



ELIMINATING VIRAL HEPATITIS

THE INVESTMENT CASE

Report of the WISH Viral Hepatitis Forum 2018

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FOREWORD

Hepatitis B and hepatitis C, viral hepatitis (VH), affects more than 320 million people globally – more than HIV/AIDS, tuberculosis and malaria – and is the seventh biggest annual killer worldwide.¹ In 2015, the United Nations (UN) General Assembly adopted the 2030 Agenda for Sustainable Development, which calls on the international community to combat VH. In 2016, the World Health Organization (WHO) set targets for the elimination of VH as a public health threat by 2030 and provided a global health sector strategy on viral hepatitis for 2016–2021 that has since been adopted and endorsed by 194 countries. Despite these calls, improving investment in elimination programs has been slow. The global response to HIV has shown us what can be achieved when government, civil society, international organizations and the private sector work together with a common goal to provide prevention, care and treatment to those in need. Such a response is required for viral hepatitis.

Now is the time for everyone to come together and work toward eliminating VH as a major global killer. We have the necessary tools to eliminate VH, including highly effective treatments to cure hepatitis C and a highly effective vaccine to prevent new cases of hepatitis B. What we lack is the commitment, the leadership and the funding to best use these tools and achieve elimination.

This report is about realizing a global vision. Taking a non-siloed approach to this major health issue, consistent with the Sustainable Development Goals and universal health coverage, this report aims to unify the global community, national leaders and people affected by VH around a common goal: to empower countries to take the practical steps to prioritize activities that eliminate VH.



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**Professor the Lord Darzi of Denham,
OM, KBE, PC, FRS**
Executive Chair, WISH, Qatar Foundation
Director, Institute of Global Health Innovation,
Imperial College London



A handwritten signature in black ink, appearing to read 'M. Hellard'.

Professor Margaret Hellard
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EXECUTIVE SUMMARY

Only 12 countries are on track to meet WHO hepatitis C elimination targets:

- Australia
- Egypt
- France
- Georgia
- Iceland
- Italy
- Japan
- Mongolia
- Netherlands
- Spain
- Switzerland
- UK

Viral hepatitis (VH) – hepatitis B and hepatitis C – is a leading global health threat affecting hundreds of millions of people annually. Hepatitis B and hepatitis C cause liver inflammation due to a viral infection spread by blood or other fluids. Transmission occurs through unsterile medical and other procedures, sharing of injecting equipment and sexual transmission – albeit for hepatitis C this is uncommon outside the setting of HIV-positive gay and bisexual men.

Without increased investment in testing and treatment for hepatitis B and hepatitis C, VH will continue to spread, leading to an estimated 63 million avoidable new infections and 17 million preventable deaths from hepatitis B, and an estimated 13 million avoidable new infections and 1.1 million preventable deaths from hepatitis C by 2030.²

Today, we have effective testing and treatment options, with the potential to meet the WHO goal of elimination by 2030. However, the main barriers are limited financial resources and lack of political commitment. This report builds on the work of the WHO's Global Health Sector Strategy on Viral Hepatitis 2016–2021 by supporting a public health approach to investing in viral hepatitis elimination.

This report examines the scale of the issue ([Section 1](#)). We look at countries that have successfully implemented VH elimination programs ([Section 2](#)), examine the challenges highlighted by the case studies and outline actions that can be taken to overcome each of the issues.

We present an economic case for investing in elimination programs in [Section 3](#) and proceed to outline an investment structure for how to finance VH elimination in [Section 4](#). The [Appendix](#) lists some of the currently available resources and tools for policymakers to guide investment decisions.

The report concludes with our recommendations for global leaders of communities and nations to encourage investment in VH elimination.

Recommendations

This report proposes the following recommendations for the global community, country leaders and people affected by VH, to advocate and encourage investment in VH elimination:

- 1.** Raise the profile of VH elimination and build political commitment through global, regional, national and local forums that engage affected communities, healthcare professionals and the broader community.
- 2.** Build an investment case for elimination that provides achievable country-specific targets and strategic actions to optimize resource allocation and embed these within universal health coverage (UHC) activities.
- 3.** Informed by the investment case, mobilize domestic, private and international resources to support countries to implement elimination programs.
- 4.** Increase access to low-cost diagnostics and treatment through advocacy, international support, private partnerships and community mobilization.
- 5.** Strengthen health systems, including improving workforce skills and investments in technology and surveillance systems.
- 6.** Integrate activities into existing health programs to strengthen infrastructure, improve co-ordination and optimize resource allocation.

Figure 1 shows how governments and global funders can maximize investments in health to achieve elimination of VH, and Figure 2 shows a global map of countries that are implementing successful viral hepatitis elimination strategies.

Figure 1. Proposed investment framework for VH elimination





"The Scottish Government's investment in the new highly-effective hepatitis C therapies has led to a major reduction in people presenting with the life-threatening consequences of this disease. This will create considerable future savings for healthcare in Scotland, but more importantly, we know from patients being treated for hepatitis C how transformative this is for individuals, and the positive impact it has on their lives."

Aileen Campbell, Member of Scottish Parliament, Minister for Public Health and Sport



"We already have almost all the tools needed to eliminate viral hepatitis. What we don't have yet is the commitment, the know-how and the funding to use these tools. It is about empowering countries to take the practical steps needed at a national level; it is about how to take a vision and make it happen."

Charles Gore, Founder and former President of the World Hepatitis Alliance



"For decades I lived with hep C. I lived with the fear and the worry and the dread of discrimination. Now I just live."

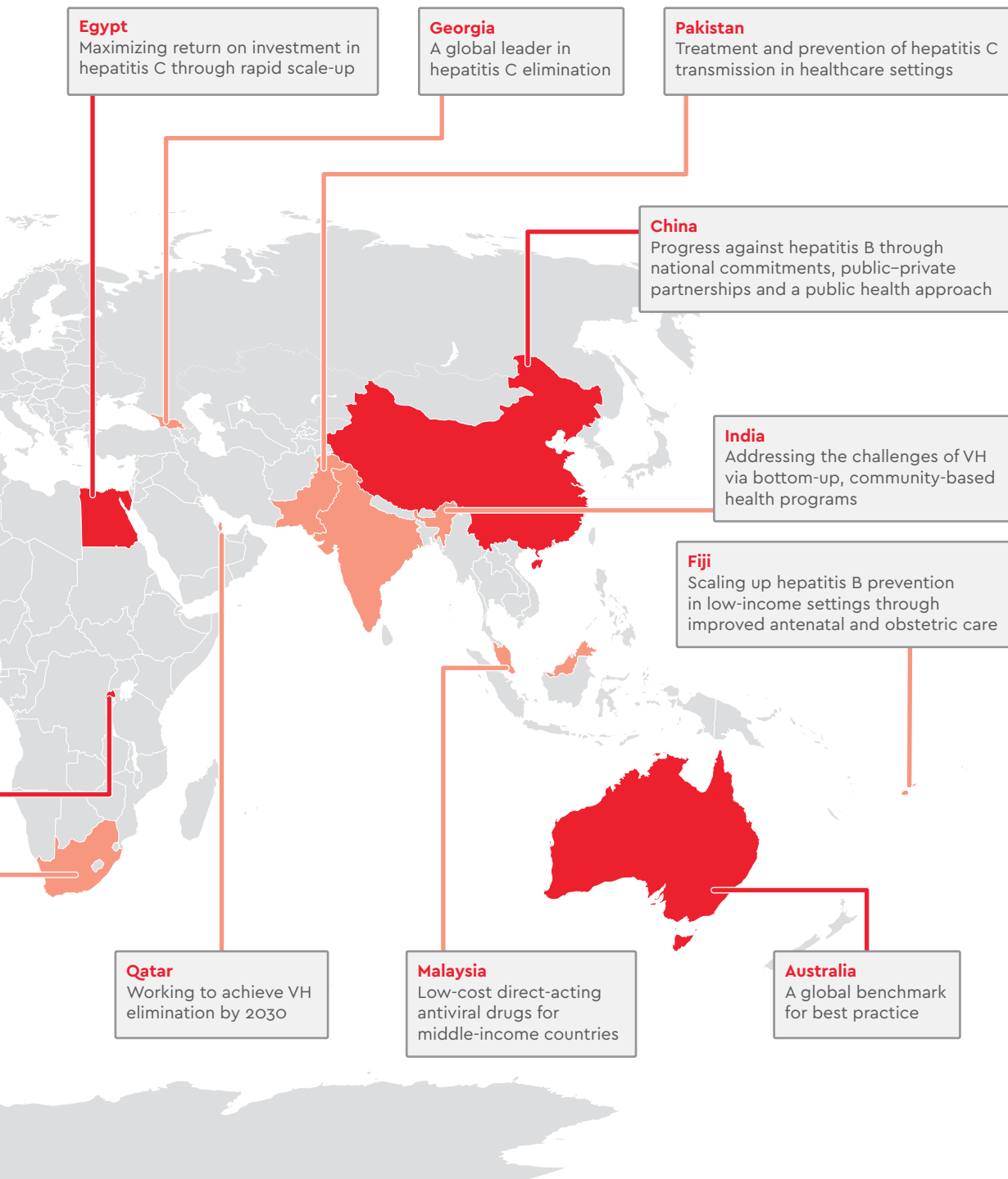
Lisa Carter, cured with direct-acting antivirals, Australia

Figure 2. Global map of countries with highly effective viral hepatitis responses

■ WISH report ■ WISH online*



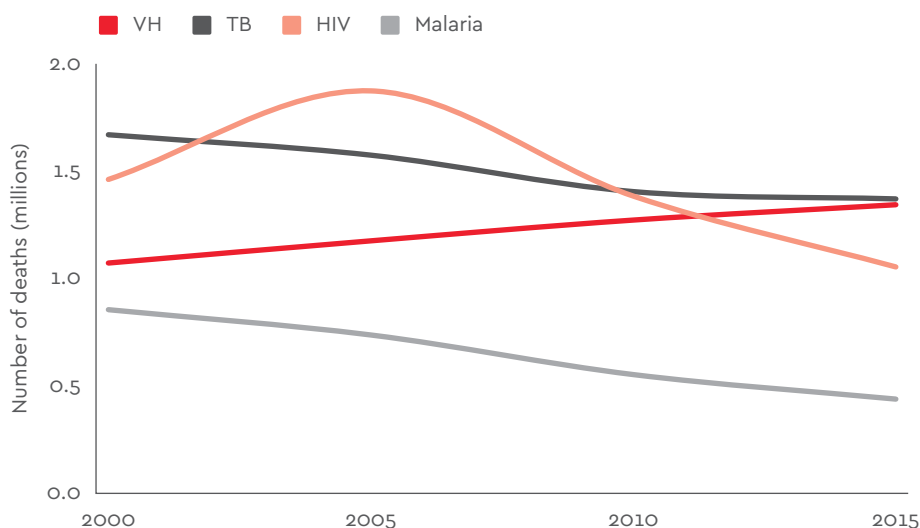
* Available online at: www.wish.org.qa/viral-hepatitis



SECTION 1. THE SCALE OF THE ISSUE

VH is one of the leading killers globally and has now surpassed HIV as a cause of death worldwide. In 2015, 1.34 million people died from VH – comparable to the number of deaths from tuberculosis (TB) in that year.³ Since 1990, the death rate from VH has risen rapidly,^{4,5} contrasting sharply with the fall in HIV and TB-related deaths over the same period (Figure 3).⁶

Figure 3. Global deaths due to VH, TB, HIV and malaria



Source: WHO, Global health sector strategy on viral hepatitis 2016–2021

VH has a major impact on overall health and quality of life. People living with hepatitis B and hepatitis C suffer worse health and wellbeing, experience considerable social stigma and have lower self-esteem.^{7–11} People with hepatitis C also have a greater burden of cardiovascular disease, kidney disease and type 2 diabetes.¹² VH often affects people in the prime of their working life and reduces social and workforce participation and personal financial security, with major implications for national economies.¹³

Hepatitis B: key facts

Hepatitis B is a serious viral liver infection spread by blood and body fluid contact and from mother to child at birth. It causes both acute and chronic disease and can lead to potentially life-threatening cirrhosis and liver cancer.

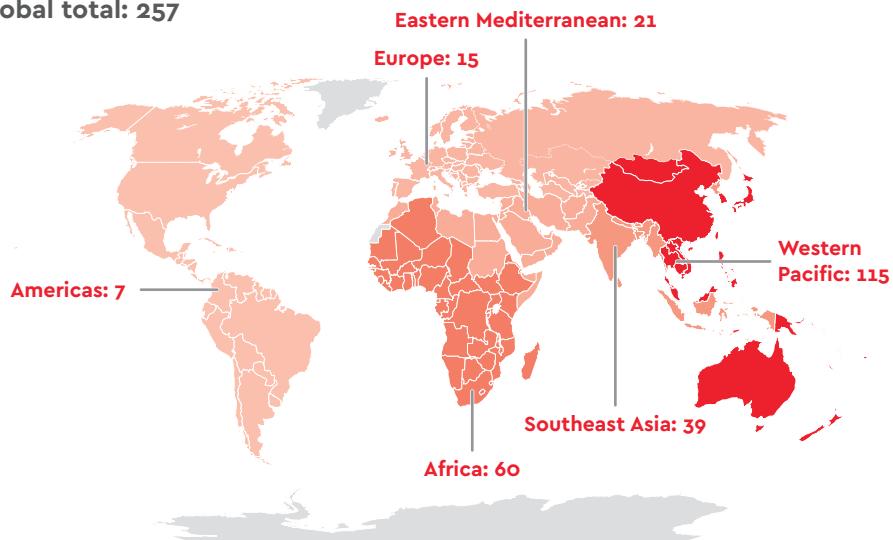
More than 257 million people (3.5 percent of the global population) are chronically infected with hepatitis B (Figure 4).¹⁴

Hepatitis B is a major cause of premature death, responsible for over 700,000 deaths in 2015 alone.¹⁵

The number of deaths from hepatitis B in the WHO Western Pacific region is greater than from TB, HIV and malaria combined.¹⁶

Figure 4. Global hepatitis B prevalence (millions)

Global total: 257



Source: WHO, Global hepatitis report 2017

Hepatitis C: key facts

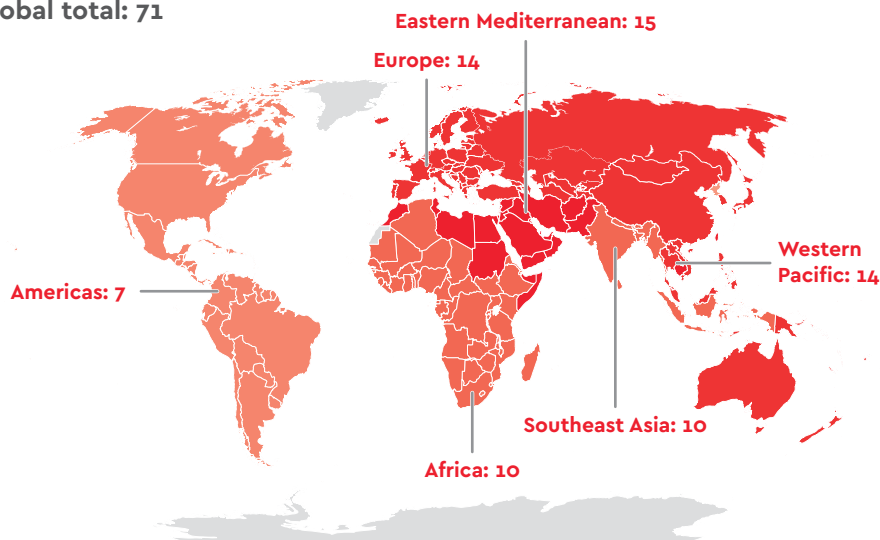
The hepatitis C virus can cause acute and chronic liver infection and is transmitted through blood contact via unsterile medical and other procedures, sharing of contaminated injecting equipment among people who inject drugs, and sexual transmission, predominately in HIV-positive gay and bisexual men. Disease severity varies from a mild, temporary infection to chronic, lifelong infection and risk of cirrhosis.¹⁷⁻²¹

More than 71 million people (1.1 percent of the global population) are chronically infected with hepatitis C (Figure 5).^{22,23}

Hepatitis C is a major cause of premature death, responsible for nearly 500,000 deaths in 2015.²⁴

Figure 5. Global hepatitis C prevalence (millions)

Global total: 71



Note: Regional figures do not combine to equal global total due to rounding.
Source: WHO, Global hepatitis report 2017

Despite these staggering figures, scientific advances have made elimination of VH achievable. A combination of highly effective, evidence-based prevention and treatment strategies are cost-effective across a range of incomes and healthcare settings.²⁵⁻⁴²

Strategies to combat viral hepatitis

Prevention strategies include:

- Routine screening of blood products and adoption of safe practices including sterile injection and medical procedures, tattoos/piercings and other non-medical procedures such as barbering.⁴³
- Harm reduction strategies for people who inject drugs (needle and syringe programs and opioid substitution therapy⁴⁴⁻⁴⁶ can reduce VH transmission by 74 percent).^{47,48}
- Education programs and condom-use campaigns targeting sexual transmission and reinfection, particularly among HIV-positive men who have sex with men.⁴⁹

Hepatitis B vaccination and treatment strategies are well-established. Birth dose vaccination given less than 24 hours after birth is more than 75–90 percent^{50,51} effective at preventing mother-to-child transmission and infection later in life.^{52,53} Vaccination of infants and newborn babies prevented 210 million chronic infections by 2015 and will have averted 1.1 million deaths by 2030.⁵⁴ Affordable generic treatments for hepatitis B are now available for as little as \$48 per patient, per year.⁵⁵

New hepatitis C drugs, direct-acting antivirals (DAAs), which have cure rates of over 95 percent, are simple to administer and allow treatment to occur in community settings by non-specialists, rather than being limited to hospital settings.^{56,57} A course of generic hepatitis C treatment can now be purchased for less than \$100 in a number of countries, and is shown to be cost-effective across a range of settings, despite the discrepancy in price of DAA drugs across low-, middle- and high-income countries.⁵⁸⁻⁶³

Many of the strategies and infrastructures required for hepatitis B and hepatitis C elimination can be effectively added to existing HIV programs at little additional cost. As outlined in the WHO's Global Health Sector Strategy on Viral Hepatitis 2016–2021, strategies need to promote high-quality and equitable service delivery approaches, prioritize effective intervention scale-up and establish clear stakeholder responsibility, accountability and funding models.

We have an opportunity to address a major health issue by aligning the hepatitis response with other global health and development strategies, including the growing support for UHC – an overarching health target for the SDGs and the broader 2030 Agenda.

SECTION 2. IMPLEMENTING VIRAL HEPATITIS ELIMINATION PROGRAMS

Some countries have successfully used investment cases and economic analyses to gain political support and help secure investment and funding for VH elimination programs. We highlight six case studies from low-, middle- and high-income countries that have successfully implemented VH elimination strategies. For each country we include statistics on population, life expectancy, gross national income (GNI) and prevalence of chronic hepatitis B and hepatitis C infection.

The case studies show the importance of political commitment, country investment and community network empowerment. After the case studies, we outline a clear plan of action for governments and policymakers to enable VH elimination.



CASE STUDY 1

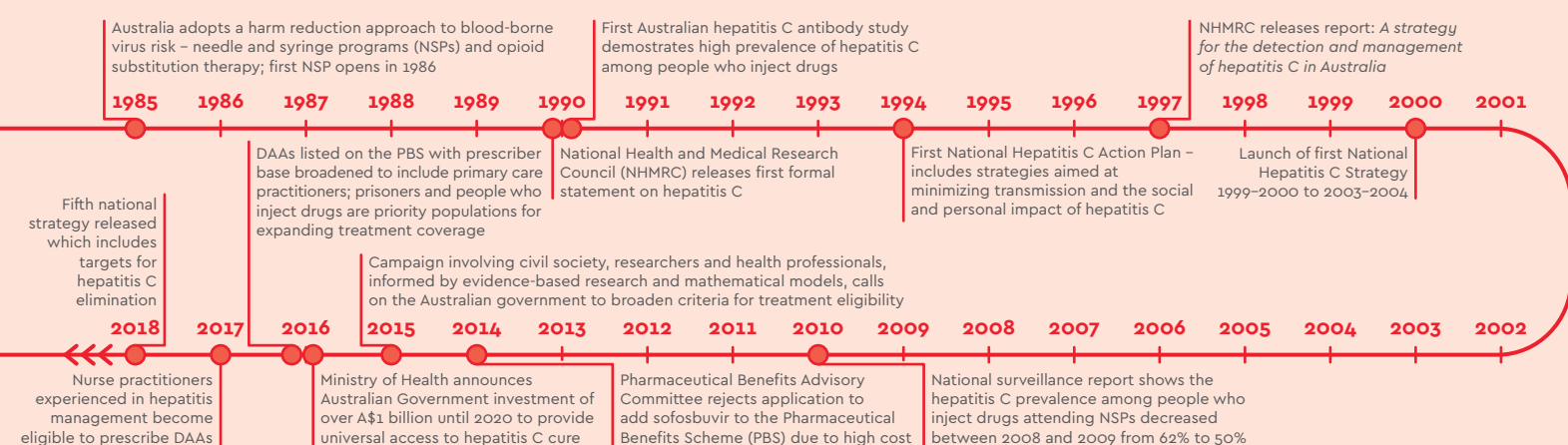
Australia – a global benchmark for best practice

Population total (2016)	24.21 million
Life expectancy at birth	83 years
GNI per capita, Atlas method	\$54,230
Hepatitis C virus (HCV) prevalence (2016)	230,000 (0.95%)
HBsAg-positive population (prevalence, 2013) ⁶⁴	83,121 (0.34%)

Australia's hepatitis C strategy has been used as a global benchmark for best practice.⁶⁵ Long-standing partnerships between community organizations, people living with hepatitis C, clinicians and policymakers ensure the strong prevention component in the Australian response to hepatitis C and support improved access to diagnosis and treatment scale-up.

By negotiating a volume-based, risk-sharing agreement with originator pharmaceutical companies, Australia has obtained major discounts on drug list prices and limited its expenditure. With no cap on treatment numbers,⁶⁶ there is an incentive to diagnose and treat as many people as possible to maximize the impact of Australia's investment. Prioritization of high-prevalence groups with ongoing risks for treatment, such as people who inject drugs and prisoners, makes hepatitis C elimination possible. In addition, all registered medical practitioners are able to prescribe DAA therapy, enabling more convenient, patient-centered care.

Australia aims to treat around 15,000 to 20,000 hepatitis C patients per year, and is currently on track to achieve the WHO target of viral hepatitis elimination by 2030.^{67, 68}





CASE STUDY 2

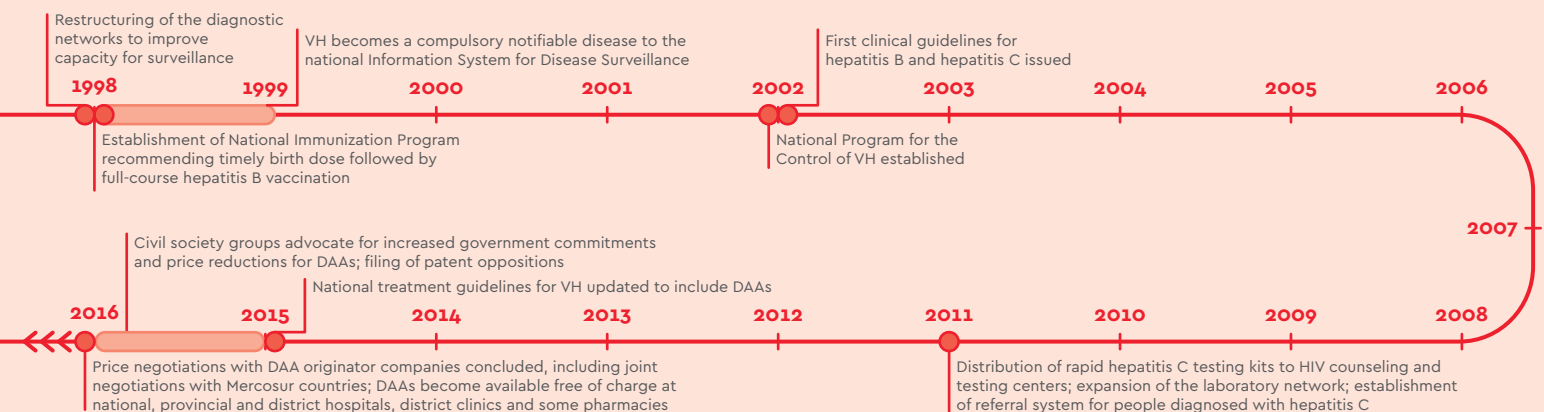
Brazil – taking action on viral hepatitis to achieve SDGs

Population total (2016)	207.65 million
Life expectancy at birth	76 years
GNI per capita, Atlas method	\$8,840
HCV prevalence (2007) ⁶⁹	2,616,600 (1.38%)
HBsAg-positive population (prevalence, 2013) ⁷⁰	1,275,813 (0.65%)

Brazil has championed the cause of VH and advocated for an intensified global response for many years. Brazil has been providing universal access to antiretroviral therapy for HIV since 1996, driven by strong political will, multisectoral mobilization and civil society engagement.⁷¹ Learning from this success in reversing HIV, Brazil established a national hepatitis program informed by up-to-date estimates of disease prevalence, international guidelines and cost-effectiveness impact in the Brazilian Unified Health System.⁷² Brazil invested in universal hepatitis B vaccination, increased capacity for hepatitis C testing in HIV services, expanded its laboratory network and set up a referral system for hepatitis patients.

Brazil was able to obtain an unprecedented discount for an upper-middle-income country through price negotiations with originator pharmaceutical companies. It provided treatment to more than 7,000 people in the last two months of 2015 and expected to treat 38,000 new patients in 2016.

The remarkable process applied in Brazil was based on epidemiological data and scientific evidence, and motivated by the engagement of the country with the SDGs, which may inspire other countries to identify ways to achieve these goals by 2030.⁷³ Brazil has pledged to provide free hepatitis C treatment to everyone infected. It is one of the few countries currently on track to achieve hepatitis C elimination by 2030.⁷⁴





CASE STUDY 3

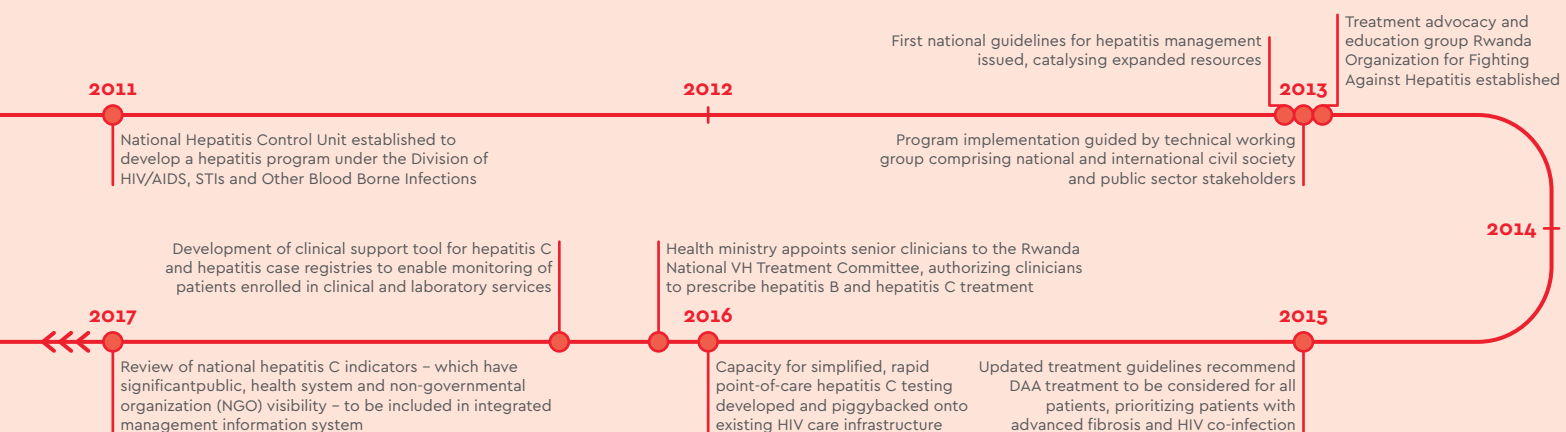
Rwanda – using a public health framework for hepatitis control and care

Population total (2016)	11.92 million
Life expectancy at birth	67 years
GNI per capita, Atlas method	\$700
HCV prevalence (2016) ⁷⁵	175,000 (3.1%)
HBsAg-positive population (prevalence, 2013) ⁷⁶	722,449 (6.67%)

The Rwandan Government now invests major resources in VH, using programmatic steps that form a blueprint for other low-income countries in the region.⁷⁷ Key elements of Rwanda's program for VH prevention and treatment include:

- Simplified treatment algorithms not requiring hepatitis C genotype or hepatitis B viral load
- Selective partnerships and preferred suppliers to drive down price, consolidate the supply chain and streamline diagnostic platforms to avoid siloed approaches to healthcare⁷⁸
- Study of necessary resources for efficient implementation
- Development of a training program for healthcare staff
- Development, funding and implementation of birth dose vaccination for hepatitis B.

Several initiatives were used to secure funding for the program, including support from international donors, in particular Clinton Health Access Initiative (CHAI). Rwanda has a voluntary licensing agreement for DAAs (current cost about \$560).^{79, 80} Rwanda's list of essential medicines for adults includes generic hepatitis B medicines treatment, subsidized by government for people with HIV co-infection. As of June 2017, 2,500 patients had been treated with DAAs and treatment for 9,000 additional patients had been procured. Rwanda aims to establish treatment capacity at all 48 district hospitals countrywide by 2020.





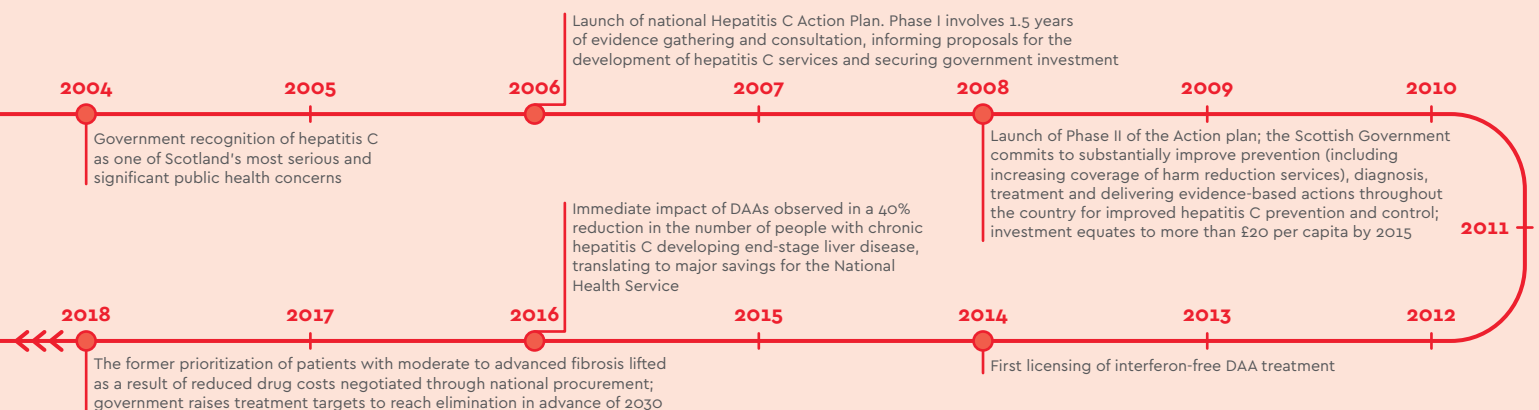
CASE STUDY 4

Scotland – a case for a comprehensive hepatitis response

Population total (2011)	5.3 million
Life expectancy at birth	79 years
GNI per capita, Atlas method	\$42,370 (UK total)
HCV prevalence (2016)	34,500 (0.7%)
HBsAg-positive population (prevalence, 2009) ^{81,82}	8,700 (0.2%)

Scotland's Hepatitis C Action Plan to improve prevention, diagnosis and treatment services has led to a significant decline in hepatitis C, a 30 percent increase in new diagnoses, sharp increases in people being treated and cured of hepatitis C, and an overall decrease of the population prevalence of chronic hepatitis C.^{83,84} The plan has demonstrated that evidence-based national hepatitis C strategies can reduce the financial and societal burden of the epidemic⁸⁵ and provides a working model for other countries to follow.

Social and political recognition of the scale of the problem galvanized policy-makers into action. Advocates used political pressure and scientific evidence to raise awareness of the human impact of hepatitis C and its links to inequalities. This generated the necessary political consensus to support significant funding and evidence-based policy initiatives. Innovative strategies such as the introduction of dried blood spot sampling in community drug services helped overcome barriers to testing.⁸⁶ Adopting a project management approach ensured achievable goal-setting and controlled ongoing cost. Investment in a robust monitoring and surveillance system, combined with ambitious targets, facilitated progress and yielded evidence of immediate impact of the investment.





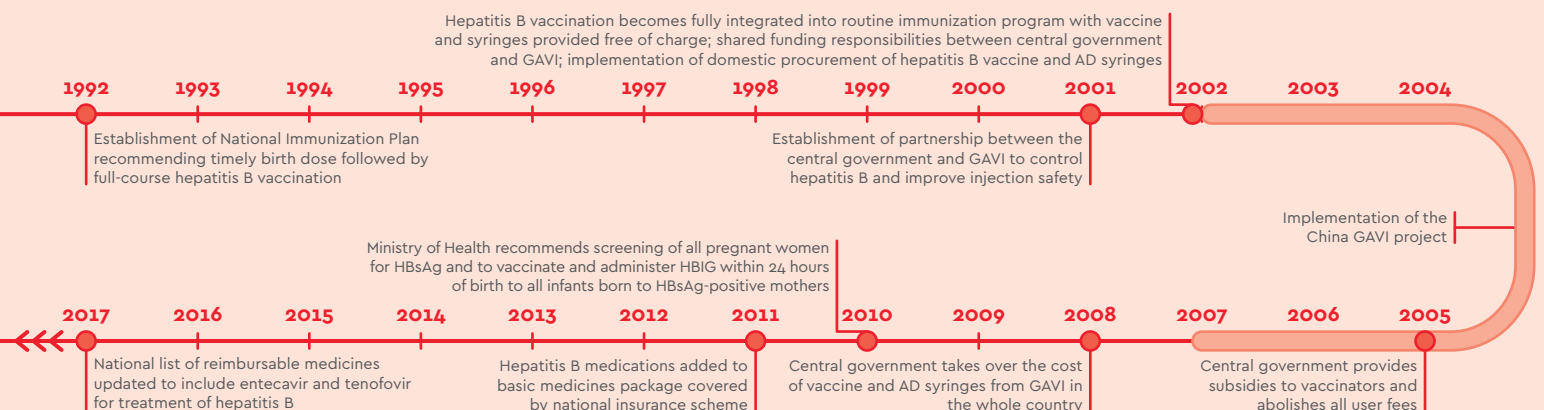
CASE STUDY 5

China – progress against hepatitis B through national commitment, public-private partnerships and a public health approach

Population total (2016)	1,378.67 million
Life expectancy at birth	76 years
GNI per capita, Atlas method	\$8,250
HCV prevalence (2016)	1.3%
HBsAg-positive population (prevalence, 2013) ⁸⁷	74.6 million (5.49%)

China is home to nearly one-third of all people living with hepatitis B infection globally. Hepatitis B surface antigen (HBsAg) prevalence is 10–15 percent and hepatitis B causes 300,000 deaths annually due to hepatitis B-related cancers.⁸⁸ Due to the implementation of a universal hepatitis B vaccination program for infants, the incidence of chronic hepatitis B has declined dramatically during the past two decades. The introduction and full implementation of a national program for the prevention of mother-to-child transmission guarantees adequate supply of hepatitis B immunoglobulin (HBIG) for at-risk newborns. Domestic procurement of the hepatitis B vaccine and auto-disable (AD) syringes ensures sustainable supply and stimulates regional industry and technology markets.^{89, 90}

Driven by strong political commitment and support from the Global Alliance for Vaccines and Immunization (GAVI), including an investment of around \$76 million to subsidize the hepatitis B catch-up vaccination program for 15 million children through public-private partnerships,⁹¹ multiple strategies were developed and implemented collaboratively. As a result, more than 95 percent of infants receive the hepatitis B vaccine within 24 hours of birth.^{92–94} Between 1992 and 2013, China's efforts have prevented 90 million cases of chronic hepatitis B infection and 24 million fewer people are carriers of the virus – representing a large contribution to the global burden of VH.⁹⁵





CASE STUDY 6

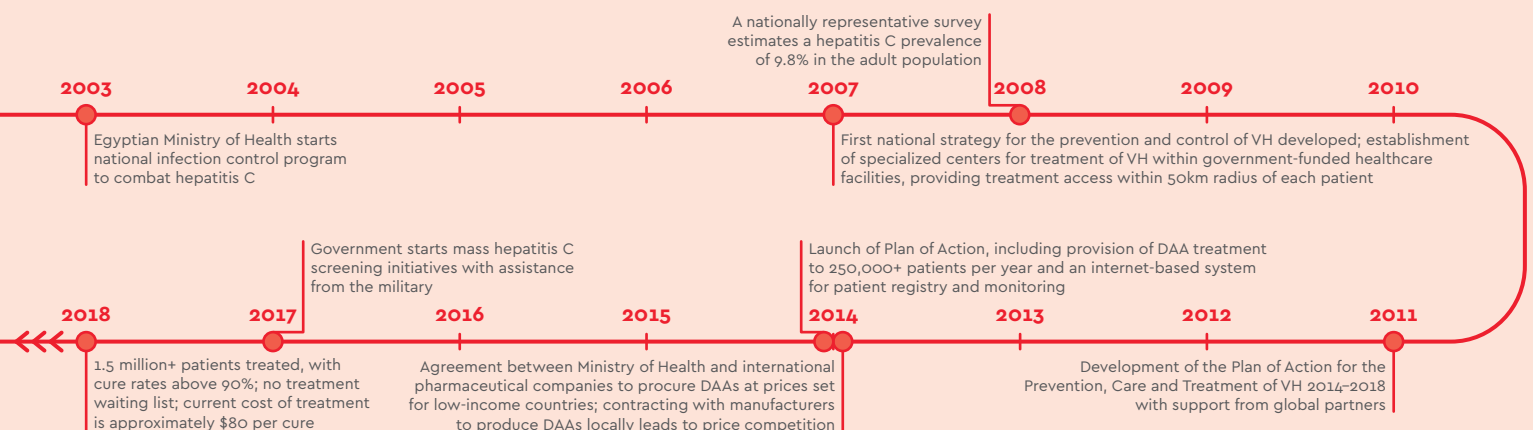
Egypt – maximizing return by rapidly scaling up hepatitis C treatment

Population total (2016)	95.69 million
Life expectancy at birth	67 years
GNI per capita, Atlas method	\$3,410
HCV prevalence (2015) ⁹⁶	3,807,382 (7%)
HBsAg-positive population (prevalence, 2013) ⁹⁷	1,338,923 (1.71%)

Egypt, a low-income country, has a very high burden of hepatitis C infection and disease, with about 7 percent of Egyptians aged 18–59 living with chronic hepatitis C infection in 2015.⁹⁸ This large pool of people living with hepatitis C and continued unsafe medical practices contribute to ongoing transmission; 150,000 Egyptians were estimated to be newly infected in 2016.⁹⁹

Egypt is committed to ending its hepatitis C epidemic and has developed one of the largest national programs for hepatitis C treatment. The program is considered to be a success, serving up to six million patients. It is a model for other nations facing similar disease burdens and resource constraints.¹⁰⁰

Egypt provides free and universal access to effective hepatitis C treatment, which is part of its national action plan for the prevention and control of VH. To date, Egypt has treated more than 1.5 million people¹⁰¹ and is on track to achieve WHO elimination targets in spite of their high hepatitis C prevalence.¹⁰² Egypt's response has been facilitated by strong Government commitment, effective price negotiations, removal of patent barriers on DAAs and ability to produce DAAs locally.^{103, 104}



Challenges and actions to address VH

Despite the clinical benefits and cost-effective solutions described in the case studies, there are several challenges to tackling VH. This section provides a summary of the key challenges for policymakers, governments and international organizations, and sets out clear actions to take to eliminate VH.¹⁰⁵

Increase awareness

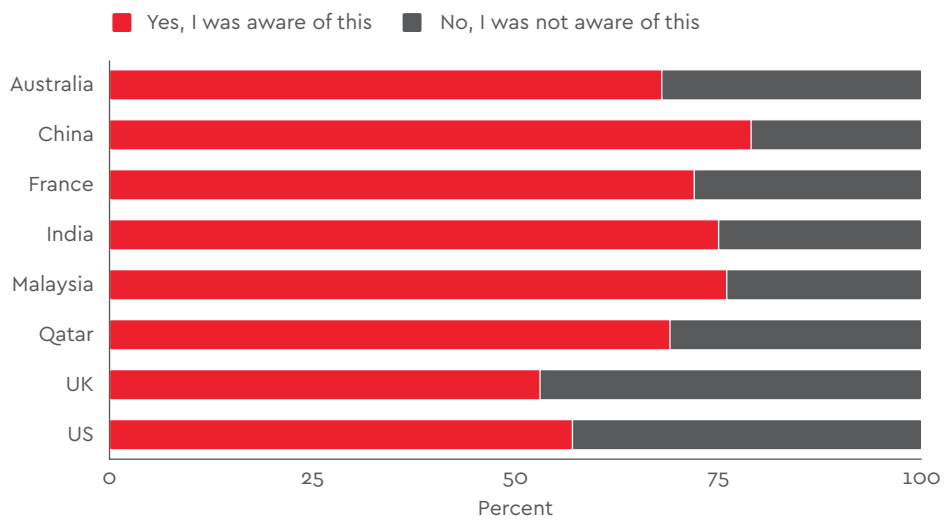
Challenge

VH elimination is not a public health priority in many countries due to competing health priorities, opportunity costs and limited health budgets. A lack of awareness and prioritization among policymakers is often caused by inadequate data and weak surveillance systems. This is often compounded by a lack of awareness in the general population and at-risk communities, who as a consequence do not demand action by their government.¹⁰⁶ This reduces the country's capacity to prioritize resource allocation and finance actions toward national VH elimination, a non-virtuous circle. Low awareness means the true national economic impact of VH is substantially underestimated, including healthcare costs, reduced quality of life, workforce participation and productivity.

Many global donors, including The Global Fund to Fight AIDS, Tuberculosis and Malaria and the Bill & Melinda Gates Foundation do not currently fund viral hepatitis activities, other than on a limited scale, for persons co-infected with HIV. Limited investment in global public goods to date has stagnated innovation and development of new, low-cost, simple technologies (medicines, diagnostics, vaccines), which could be used globally to support national viral hepatitis elimination plans and implementation efforts.

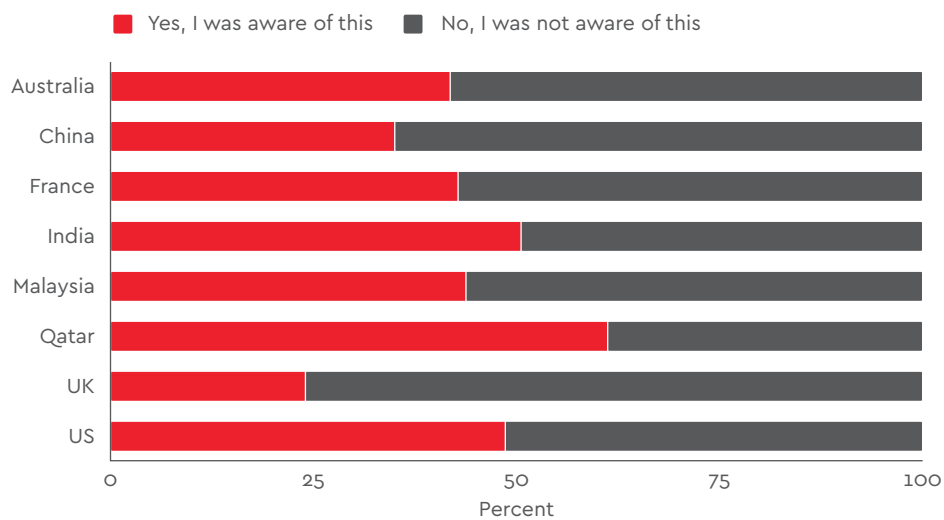
There is also a lack of awareness around the effectiveness of prevention and treatment for VH. A survey of eight countries conducted by YouGov,¹⁰⁷ an international internet-based market research and data analytics organization, found that around one in five respondents were unaware that hepatitis B can be prevented by vaccination, while more than 40 percent of respondents were unaware that hepatitis C can be cured (see [Figures 6 and 7](#)).

Figure 6. Community awareness of hepatitis B vaccination



Source: YouGov

Figure 7. Community awareness of hepatitis C cure



Source: YouGov

Action

International organizations and agencies can raise awareness among the community and policymakers through regularly reporting on progress toward 2030 elimination targets at the global, regional and country levels. International organizations should also provide technical assistance to countries to set ambitious but achievable national targets and develop national hepatitis plans and activities with sustainable budgets.

At a national level, VH advocates can raise awareness through policy reports and briefing meetings with policymakers. They can use publicity opportunities through World Hepatitis Day and other public events. Developing a national hepatitis plan can:

- Mobilize political commitment
- Identify potential and reliable sources of funding
- Develop country-specific targets and monitoring activities
- Ensure supportive laws, policies and guidelines
- Advocate for inclusion of VH activities in UHC packages and broader health financing approaches.

Establish sufficient community demand for testing and treatment and eliminate stigma

Challenge

Only a minority of those infected with hepatitis B and hepatitis C have been tested and know their status: 9 percent of people living with hepatitis B (22 million) and 20 percent of people living with hepatitis C (14 million) are aware of their status.¹⁰⁸ There is low community awareness that having VH is not a death sentence and that VH can be easily prevented, treated and cured (see [Figures 6 and 7](#)). Limited access reduces the demand for testing and treatment among affected populations, with non-evidence-based, restrictive and discriminatory policies often determining who can access VH testing and treatment. Many countries lack well-established, strong and independent civil society groups¹⁰⁹ to advocate for affected communities due to inadequate funding or because these groups are undervalued in the planning process.

Action

International, national and local organizations should all contribute to raising awareness of VH elimination through community campaigns that highlight the issue and demand government investment. It is essential to support, fund and involve community organizations and civil society groups in planning, delivering and monitoring VH country action and implementation plans. These plans should be informed by surveillance data and local epidemiology and include community-focused activities. Finally, we must identify and advocate for the reform of laws, policies and guidelines that restrict access to medicines or perpetuate stigma, such as criminalization of syringe possession and drug use.

Strengthen surveillance systems and provide adequate data

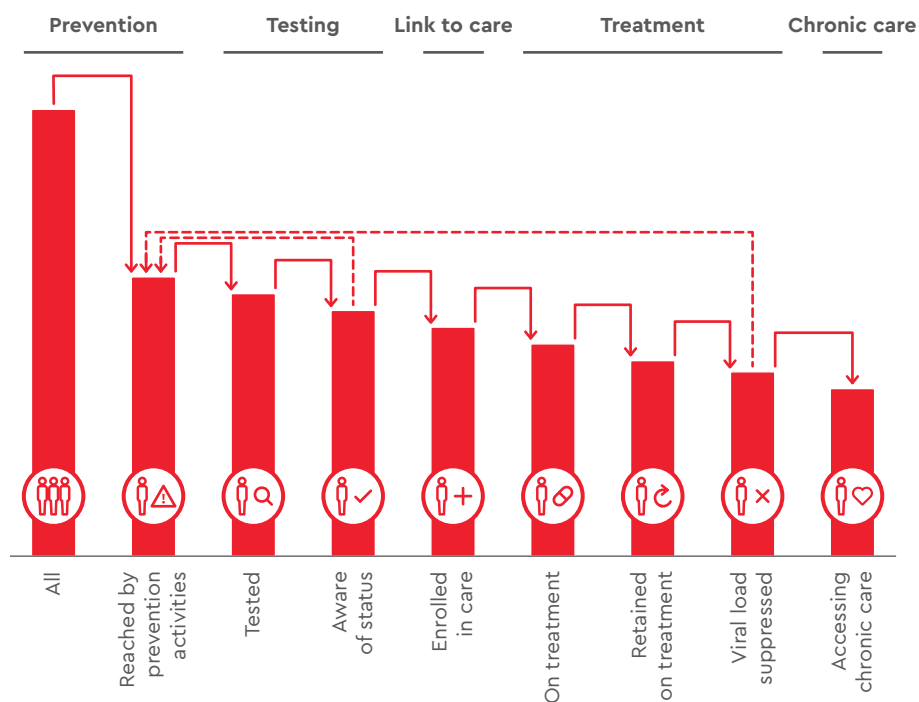
Challenge

The true public health dimensions and impact of VH epidemics are poorly understood. This is due to low-quality surveillance systems and a lack of reliable cause-specific mortality data for liver cancer and liver failure. Weak surveillance and data systems¹¹⁰ limit countries' capacity to direct policy change, prioritize resource allocation, and plan, implement and monitor VH elimination programs.

Action

Key figures working in the field should advocate for the WHO VH cascade monitoring and evaluation framework to be included as a key component of national hepatitis plans, and provide technical assistance for this work (see [Figure 8](#)).

Figure 8. The continuum of VH services and the retention cascade



Source: Global health sector strategy on viral hepatitis 2016–2021¹¹¹

Governments should include VH indicators in existing surveillance systems – for example, HIV surveillance systems, programs for the prevention of mother-to-child transmission – to improve data while achieving related cost savings. All countries should also invest in workforce training for enhanced surveillance and data monitoring. This will guide service improvement by ensuring improved monitoring of access to, uptake and quality of VH services.

Promote public health programs and strengthen health infrastructure

Challenge

Many hepatitis B and hepatitis C treatment programs currently do not use a public health approach to provide the maximum benefit for the largest number of people. A public health approach promotes standardization, simplification and decentralization of health services to reach and actively involve those populations most affected. Restrictions on the use of funds beyond a single disease or health program lead to a siloed approach to health programs, limited health service coverage and lost opportunities to strengthen health systems.

The effectiveness of VH programs is limited by poor health infrastructure, including limited laboratory capacity and a lack of reliable supply chains for vaccines, medicines and diagnostics. The health workforce has limited skills and capacities. A lack of appropriate governance and quality assurance programs leads to ongoing VH transmission in formal and informal health sectors. This is caused by unsafe blood supplies, medical injections and other inadequate procedures. Many countries rely on centralized specialist services or tertiary hospitals to deliver VH services, despite evidence of the effectiveness of community health systems.

This leads to missed opportunities for task shifting (using nurses or healthcare workers instead of physicians), which lowers costs but doesn't harm quality.

Action

The viral hepatitis response needs to sit within a framework of UHC and the SDGs. A non-siloed response is essential. Also essential is the use of WHO policies and guidelines:

- Global health sector strategy on viral hepatitis 2016–2021
- Essential Medicines List
- Guidelines on hepatitis testing, treatment and care
- Injection safety and blood safety policies
- National hepatitis procurement and supply management structures and processes.

Policymakers can leverage the roll-out of UHC for investment in hepatitis programs that also facilitate prevention and management of other major health conditions, such as HIV, liver cancer and diabetes. National health workforce

strategies should identify opportunities for task shifting and task sharing to increase access to care while controlling costs. Finally, strengthening national laboratory systems is essential to provide quality diagnosis of hepatitis with timely reporting of results.

Enable access to affordable diagnostics, prevention and medications

Challenge

The high costs of diagnostics and medicines mean that many countries cannot access VH testing and treatment and the hepatitis B vaccine, despite strong evidence of their feasibility and cost-effectiveness. Low- and middle-income countries (LMICs) are most affected by the high cost of diagnostics and medicines. Many are missing opportunities to access cheaper medicines through voluntary licenses that allow production and supply of generic antiviral medicines to 112 LMICs.¹¹² Conversely, upper middle-income countries (UMICs) have challenges in accessing low-cost medicines because they are not included in voluntary license agreements. Also, while treatments for VH are included in the 20th WHO Essential Medicines List (EML), many countries have not included them on national EMLs due to the initially prohibitively high prices.¹¹³ This is despite the market price of DAAs falling dramatically since their release to less than \$100 for an entire course of treatment in a number of countries.^{114, 115}

Many countries are not using the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities and legal public health safeguards to access generic versions of patented medicines without the patent holder's permission – for example, by issuing compulsory licenses (CLs), or challenging unmerited patents.¹¹⁶

VH services are often not available in primary care due to restrictive testing and treatment policies and guidelines which prevent people from accessing health services in a timely manner.¹¹⁷ This results in delayed diagnoses, increased risk of onward transmission and further healthcare costs. A lack of focus on prevention results in poor coverage of highly cost-effective, evidence-based prevention strategies such as routine screening of blood products, safe injection practices and harm reduction strategies for people who inject drugs.¹¹⁸

Action

International health organizations can promote access to affordable medicines through:

- Price regulation
- Supporting generic competition to drive prices down

- Negotiations under differential pricing schemes
- Patent challenges
- Using TRIPS flexibilities – such as CLs and patent oppositions
- Eligible voluntary licensing agreements, including from the Medicines Patent Pool.

International organizations should also provide clear guidance to countries about their rights to engage in the strategic procurement of DAAs from various sources and achieve better deals through competitive bidding processes and/or volume-based strategies.

National policymakers can also ensure greater access to affordable medicines, prevention and diagnostics by:

- Including VH medicines on the WHO EML, including WHO prequalified generic DAAs to facilitate national level access
- Including VH diagnostics on the WHO Model List of Essential In Vitro Diagnostics¹¹⁹
- Simplifying clinical guidelines and testing policies that increase access to timely diagnosis, treatment and prevention, including supporting community-based treatment programs and community-based organizations
- Accelerating regulatory approval for WHO prequalified products or those approved by stringent regulatory authorities
- Encouraging investment in innovations for development of low-cost medicines, diagnostics and prevention products.

Countries should develop and implement national hepatitis plans that include strategies to reduce prices of prevention, diagnostics and medicines, and improve integration of hepatitis services with other health services. Strengthening community-based services is also essential to provide opportunities to reach marginalized groups, improve acceptability and support rapidly scaling up services.

SECTION 3. THE ECONOMIC CASE FOR INVESTING IN VIRAL HEPATITIS ELIMINATION PROGRAMS

Policymakers around the globe must constantly balance health priorities across sectors and within healthcare. Building a strong investment case is essential to gain support for program investment. This section provides the business case for investing in VH elimination programs.

Direct economic benefits of investment to eliminate VH: Hepatitis C

Individuals infected with VH experience a reduction in quality of life. They may require healthcare services to manage their disease, generating direct costs to a country's health system. Most of these healthcare costs are typically incurred many years after initial infection, with the onset of cirrhosis and liver cancer.

Epidemic and economic analyses help to calculate the return on investment of changes in hepatitis disease control strategies. These strategies can be compared to the status quo, which is currently observed in the passive management of the disease and the testing and treating of people without increasing programs. Here, the impact of two investment strategies for hepatitis C were assessed for each of the WHO world regions:

- An *elimination* strategy, involving increasing hepatitis C testing and treatment to reach the WHO targets of 90 percent of people living with hepatitis C diagnosed and 80 percent of diagnosed people started on treatment by 2030¹²⁰
- A *progress* strategy, involving increasing hepatitis C testing and treatment to have 45 percent of people living with hepatitis C diagnosed and 80 percent of diagnosed people started on treatment by 2030.*

The analyses provide evidence that, if hepatitis C testing and treatment were increased according to the elimination strategy, an 85 percent reduction in hepatitis C incidence and a 68 percent reduction hepatitis C-related mortality could be achieved by 2030 (Figures 9C and 9D respectively). This was estimated to prevent 2.1 million hepatitis C-related deaths and 12 million new

* Based on WHO recommendations that general population hepatitis C testing only occurs in settings with ≥ 2 percent hepatitis C prevalence. Globally, countries with ≥ 2 percent prevalence were estimated to contain about 45 percent of people living with hepatitis C.

hepatitis C infections between 2018 and 2030. The application of the elimination strategy would substantially reduce the overall number of people living with hepatitis C (Figure 9B).

Estimated impact of the elimination and progress investment scenarios*

Figure 9A. Total people living with hepatitis C

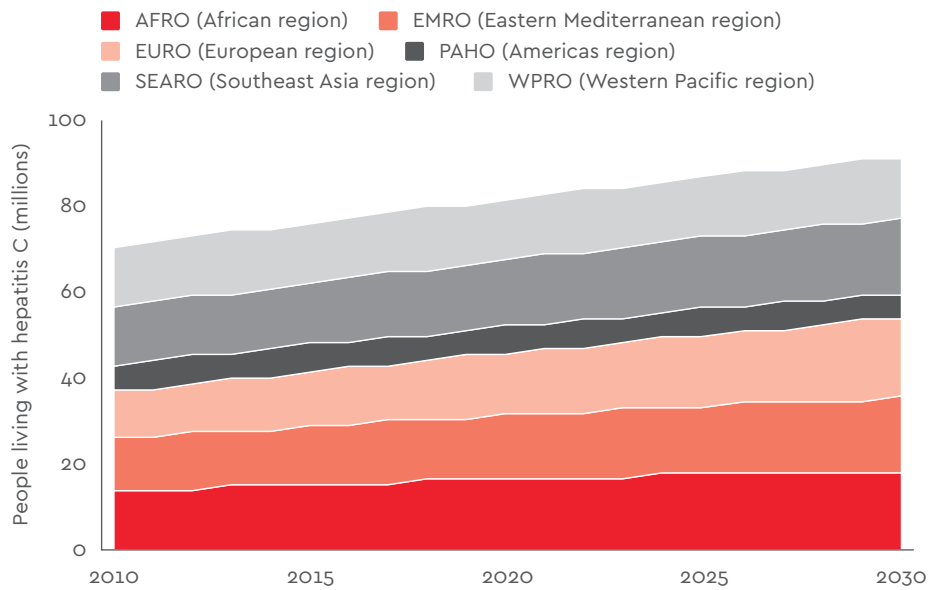
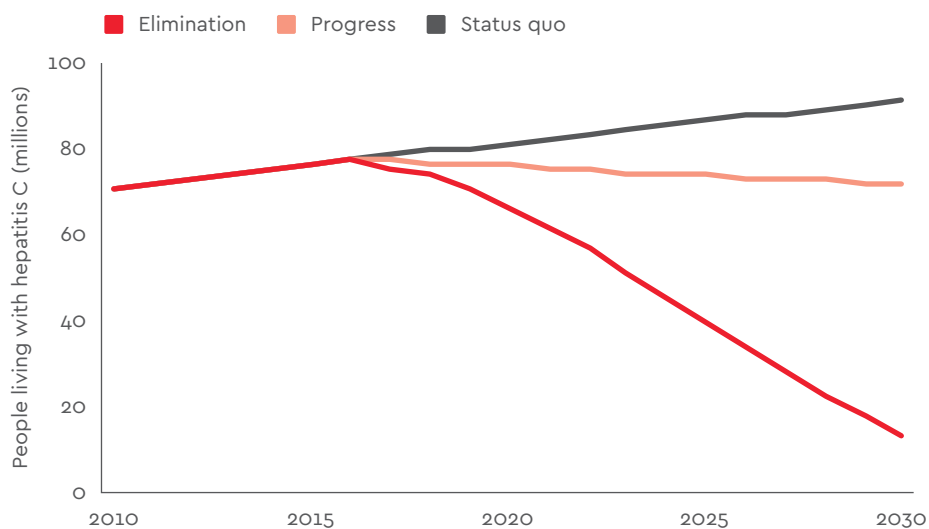


Figure 9B. Total people living with hepatitis C



* Estimated impact of the elimination and progress investment scenarios on the projected number of people living with hepatitis C, hepatitis C incidence and hepatitis C mortality. Further details are available at: www.wish.org.qa/viral-hepatitis

Figure 9C. Global hepatitis C incidence

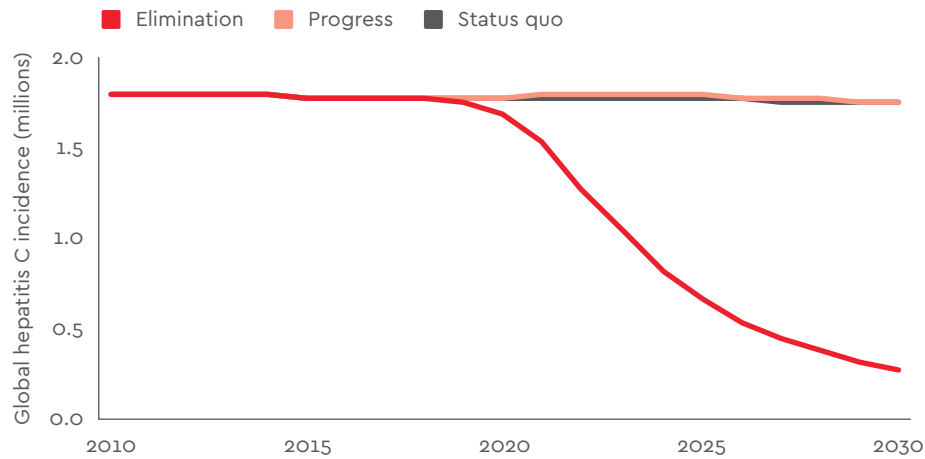
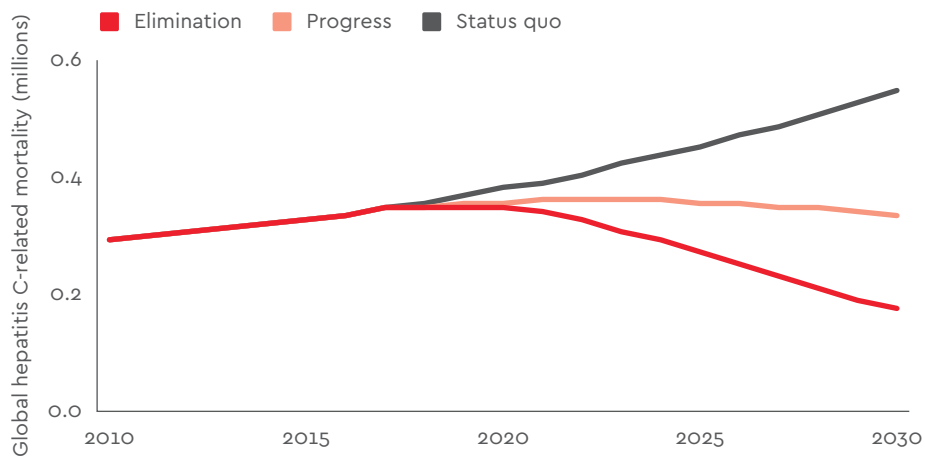
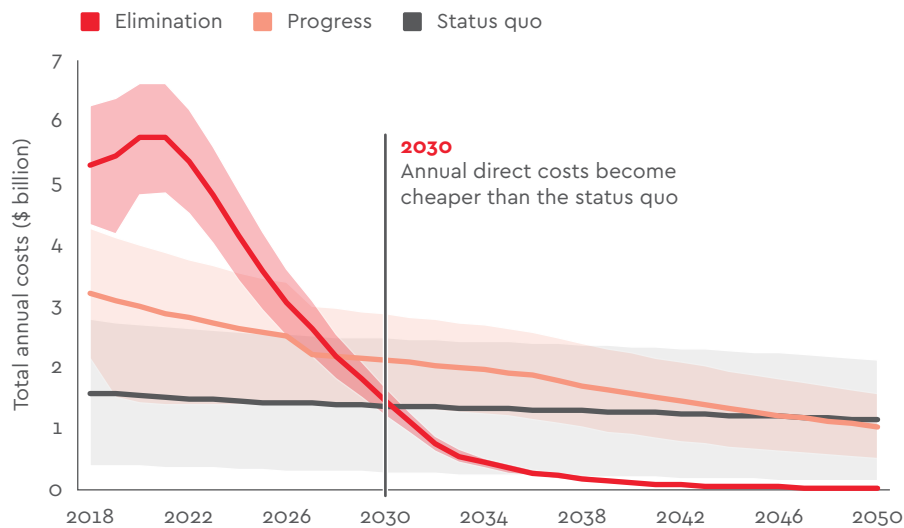


Figure 9D. Global hepatitis C-related mortality



The models further suggest that large up-front investment in testing and treatment is required to control the epidemic. The elimination scenario required an increase in investment to a peak of \$5.7 billion globally in 2021 (Figure 10). However, by 2030, the annual direct costs of elimination became less than the status quo.

Figure 10. Estimated global annual direct costs of the status quo, elimination and progress scenarios*



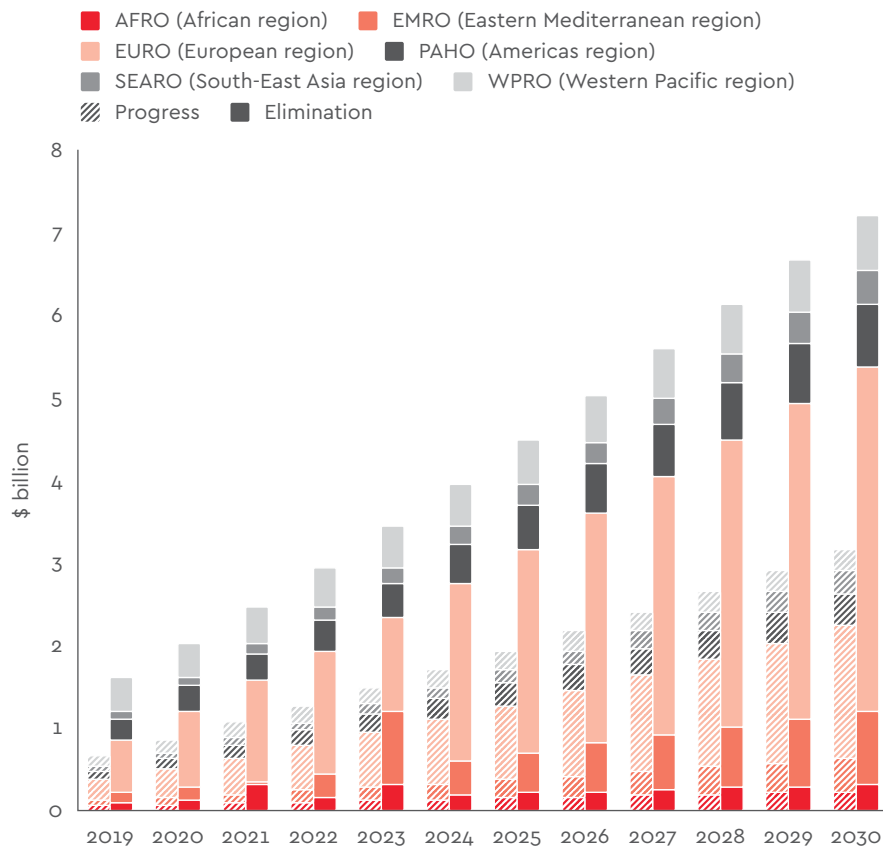
Indirect economic benefits of investment to eliminate VH: Hepatitis C

Increased testing and treatment can produce indirect economic benefits due to the prevention of premature deaths and the increased workforce participation among people who are cured from VH. To illustrate the economic impact of VH and indirect savings from investment, the human capital approach¹²¹ was used for estimating absenteeism (due to a reduced workforce or from individuals working fewer hours) and 'presenteeism' (where individuals come to work while they are ill and are less productive at work due to their illness) attributable to hepatitis C in each of the WHO world regions.

Calculations based on this approach showed that the indirect economic benefits from increasing testing and treatment of hepatitis C continue to grow over time. This was a result of the cumulative morbidity and mortality averted, leading to a larger and more productive workforce (Figure 11).

* All costs include discounting at 3 percent per annum. Further details are available at: www.wish.org.qa/viral-hepatitis

Figure 11. Estimated economic productivity gains due to the elimination and progress investment scenarios*

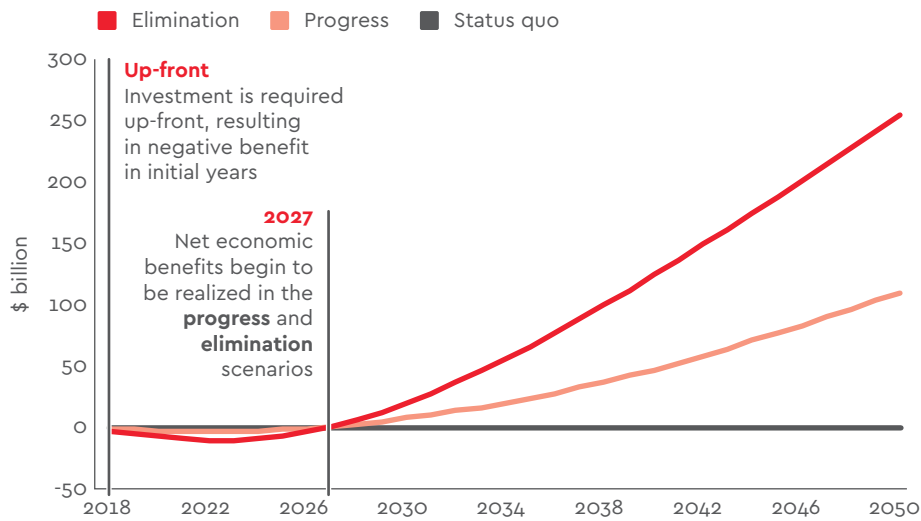


Return on investment of eliminating VH: Hepatitis C

The net economic benefit of eliminating hepatitis C can be examined over time by comparing the cost of investing in hepatitis C to the direct costs averted and productivity gains. Alongside substantial reductions in transmission, morbidity and mortality, investing in hepatitis C elimination is estimated to save costs. **Figure 12** shows that both the progress and elimination scenarios would become cost saving by 2027. In the longer term, investing to eliminate hepatitis C provides the greater return on investment, since the ongoing transmission occurring in the progress scenario results in perpetual treatment costs. Therefore early financial commitment is required to obtain the maximum returns and prevent ongoing costs.

* All costs include discounting at 3 percent per annum. Further details are available at: www.wish.org.qa/viral-hepatitis

Figure 12. Net economic benefit of the elimination and progress investment scenarios compared to the status quo



Affordability

The annual cost of testing and treatment (that is, excluding disease management) in the hepatitis C elimination scenario is expected to reach a maximum of \$4.8 billion in 2021, before reducing to \$12 million by 2050 and continuing to decline. The total cost of the elimination scenario between 2018 and 2030 is estimated to be \$51 billion, with minimal ongoing costs.

This is a small investment compared to the \$343.2 billion that would be spent on HIV, TB and malaria over the same time period, assuming the current investment levels in these diseases were maintained (\$19 billion per annum on HIV, \$6.9 billion per annum on TB and \$2.7 billion per annum on malaria). Particularly as the current expenditure on HIV, TB and malaria is unlikely to lead to an end of those epidemics by 2030.

Cross-sectoral economic benefits of investment in viral hepatitis

We must increase investment in infrastructure and health service delivery in order to reach the SDGs target for UHC. Ensuring that hepatitis services are integrated within these systems can reduce costs compared to an isolated, non-strategic approach. The simplicity of VH care for most people means that most services could be delivered in the community health sector, making integration highly achievable.

Staffing costs associated with testing and treatment vary by region, but can be more than double the commodity costs required to be diagnosed and treated. Our projections assume that half of the testing and treatment activities could

be absorbed by staff in the context of UHC; however given the simplicity of VH testing and treatment, it is possible that adequate human resources would already be available for all of these services. This would reduce the cumulative costs of the elimination and progress scenarios by \$20.2 billion and \$10.3 billion respectively. Any investment in staffing costs for hepatitis C elimination that cannot be absorbed among the existing healthcare workforce will make a positive impact on the provision of healthcare for other diseases and contribute to broader UHC targets.

Return on investment of eliminating VH: Hepatitis B

An epidemiological mathematical model has been developed for hepatitis B globally,¹²² clearly showing that an ambitious approach to increasing vaccination coverage (90 percent birth dose), prevention of maternal–child transmission (80 percent) and population-wide testing and treatment (80 percent) are needed to achieve the WHO 2030 elimination targets. The increase in vaccination coverage is estimated to avert 7.3 million deaths, including 1.5 million cases of cancer deaths, with a peak global annual cost of \$7.5 billion in 2025, after which costs reduce rapidly to \$4.7 billion per year. Several country-specific investment cases for hepatitis B and hepatitis C^{123,124} have also been developed and provide useful examples of how countries can plan for rapid increase in VH elimination efforts.

The World Bank has published a series of cost-effectiveness analyses, including for hepatitis B vaccination.¹²⁵ This analysis clearly demonstrates that hepatitis B vaccination in low-income countries is a cost-effective intervention, at a cost of less than \$100 per disability-adjusted life year averted for adults.*

There is no current model that provides estimates for both indirect and cross-sectoral economic benefits for hepatitis B, but this would be useful in developing a full investment case for hepatitis B.

* For more information on these cases, see www.wish.org.qa/viral-hepatitis

SECTION 4. HOW TO FINANCE VIRAL HEPATITIS ELIMINATION

How can VH elimination be financed and made affordable?



Investing in VH elimination requires investing in strengthening health systems and hepatitis-specific activities. Costs specific to the health system include improving injection and blood safety, harm reduction programs and services, and strengthening surveillance systems/investments in technology to link patients into care. Hepatitis-specific costs include vaccines and treatment for hepatitis B and hepatitis C, distributed between health system and hepatitis programs. Strategies to increase investment in hepatitis need to be part of broader efforts to increase overall investments in health so that all priority health services can be scaled towards UHC, including expanding the range of services provided, covering the populations in need of services and reducing the direct costs of services.

Diverse factors influence the success and sustainability of financing models. For example: economies of scale and population coverage may attract private investment for new, low-cost diagnostics; cost-effectiveness studies may be more useful to convince donors; and policymakers may be more motivated by affordability, short-term impacts, geo-referencing of impact and comparison to other countries in the same region. Countries must therefore consider the most appropriate and cost-effective financing solution within their local context.


Economic models can be used to help develop country-specific investment cases that maximize output and minimize expenditure, as South Africa¹²⁶ and the Gambia¹²⁷ have done.

Table 1 summarizes a number of mechanisms that can improve the affordability of VH elimination.

Table 1. Mechanisms to improve affordability of VH elimination*

Mechanism	Description	Examples
 Reductions in treatment costs	Effective price negotiations with pharmaceutical manufacturers for hepatitis treatment and diagnostics	Australia, Brazil and Mercosur countries, Portugal
	Local production of generics	China (hepatitis B vaccine), Egypt, Pakistan, India
	Patent opposition/CLs	Malaysia
 Maximizing effectiveness of public health spending	Adopting an investment case approach to guide investments for maximum impact creates opportunities to finance substantial improvements in hepatitis care without further straining health sector budgets – eg via integration of VH into existing services	South Africa ¹²⁸ and Scotland See Gambia and South African online case study for economic evaluation of hepatitis B management activities ¹²⁹ and requirements for global elimination. ¹³⁰
 Sharing costs with other strategies	Harm reduction costs	Portugal, Scotland
	Immunization and blood safety	China, Taiwan
	Co-infection with HIV and service delivery	Rwanda, Brazil, South Africa
 Innovations and efficiencies over time	Dried blood sampling	Scotland
	Non-specialist care	Australia
	Hepatitis B cure	
 International donor investment	Provision of effective treatment	Cambodia – Médecins San Frontiers (MSF), Myanmar – Foundation for Innovation New Diagnostics, Georgia – Gilead, Rwanda – CHAI
	Low-cost vaccines	GAVI has amassed commitments of about \$1.3 billion to finance the expansion of existing childhood immunization programs and the accelerated introduction of hepatitis B vaccines
	Low-cost diagnostics	The International AIDS Vaccine Initiative, the Medicines for Malaria Venture, and the International Partnership for Microbicides provide funding. Estimates indicate that the 10 largest public–private partnerships have raised more than \$1 billion over the past five years. ¹³¹

* Further country case studies: Case studies for Portugal, Fiji, Malaysia, Pakistan, South Africa, Taiwan, Qatar and India that provide examples of the importance of political commitment, country investment cases, and community network empowerment can be found at www.wish.org.qa/viral-hepatitis.

Mechanism	Description	Examples
 <p>Innovative blended financing models</p>	<p>Pooled financing: Bringing together development and commercial actors to pool financing and offer opportunities to increase the number of blended finance models.</p>	<p>Tamil Nadu Urban Infrastructure Financial Services Limited, an asset manager jointly owned by the Government and private financial institutions.¹³²</p>
	<p>Technical assistance: Supplements the capacity of investees and lowers origination and transaction costs. This approach has been particularly successful in the agricultural, energy and finance sectors.</p>	<p>African Agricultural Capital Fund, Beira Agricultural Growth Corridor Catalytic Fund, and responsibility development investors.</p>
	<p>Results-based financing: Seeks to create market incentives to achieve critical social outcomes by only paying when results are achieved. Two main types: <i>Performance-based financing</i> targets the supply side, whereas <i>conditional cash transfers</i> target the demand side of a given market.</p>	<p>Health systems strengthening support and GAVI's immunization services support.</p>
	<p>Social and development impact bonds: These draw on elements of impact investing or blended finance as well as public-private partnerships, and allow outcome funders to pay directly for the achievement of outcomes rather than for inputs or compliant behavior. Investors provide the up-front risk capital with an opportunity for return. They can play a critical role in helping to improve service delivery by bringing private sector discipline into practices of monitoring and performance management.</p>	<p>The Department for International Development is working on a Development Impact Bond to tackle sleeping sickness in Uganda.</p> <p>The Inter-American Development Bank has announced a \$5.3 million Social Impact Bond (SIB) facility to address social challenges in Latin America.</p>
	<p>Dedicated hepatitis fund: Create a global VH fund to leverage resources and cultivate synergies through innovative public-private partnerships and catalyze action on VH. The proposed fund would primarily support the most affected countries and communities where, despite national commitment, national health systems cannot adequately or effectively address hepatitis epidemics. Specific high-impact activities would be supported through the structures of the UN World Health Assembly and Regional Committees.</p>	<p>Fund for Elimination of Viral Hepatitis 'EndHEP2030'.</p> <p>The European Investment Bank-managed Global Energy Efficiency and Renewable Energy Fund was initiated by the European Commission in 2006 and has €222 million in assets under management.¹³³</p>

SECTION 5. CONCLUSIONS AND RECOMMENDATIONS

This report proposes the following recommendations for the global community, country leaders and people affected by VH, to advocate and encourage investment in VH elimination:

- 1.** Raise the profile of VH elimination and build political commitment through global, regional, national and local forums that engage affected communities, healthcare professionals and the broader community.
- 2.** Build an investment case for elimination that provides achievable country-specific targets and strategic actions to optimize resource allocation and embed these within universal health coverage (UHC) activities.
- 3.** Informed by the investment case, mobilize domestic, private and international resources to support countries to implement elimination programs.
- 4.** Increase access to low-cost diagnostics and treatment through advocacy, international support, private partnerships and community mobilization.
- 5.** Strengthen health systems, including improving workforce skill and investments in technology and surveillance systems.
- 6.** Integrate activities into existing health programs to strengthen infrastructure, improve co-ordination and optimize resource allocation.

APPENDIX

The following resources and tools are available to help policymakers direct their investments in VH prevention and treatment.

- **Optima HCV** (www.ocds.co/hcv) The Burnet Institute have developed this tool to help decision-makers understand what it will take to reach targets and choose the best public health investments with current resources for their local setting.
- **Let's end HepC policy dashboard** (www.letsendhepc.com) Instituto de Ciências da Saúde, Portugal, with support from Gilead Sciences Europe, has developed a policy calculator for Portugal that is now being expanded to five European countries (Bulgaria, England, Germany, Romania and Spain).
- **Cost-effectiveness analysis registry database** (www.cearegistry.org) Center for the Evaluation of Value and Risk in Health analyzes the benefits, risks and costs of strategies to improve health and healthcare.
- **Medicines Law & Policy legal and policy analysis hub** (www.medicineslawandpolicy.org) provides policy and legal analysis, best practice models and other information for governments, NGOs, UN agencies and others to assist country negotiations on medicine and diagnostics prices.
- **WHO resources:**
 - Global report on access to hepatitis C treatment (www.who.int/hepatitis/publications/hep-c-access-report/en)
 - Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection (www.who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en)
 - Monitoring and evaluation for viral hepatitis: Recommended indicators and framework (www.who.int/hepatitis/publications/hep-b-c-monitoring-evaluation/en)
 - Manual for the development and assessment of national viral hepatitis plans (www.who.int/hepatitis/publications/manual-hep-plan/en)
 - Standards and tools to strengthen country monitoring and evaluation (www.who.int/healthinfo/topics_standards_tools/en).

ABBREVIATIONS

AD

auto-disable

CHAI

Clinton Health Access Initiative

CLs

compulsory licenses

DAA

direct-acting antiviral

EML

Essential Medicines List

GAVI

Global Alliance for Vaccines and Immunization

GNI

Gross National Income

HBsAg

hepatitis B surface antigen

HBIG

hepatitis B immunoglobulin

LMICs

lower middle-income countries

NGO

non-governmental organization

PBS

Pharmaceutical Benefits Scheme

SDGs

Sustainable Development Goals

TB

tuberculosis

TRIPS

Trade-Related Aspects of Intellectual Property Rights

UHC

Universal Health Coverage

UMICs

upper middle-income countries

VH

viral hepatitis

WHO

World Health Organization

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