



ELIMINATING VIRAL HEPATITIS

THE INVESTMENT CASE

Appendix to the Report of the WISH Viral
Hepatitis Forum 2018

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CASE STUDY 1

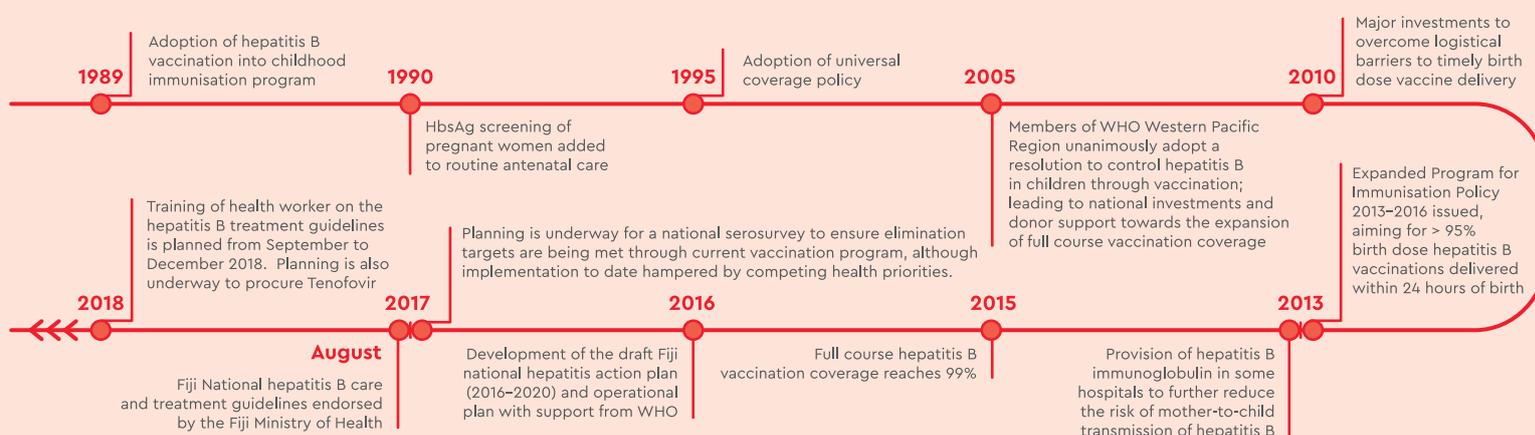
The case of Fiji – Upscaling hepatitis B prevention in low income settings through improved antenatal and obstetric care

Population total (2017)	884,887
Life expectancy at birth total	70 years
GNI per capita (US\$)	\$4,780
HBsAg-positive population (prevalence, 2014) ¹	38,400 (4.8%)

Fiji is part of the Pacific Islands and Territories and comprises more than 100 inhabited islands. The country has moderate-high prevalence of hepatitis B, with 4.8% of its population chronically infected. In the WHO Western Pacific Region to which Fiji belongs, hepatitis B-related mortality is greater than for tuberculosis, HIV infection and malaria combined. ^{2,3}

Fiji invested substantially in antenatal care and improvements in healthcare access to ensure virtually 99% of the Fijian population deliver their babies within a health facility or with a skilled birth attendant where hospital access is not possible.⁴ These investments have not only improved antenatal care and maternal and child outcomes, but provided the vehicle for successful delivery of the hepatitis B vaccine to all newborns. In 2014, hepatitis B birth dose vaccination coverage had increased to 98% and increased vaccination coverage has resulted in substantial reductions in the HBsAg prevalence among children under 5 years, from 5–10% prior to 1995 to 0.7% by 1998.⁵

Fiji offers government subsidised, quality assured hepatitis B testing for all and blood donation screening for hepatitis B. Despite limited health infrastructure, diverse geographical populations and no GAVI sponsorship of national vaccination programs in Fiji, the WHO 2017 milestone of < 1% prevalence among children under 5 years was achieved.⁶Case study 2



CASE STUDY 2

The case of Georgia – a global leader in the hepatitis C elimination efforts

Population total (2016)	3.72 million
Life expectancy at birth, total	73.3 years
GNI per capita, Atlas method (current US\$)	\$3,830
HCV cases (prevalence, 2015)	150 000 (7.7%) ¹
HBsAg-positive population (prevalence, 2015)	(2.64%) ²

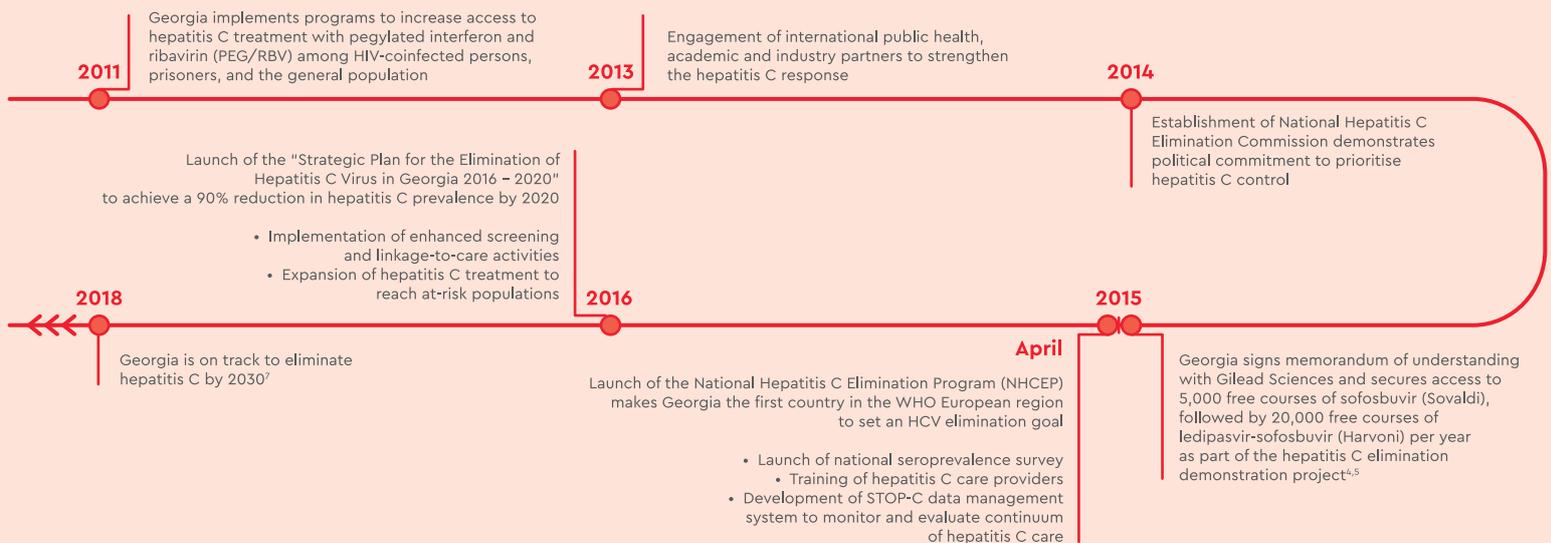
Committed to addressing the public health threat of hepatitis C, Georgia became the first country in the WHO European region to set its hepatitis C elimination goal. Georgia's significant experience with HIV prevention and control programs and the existing human and technical capacities to implement large-scale health programs facilitated the implementation of a national hepatitis C elimination program.³ An international Technical Advisory Group (TAG) assisted with proposing strategies, objectives, and actions that would address gaps in advocacy and awareness, surveillance, harm reduction, blood safety, infection control and evidence-based screening and linkage to care.

The program's first objective was to increase access to affordable diagnostics; provide free DAA treatment to persons with severe liver disease at highest-risk of HCV-related mortality; and build capacity to achieve program goals of prevention of transmission and elimination of the disease.⁴

The second phase intends to expand its scope and treat every person chronically infected with HCV, as outlined in the "Strategic plan for the Elimination of Hepatitis C Virus in Georgia, 2016–2020". Hepatitis C treatment services are provided at treatment centres located throughout the country and patients are charged based on their ability to pay using a sliding-scale approach for diagnostics and clinical monitoring. Importantly Georgia is working to integrate the hepatitis C elimination program into the overall health system as this will benefit the management of other health problems such as HIV and TB.⁵

The implementation of the national action plan has increased access to hepatitis C testing and linkage to care, as well driving improvements in monitoring and surveillance, infection control and prevention.^{3,5} The evaluation of a harm-reduction based peer-supported HCV treatment demonstrates excellent treatment uptake and retention among PWID based in Tbilisi.⁶

By August 2017, almost 40.000 people had initiated treatment with the new DAAs, of which almost 32,000 had already achieved hepatitis C cure.



CASE STUDY 3

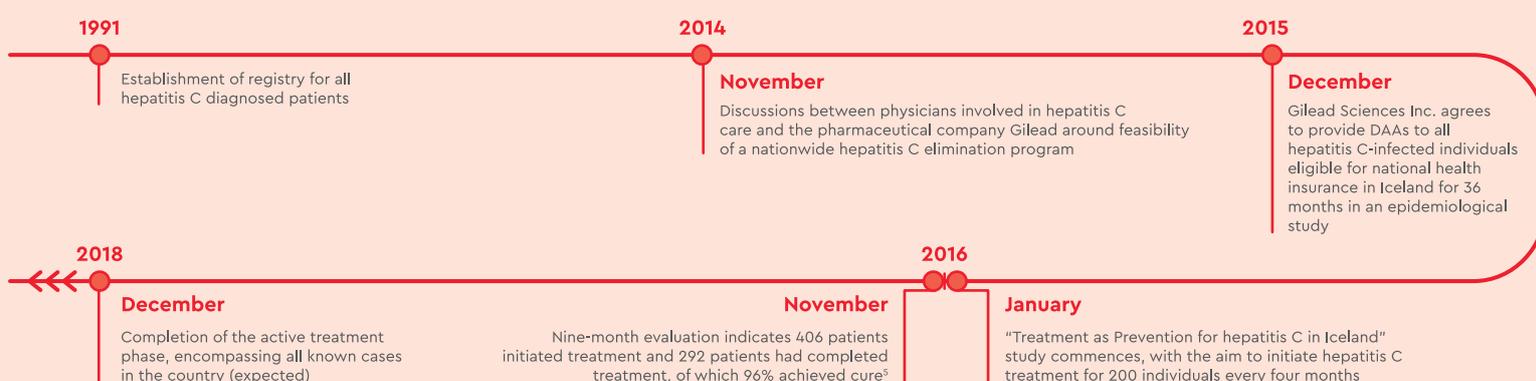
The case of Iceland – implementing a nationwide hepatitis C treatment as prevention program

Population total (2016)	335,439
Life expectancy at birth, total	82.5 years
GNI per capita, 2015 (US\$)	\$56,760
Hepatitis C viraemic population (prevalence, 2014 ¹)	1100 (0.3%)
HBsAg-positive population (prevalence, 2013 ²)	448 (0.14%)

Iceland is a high-income country whose population of 340,000 is covered by national health insurance. Approximately 1100 Icelanders are chronically infected with hepatitis C, the majority of whom have a history of injecting drug use.³

In 2016 Iceland launched a nationwide hepatitis C elimination program offering direct-acting antiviral (DAA) therapy to everyone infected with hepatitis C. Aiming to treat the majority of patients within the first two years of the program, the initial focus was on reaching people who inject drugs, prisoners and those at highest risk of liver cirrhosis. Rapid point-of-care testing for hepatitis C and HIV facilitates access to hepatitis diagnostics and treatment for hard to reach populations. To further stimulate uptake of hepatitis C care, testing and treatment activities are complemented by tailored public awareness campaigns in the mass media.

This multipronged approach, combining improved harm reduction strategies, scale-up of prevention, testing and early treatment of hepatitis C in hospital and community settings puts Iceland on track to achieving hepatitis C elimination well in advance of the 2030 WHO elimination targets.⁴



CASE STUDY 4

The case of India – addressing the challenges of viral-hepatitis via bottom-up, community-based health programmes

Population total (2016)	1.324 billion
Life expectancy at birth, total	86.6 years
GNI per capita (US\$)	\$1,670
HBsAg-positive population (prevalence, 2014) ¹	17.55 million (1.46%)
Hepatitis C viraemic population (prevalence, 2012) ²	8.66 million (0.7%)

Given its population size, the immense burden of hepatitis B and hepatitis C in India contributes enormously to the global disease burden. The country has played an important role in the progress against HIV in low-income countries by providing affordable generic alternatives to anti-retroviral therapy. A combination of pharmaceutical manufacturing capacity and political will helped with the expansion of the global HIV drug market, supported by technology transfer from and partnership with research and development-based pharmaceutical companies.³

Indian pharmaceutical manufacturers continue to play a vital role in global efforts to address hepatitis C by supplying affordable direct-acting antivirals to the 105 and 112 low- and middle-income countries included in the voluntary licence agreements of originator companies Gilead Sciences Inc. and Bristol-Myers Squibb.⁴⁻⁶

On a national level, India is facing numerous complex challenges on the path to achieving the WHO elimination targets. Grassroots' and community-based initiatives are responding by developing innovative measures towards ending illness and death from chronic hepatitis B and hepatitis C in the communities.

Community Network for Empowerment (CoNE) – Completing the hepatitis C screening, diagnosis & treatment cascade

Based in Manipur state, India, the network of community organisations for people who use drugs (CoNE) plays an important role in the response to HIV and viral hepatitis for at-risk populations.

A cycle of interventions developed and implemented by CoNE aim to improve access to hepatitis C testing, diagnosis, and treatment among marginalised populations and people diagnosed with hepatitis C.; made possible through a public-private partnership between the Department of Health, pharmaceutical manufacturers, and community-based organisations.

Integrated activities towards eliminating hepatitis C by improving uptake of hepatitis C care include:

- Active outreach and mobilization of hidden high-risk populations to increase demand for hepatitis C testing and treatment
- Testing and treatment provision for inmates in Manipur's central prison
- Camps for knowledge, awareness, and confidence building among key populations; including opportunities for testing and post-test counselling
- RNA-testing provided by CoNE free of charge for people with limited capacity to pay, or through preferential pricing as negotiated with pharmaceutical manufacturers
- DAA-treatment provided free of charge or through preferential pricing

Advocacy in print and digital media addresses stigma and discrimination and helps raise hepatitis C awareness in the general population. CoNE uses political advocacy to facilitate the broadening of eligibility criteria for access to subsidised DAAs and reimbursement scheme. The network is developing training resources and hosting training workshops for health personnel to increase prescribing capacity among physicians across the state, and improve knowledge and awareness among health care workers. It has also contributed to the development of appropriate education material for people who use drugs.

Finally, CoNE is involved in continuous negotiations and advocacy with pharmaceutical manufacturers and laboratories to provide preferential prices for hepatitis C treatment. Since November 2014, more than 3000 people have accessed hepatitis C testing in 76 viral hepatitis camps.

The Yuvroshni Project – taking action to stanch the hepatitis B and hepatitis C virus in Mumbai slums

With over 18 million residents Mumbai is India's most populous city, facing enormous challenges in controlling the spread of hepatitis B and hepatitis C in its poorest, most densely populated areas. In 2011, the non-governmental

organisation United Way Mumbai launched the Yuvroshni Project for Prevention of Hepatitis B & C Infections to overcome these challenges. The project comprised of medical interventions and preventive education among the general population and at-risk groups in the Mumbai slums. These activities were carried out in collaboration with medical providers, community outreach workers, local non-governmental organizations, community-based organizations, student volunteers and Mumbai's public health department.

The project evaluation highlighted its participatory approach as a particular strength of the project; health outreach workers and student volunteers in the project were able to increase their hepatitis awareness, learn about the challenges in prevention efforts and experience the benefits of a community-led strategy to address community issues.⁷

CASE STUDY 5

Malaysia – low-cost DAAs for middle-income countries

Population total (2016)	31,190,000
Life expectancy at birth, total	75 years
GNI per capita, Atlas method (current USD)	\$9,860
Chronic hepatitis C cases (prevalence, 2017 ¹)	380,000 (2.5%)
HBsAg-positive population (prevalence, 2017 ²)	291,000 (0.9%)

Malaysia made a commitment to address its high hepatitis C burden and achieve the WHO elimination targets by 2030, requiring a drastic scale-up in both hepatitis C screening and treatment.³ An exclusion from Gilead's voluntary licensing agreement, which prioritises low- and middle-income countries with greatest disease burden⁴⁻⁶ impeded Malaysia capacity for treatment scale-up. A 12-week course of treatment with sofosbuvir cost nearly half the average annual household income in Malaysia (US\$ 12,000),⁷ putting it well out of reach of most patients. In response, Malaysian NGOs lobbied the government to issue a compulsory licence and expand access to effective direct-acting antiviral (DAA) therapy in the public health sector.

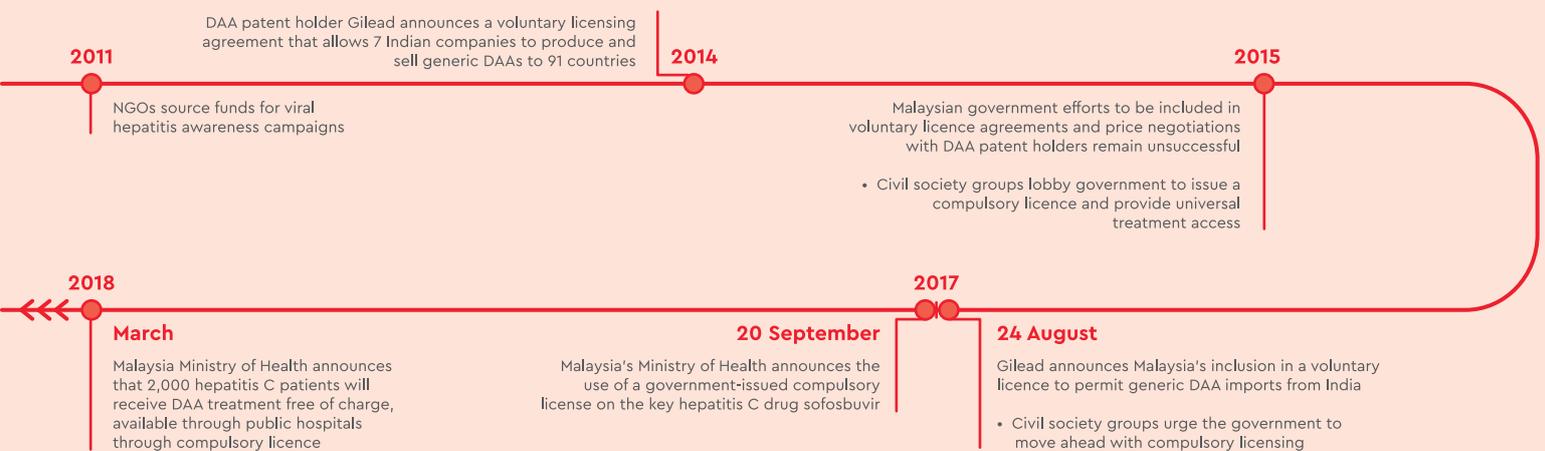
Compulsory licences allow local production or importation of generics from other countries, predominantly for the supply of the domestic market without the consent of the patent holder and against royalty payments to the holder to the patent. However, countries who enact a compulsory licence may face significant opposition from manufacturers defending their patent monopoly or from high income countries that have multinational pharmaceutical companies, although it is within their rights.⁸ There are important lessons to be learned from the use of TRIPS flexibilities including compulsory licensing in the procurement of low priced medicines for the treatment of HIV.

The Malaysia case shows the direct and indirect power of compulsory licensing.⁹ When Malaysia decided to issue a compulsory licence for sofosbuvir, Gilead announced the inclusion of Malaysia, Thailand, Ukraine and Belarus in their licence agreement. Malaysia proceeded to issue a compulsory licence which permits

the import of high quality generics from an Egyptian manufacturer at affordable prices.⁷ The compulsory licence enables access to generic DAA regimens of sofosbuvir and daclatasvir in 18 public hospitals in Malaysia free of charge.

Malaysia's inclusion in the voluntary license further enables access to other DAA combinations and will support treatment scale-up nationwide, including through all private and university hospitals.

Malaysia aims to treat all 23,000 patients in the hepatitis registry and to progressively increase testing and treatment over time.¹⁰



CASE STUDY 6

The case of Pakistan – treatment and prevent of transmission in health care settings

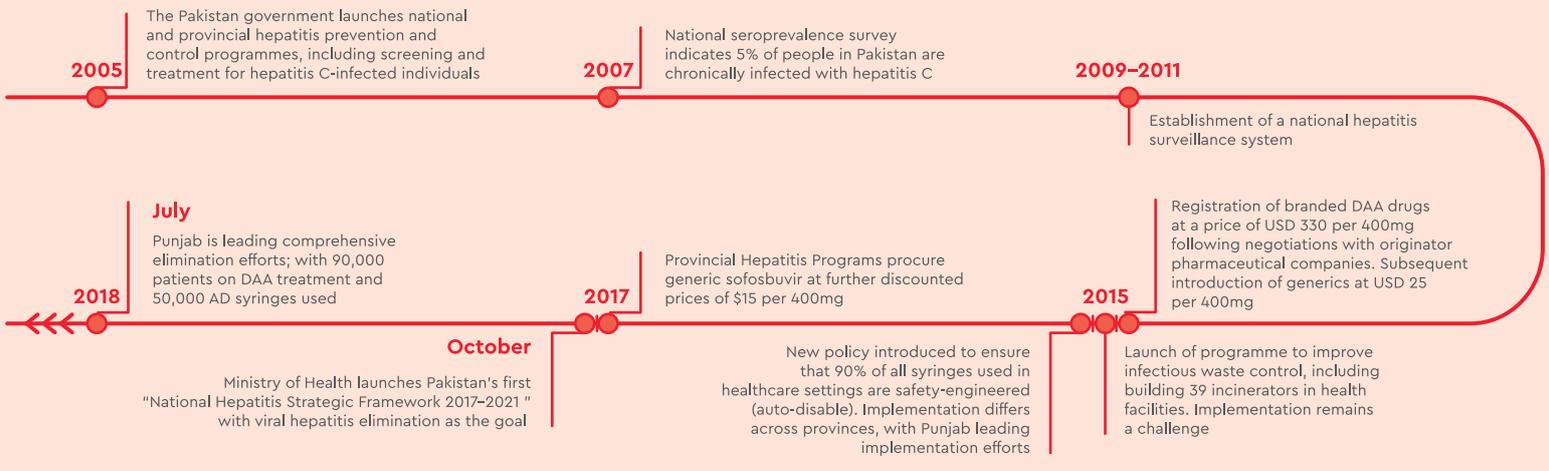
Population total (2018)	193.2 million
Life expectancy at birth, total	66.5 years
GNI per capita (US\$)	\$1,500
HCV cases (prevalence, 2013)	7.04 million (5.6%) ¹

Pakistan is a lower-middle income country that harbours 10% of the global hepatitis C burden.²

Modelling data suggests at least 880 000 annual direct-acting antiviral treatments are required to achieve hepatitis C elimination by 2030. Targeting treatment towards persons with cirrhosis and people who inject drugs would reduce this number to 525 000 annual treatments, based on the premise that prevention activities halve current transmission risks.²

Risk factors for hepatitis C transmission in Pakistan are primarily health system related; including unnecessary injections and poor infection control practices in the healthcare setting.³ Few hepatitis C-infected individuals know their status,⁴ calling for a significant upscale of testing and linkage to care.

Significant political commitment to address this public health concern enabled the launch of the National Hepatitis Strategic Framework 2017–21 in Pakistan. New policies target iatrogenic transmission. Automatic screening of all patients in contact with the hospital system improves hepatitis C diagnosis rates.² Following negotiations between the National Technical Advisory Group of hepatitis experts and originator pharmaceutical companies, new DAAs were registered in Pakistan at a 98% discount from the US market price. Subsequently, generic competition has resulted in DAA prices of US\$ 40–50 per 12-week course – to date the lowest price worldwide.^{4,5} This has set the stage for scale-up of treatment by the public sector. Pakistan now provides free diagnosis, treatment and care to hepatitis patients in all provinces, through four Hepatitis Prevention and Control programmes.⁶ Implementation is challenging and the scale of treatment delivery differs between provinces. With 90,000 patients on DAA treatment in 2018, the province of Punjab is currently spearheading elimination efforts. More recently significant efforts to scale up treatment have commenced in other provinces such as the Sindh where an initiative to treat 7000 individuals in high prevalence districts has commenced.



CASE STUDY 7

The case of Portugal – demonstrating immediate impact of strategic investments in hepatitis C

Population total (2016)	10.33 million
Life expectancy at birth, total	81.1 years
GNI per capita (US\$)	\$19,870
HCV cases (prevalence, 2015)	82640 (0.8%) ¹

Considering its many fiscal, political and social challenges in developing HCV policies – including a low investment in public health, high number of undiagnosed patients, and outdated HCV care guidelines – Portugal's willingness and ability to provide universal access to HCV treatment today is remarkable. Portugal provides a striking example that policy change is possible, using evidence-based, data-driven and decision-oriented policy making.¹

Portugal negotiated a volume-based agreement with the direct-acting antiviral (DAA) originator company, Gilead Science Inc.. Importantly, this was the first value-based/risk-sharing agreement in which pharma companies were paid per cure as opposed to paying per pill or per cycle of treatment. The full negotiation and payment procedures are centralized by the government, freeing up hospital boards to focus on treating as many patients as possible instead of limiting access due to budget constraints.

All new DAAs have become available in Portugal, leading to an overall reduction of hepatitis C treatment cost such that DAA prices are no longer a limiting factor to the Portuguese hepatitis C response. Challenges remain in the prevention, testing, and diagnosis of HCV as the majority of patients are currently undiagnosed. Similarly, the expansion of HCV treatment access in prison settings is still pending.

As of March 2018, over 19,274 patients have been diagnosed with chronic hepatitis C in the Portuguese national hepatitis C registry and their treatment has been authorised; nearly 17,432 patients initiated treatment and 9,897 patients have been proven clinically cured.

Preliminary impact evaluations suggest a 73% reduction in the incidence of hepatocellular carcinoma; a 92.5% reduction in the need for liver transplants due to hepatitis C; and a 93.2% reduction in the development of cirrhosis.²

It is thus estimated that **the implementation of Portugal's National Action Plan reduced the lifelong healthcare cost by >270 million euros in total, or >30 000 euros per patient.**³

October 2013 – March 2014

Organized by the Católica University of Portugal, a think tank comprising of scientists, physicians, health managers, politicians and patients convenes to generate a consensus paper on hepatitis C management in Portugal

May 2014

Católica University of Portugal present the conclusions of the think tank as a book entitled "Strategic consensus on the integrated hepatitis C management in Portugal" highlighting the need for an overall focus on hepatitis C elimination and outlining key activities for hepatitis C prevention and control

2014

Introduction of direct-acting antiviral therapy to the Portuguese market

2017

Development of National Action Plan for Hepatitis C and review of clinical guidelines to include all new direct-acting antivirals

Implementation of a centralised registry database to monitor and facilitate hepatitis C treatment uptake. Patients are recalled into the health services once treatment has been authorized and made available

2015

February

- In a parliament hearing of the Minister of Health, patients in protest demand the minister "not to let them die"
- Conclusion of price negotiations with Gilead, resulting in a performance-based price-volume agreement for the procurement of direct-acting antivirals
 - The Portuguese government announces full access for all hepatitis C diagnosed patients, covered by the National Healthcare System

CASE STUDY 8

The case of Qatar – working to achieve viral hepatitis elimination by 2030

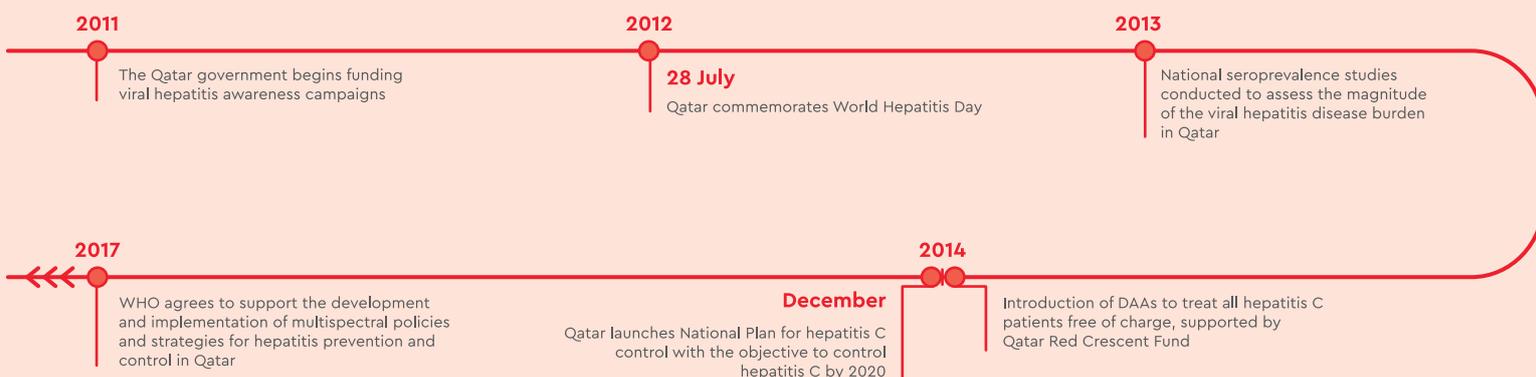
Population total (2016)	2.56 million
Life expectancy at birth, total	78.2 years
GNI per capita, 2015 (US\$)	\$75,660
HCV cases (prevalence, 2010)	1550 (0.5%) ^{1,2}
HBsAg-positive population (prevalence, 2013)	30.191 (1.73%) ¹

Qatar has low endemicity for hepatitis B and hepatitis C. Data collected from 2008 to 2010 indicate a hepatitis C antibody prevalence of 0.8% among Qatari national adults, with prevalence highest in the oldest age group in the study (55–65 years) and higher among men than women.¹

Approximately 1.7% of Qatari nationals are chronically infected with hepatitis B but effective prevention efforts are ongoing. In recent years virtually 100% of newborn infants received the first dose of hepatitis B vaccine within 24 hours of birth and 95% of one-year-olds (ages 12–23 months) received three doses of hepatitis B vaccine.²

Qatar is currently implementing a national plan for hepatitis C control, developed by a group of stakeholders from the Ministry of Public Health and supported by Hamad medical corporation. This plan incorporates investments in infrastructure for monitoring and surveillance, health systems strengthening, hepatitis C awareness campaigns, opportunistic screening activities including through rapid point-of-care testing, and procedures to ensure the continuum of care for diagnosed hepatitis C patients.^{3,4}

With the availability of effective direct-acting antiviral (DAA) therapy for hepatitis C and a commitment to upscale testing and provide treatment free of charge,³ Qatar is well positioned to achieve the WHO viral hepatitis elimination targets by 2030.^{5,6}



CASE STUDY 9

The case of South Africa – investment case for viral hepatitis in South Africa

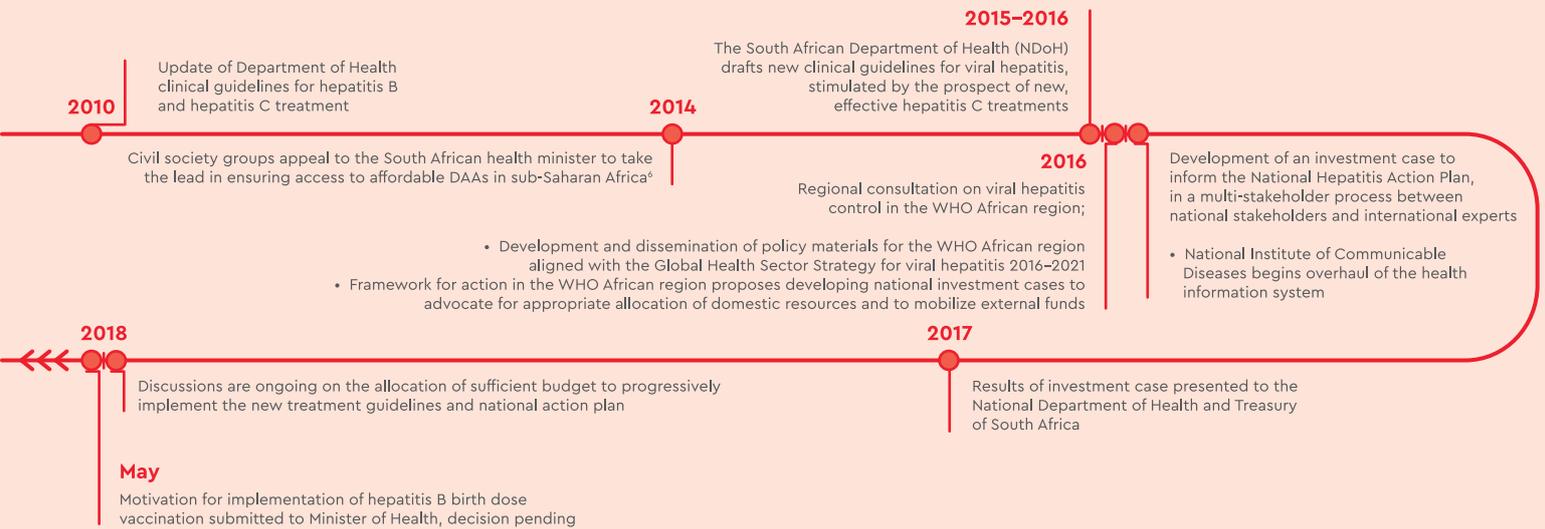
Population total (2016)	56.01 million
Life expectancy at birth, total	62.8 years
GNI per capita (USD)	\$5,480
HCV cases (prevalence, 2015)	356 000 (0.7%) ¹
HBsAg-positive population (prevalence, 2014)	3.5 million (6.7%) ²

South Africa's National Action Plan 2017–2021 is one of the first examples of an investment case that combines tools for costing, impact modelling, cost-effectiveness analysis, and fiscal space analysis for scaled-up hepatitis B and hepatitis C disease control scenarios.³ The action plan was developed in collaboration with leading South African experts, Ministry of Health officials, and external specialists in global health policy and economics who assessed cost and affordability, health impact and cost-effectiveness for four priority interventions: hepatitis B birth dose vaccination, prevention of mother to child transmission, hepatitis B treatment and hepatitis C treatment.

The model suggested expanded hepatitis B prevention and treatment and hepatitis C treatment (using DAAs) was cost-effective and affordable,³ outlining that hepatitis B birth dose vaccination should be prioritised if sufficient funds were not available to implement the full plan. The estimated cost of the five-year Action Plan was US\$270 million, whereby most funds would be consumed by the testing, care and treatment component. Whilst a significant amount of money, the cost of the Hepatitis Action Plan was estimated to be less than 4% of the projected five-year HIV expenditure in South Africa.⁴ Integrating the action plan into the existing health system, particularly maternal and child health and HIV/AIDS, would improve the feasibility of implementation.

The modelling data suggests this initial five-year investment could avert an estimated 13 000 hepatitis B-related deaths and 7000 hepatitis C-related deaths. Moreover, Hecht and colleagues demonstrate that a continued expansion of the treatment program beyond 2021 has the potential to avert 672 000 hepatitis B-infections and 60 000 deaths averted from hepatitis C-related liver disease, which would put South Africa well on the path to achieve elimination by 2030.³

The investment case on the cost effectiveness and affordability of hepatitis control and elimination developed by South Africa and the multi-stakeholder approach used provide an important template for the development of similar investment cases for other countries, as recommended by the WHO.⁵



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