV health care cascade by identifying best practices that can be applied in different settings. Below is a summary of these best practices so that policy-makers can assess the feasibility of implementation.

Figure 20 | Summary of best practices identified across the health care cascade

Flags are examples of representative countries

Awareness and prevention	Testing and diagnosis	Linkage to care, access to qualified health services	Access to medication	Monitoring and evaluation
"Network-based approach" to increase awareness and reach out through educating and training peers of those at risk	Screening and diagnosis prioritized within high prevalence groups	HCV treatment delivered in addiction clinics	Although not broad access, DAA coverage for some key risk groups patients regardless of their fibrosis level	Mandatory reporting of all HCV diagnosed patients
Awareness campaigns targeting common settings of high prevalence groups (e.g. included within harm reduction programs)	Testing sites extended to multiple settings, focused on those used by high prevalence groups	HCV treatment delivered within prison facilities	No drug or alcohol consumption restrictions to access treatment	HCV registry tracking all patients to monitor progress • Database with all diagnosed patients
Strong government support of campaigns targeting high prevalence groups' awareness	Free and anonymous testing offered to all patients	Well developed and integrated programs for PWID and PLHIV, integrating HCV testing and support in clinics	DAA coverage for all patients regardless of their level of fibrosis	• Registry with all patients eligible for DAA treatment
Strong third-sector support of campaigns targeting high prevalence groups' awareness	Initiatives to increase health care professionals' knowledge of HCV and identification of risk factors	Good referral system in place within National Healthcare Service	Full treatment coverage by national health care system, with no co-payment requirements	Treatment effectiveness measured from outcomes in the registry
HCV trainings provided to support professionals in contact with HCV patients	Well developed screening programs for key high prevalence groups • e.g. PWID and ex-PWID • e.g. Routine screening of all prisoners, and PLHIV	Direct access to specialists	Risk-sharing (e.g. funding caps) and price-volume agreements lead to significant discounts in treatment costs	
Promotion of campaigns with prevention as a priority message	Programs to reduce dropout in testing process (e.g. unique sample screening methods of blood samples)	Wide range of doctors able to prescribe treatment, including PCPs	Availability and management of funding for DAAs at national level	
Strong harm reduction programs		PCPs able to provide treatment in their office if approved by specialist		

Stakeholders must bear in mind that top-performing countries integrate best practices across the different steps of the health care cascade, thereby reinforcing the elevated importance of the continuum of care. This is reflected in the example for prisons shown below.

Prisons: the missed opportunity, what can be done to improve HCV care

Prisons have been identified by experts as a missed opportunity in many countries, given the fact that patients are easy to find and could therefore be screened and treated to ensure they are not HCV-infected when they return to society. However, for different reasons across the health care cascade, this opportunity is not fully leveraged. We identify below different recommendations identified by experts to fully leverage this opportunity.

Awareness and prevention	Testing and diagnosis	Linkage to care and Access to qualified health services	Access to medication	Monitoring and evaluation
Harm reduction programs also in prison setting	Opt-out testing both at entry and exit time	Specialist care available within prisons. If not available in all prisons, clear procedures to transfer patients where treatment is provided Integration with national health services for people who enter or leave prison during treatment	Clarity on funding of DAAs for prisoners between Ministry of Health and Ministry of Justice	Inclusion of prisoners in a national registry, including monitoring post prison release Tracking of rates of infection within prisons through periodic testing

Eliminating HCV as a public health threat requires a coordinated, comprehensive, and integrated response. In order to succeed, it is crucial that a national measurable and funded action plan be implemented. Although most countries already have a strategy in place, experts highlighted the need for all countries to have both a strategy and a clear monitoring plan. Furthermore, some of the best practices identified in certain countries could prove helpful for others as they review their plans and implement additional initiatives to ensure that HCV is eliminated by 2030.

PLANNING

Experts highlighted the importance of developing an integrated strategy which addresses the multiple steps of the health cascade in order to ensure that prevention measures are implemented and all patients can be diagnosed, linked to care, and treated. In order to ensure strategies are tailored to country requirements, the need for good quality epidemiological data to identify high prevalence groups and have a better understanding of prevalence was highlighted.

Recommendation 1
Improve understanding of the epidemiology in the country, including understanding of groups with a high prevalence, to better target strategies.

Recommendation 2
When not already available, develop or update national action plans for the health sector response to HCV which address the different steps of the health care cascade.

AWARENESS

Raising awareness in the general population and with primary care physicians is one of the best ways to identify and diagnose the large pools of "hidden" patients who need to be engaged with and treated in order to eliminate HCV. Also, media

awareness campaigns with prevention as a priority message for the general population was identified as a best practice. These general messages should be complemented by messages targeted at high prevalence populations and related activities, such as harm reduction programs. Primary care physicians are not to be forgotten, and increasing their awareness of transmission routes, high prevalence groups, and available treatment options is essential to ensuring effective HCV screening and linking to care. Consequently, HCV should be included as a priority topic in educational programs for all health professionals in contact with individuals who may be infected with HCV.

Recommendation 3
Implement HCV awareness campaigns targeted at high prevalence populations and as a complement to related activities, such as harm reduction programs.

Recommendation 4
Include HCV as a priority topic in educational programs for primary care physicians and other health professionals in contact with individuals who may be infected with HCV (transmission routes, diagnosis, high prevalence groups, available treatment options).

Recommendation 5
In countries with high prevalence among people who are not easily reached through targeted campaigns, implement HCV media awareness campaigns with prevention as a priority message for the general population.

TESTING AND DIAGNOSIS

The level of awareness among health care professionals is particularly relevant in actively detecting cases of HCV in the general population as well as in high prevalence groups. Accessible testing is also crucial for reaching the most at-risk patients including increasing testing services in non-hospital settings and existing drug addiction treatment center environments. Clear definition of high prevalence groups, considering use of age cohorts, and a national screening plan which ensures guidelines are followed is critical to identifying all HCV patients in order to be able to treat all of them and achieve elimination of the disease (as reflected in recommendations 1 and 2 above).

LINKAGE TO CARE AND ACCESS TO QUALIFIED HEALTH SERVICES

In order to promote linkage to care and access to qualified services, one of the best practices identified is to integrate diagnosis and treatment and/or support services in order to ensure patients are connected with specialist care. This can be done in informal/formal services located where high prevalence groups can be found (such as drug addiction treatment centers and prison facilities). For the general population, good referral systems from PCPs to specialized care are needed. Likewise, decentralized access to medication reduces direct and indirect travel costs, thereby improving the patient experience and accessibility.

Recommendation 6
Integrate diagnosis and treatment and/or support services that help link patients to care at locations commonly used by high prevalence groups, including prisons, addiction centers, and HIV clinics.

Recommendation 7

Ensure good and efficient referral systems from primary care physicians to specialized care, including identifying and tracing patients who were diagnosed before DAAs were available and linking them to care.

Recommendation 8

Ensure availability of specialized resources for patients, minimizing their need to travel to get access to medication.

ACCESS TO MEDICATION

Universal coverage of DAAs has also been identified by experts as crucial to eliminating HCV as a public health threat. This includes not only eliminating restrictions on fibrosis levels, but also restrictions on lifestyle conditions, which in some countries limit access to treatment for PWID and others. Risk-sharing agreements with the pharmaceutical industry and the management of funding at the national level have also been identified as best practice for countries in order for them to offer universal and equitable treatment.

Recommendation 9

Offer universal DAA coverage without restrictions.

Recommendation 10

Allocate adequate resources for the full implementation of the HCV action plan and consider the possibility of implementing risk-sharing agreements with the pharmaceutical industry to maximize the investment and assure HCV elimination.

MONITORING AND EVALUATION

In order to ensure adequate implementation of plans and follow-up for patients across the health cascade, well-developed HCV patient registries are considered fundamental as they allow clinical monitoring of patients as well as program evaluations. Existing registries usually track SVR as an outcome, but experts highlighted the importance of tracking additional outcomes beyond the completion of treatment (reinfection, liver complications, etc.) and using registry data to evaluate outcomes and value (outcomes in relation to cost) achieved through different treatment options. This monitoring can be used to adjust the implementation of plans according to their real impact, to inform clinical and reimbursement decision-making, and to define policies.

Recommendation 11

Implement a monitoring and evaluation plan for the strategy.

Recommendation 12

Implement an HCV national patient registry of all diagnosed patients to allow tracking of patients after treatment is complete and capturing of outcomes beyond sustained viral response (mortality, reinfection, liver complication rates, etc.)

We have the opportunity to eliminate HCV as a public health threat. Many countries are already dedicating significant effort and resources to the fight against this infection. But much more remains to be done to reach the ambitious goal of elimination. The reward, a world freed from hepatitis C, is immense. We sincerely hope the findings presented in this report prove useful for stakeholders fighting HCV around the world as they strive to eliminate the virus by 2030.

APPENDIX

Experts who provided input for the report

Over 50 experts from the different countries, including clinicians, academics, regulators, payers, scientists, and patient association representatives, were interviewed or provided information to complete and validate each country profile. Interviews usually lasted one hour, and the questions covered varied according to the information required to complete the review of the country, and the expertise of the interviewee. Opinions expressed may not always reflect opinions of the organizations to which the experts belong. All interviewees and experts agreed to participate on a pro-bono basis. While some wish to remain anonymous, we take the opportunity to acknowledge the following contributors to this report:

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Abbreviations

DAA: Direct-acting antivirals

ELPA: European Liver Patients Association

EU/EEA: European Union (EU) and European Economic Area (EEA)

GP: General practitioner

HBV: Hepatitis B virus

HCC: Hepatocellular carcinoma

HCV: Hepatitis C virus

HIV: Human immunodeficiency virus

MSM: Men who have sex with men

NGO: Non-governmental organization

PCP: Primary care physician

PLHIV: People living with HIV

PWID: People who inject drugs

SVR: Sustained virologic response

STI: Sexually transmitted infections

US: United States of America

WHO: World Health Organization

WHO/Europe: World Health Organization –Regional Office for Europe

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