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Pedrana, Alisa; Howell, Jessica; Scott, Nick; Schroeder, Sophia; Kuschel, Christian; Lazarus, Jeffrey V.; Atun, Rifat; Baptista-Leite, Ricardo; 't Hoen, Ellen; Hutchinson, Sharon J.; Aufegger, Lisa; Peck, Raquel; Sohn, Annette H.; Swan, Tracy; Thursz, Mark; Lesi, Olufunmilayo; Sharma, Manik; Thwaites, John; Wilson, David P.; Hellard, Margaret Published in:

The Lancet Gastroenterology & Hepatology

DOI:

10.1016/S2468-1253(20)30010-8

Publication date: 2020

Document Version Author accepted manuscript

Link to publication in ResearchOnline

DP & Hellard, M 2020, 'Global hepatitis C elimination: an investment framework', *The Lancet Gastroenterology & Hepatology*, vol. 5, no. 10, pp. 927-939. https://doi.org/10.1016/S2468-1253(20)30010-8

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Download date: 24. Apr. 2022

Global hepatitis C elimination: an investment framework

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Disclosure of Interest Statement: The Qatar Foundation provided funding for the initial World Innovations Summit for Health report to the Burnet Institute. The funders had no role in the decision to publish or preparation of the manuscript. AP has received investigator-initiated research funding from Gilead Sciences, MSD and AbbVie, and honoraria from Gilead Sciences unrelated to this work. JVL reports grants and personal fees from AbbVie, Gilead Sciences and MSD, personal fees from CEPHEID, GSK and Janssen outside the submitted work. MH and and the Burnet Institute receive investigator-initiated research funding from Gilead Sciences, Abbvie and BMS. NS receives investigator-initiated research funding from Gilead Sciences unrelated to this work. JH received the Gilead Sciences Australia fellowship (2017) and and honoraria from Gilead Sciences. AHS reports institutional grants and travel funding from ViiV Healthcare. ETH is the former director of the Medicines Patent Pool. MS holds a research grant from the Qatar National Research Fund. SJH received honoraria from Gilead, unrelated to submitted work. DW, CK, SS, RA, RBL, LA, RP, TS, MT, LO and JT declare no competing interests.

Acknowledgements: We would like to acknowledge the contributions of Mary Ribeiro Pombo (Imperial College London), M. Walid Qoronfleh (World Innovation Summit for Health, Qatar), Deidre Thompson (Imperial College London & World Innovation Summit for Health) to the WISH 2018 Viral Hepatitis Forum. We also would like to thank Stephanie Luketic (Burnet Institute). JVL is supported by a Spanish Ministry of Science, Innovation and Universities Miguel Servet grant. The authors gratefully acknowledge the contribution to this work of the Qatar Foundation. The authors gratefully acknowledge the support to the Burnet Institute provided by the Victorian Government Operational Infrastructure Support Program. AP, JH and MH are the recipients of National Health and Medical Research Council fellowships. The authors gratefully acknowledge the contributions of Campbell Aitkin for his role in review & editing of this manuscript.

Authors' contributions: AP, MH, JH, SS, NS, JVC and DW jointly conceived of the study and were involved in critical review and interpretation and the writing of the manuscript. AP, JH and SS reviewed the literature and AP drafted the manuscript. NS and CK devised, programmed, and ran the model. All authors were involved in revising the manuscript and messaging of results.

Keywords: hepatitis C; disease elimination; universal health coverage; cost-effectiveness; return on investment.

Word count: 4476

Summary

The World Health Organization (WHO) has set global targets for the elimination of hepatitis B and hepatitis C as a public health threat by 2030. However, investment in elimination programs remains low. To drive political commitment and catalyse domestic and international financing, we developed the first global investment framework for the elimination of hepatitis B and hepatitis C. This manuscript focuses on the hepatitis C investment framework. The work was accompanied by modelling demonstrating the cost of scaling up hepatitis C-specific elimination activities to meet WHO's targets, considering both direct and indirect economic benefits. The investment framework outlines national and international activities that will enable reductions in hepatitis C incidence and mortality and identifies potential sources of funding and tools to help countries build the economic case for investing in national elimination activities. The modelling demonstrated how strengthening health systems, through improving workforce capacity and surveillance systems and integrating activities into universal health programs, can improve coordination and optimize resource allocation, making hepatitis C elimination cost-saving by 2027, with a net economic benefit of US\$22.7 (\$17.1-27.9) billion by 2030. This is the first global investment framework for hepatitis C elimination; it demonstrates a way forward for countries, particularly those with limited resources, to gain the substantial economic benefit and cost savings that come from investing in hepatitis C elimination.

Funding: This work received funding from the Qatar Foundation as part of their support for the World Innovations Summit for Health, 2018. The funders had no role in the decision to publish or the preparation of the manuscript. This work received no NIH funding, and no authors are employed by NIH, or receipt funding from an NIH grant for this work.

Search strategy and selection criteria

References published between 2010 and May 1, 2019 were identified through searches of PubMed, MEDLINE; EMBASE and grey literature, using the search terms "viral hepatitis", "hepatitis C", "prevention", "testing", "treatment", "elimination", "financing", "economic modelling" and "cost-effectiveness". In addition, we reviewed published case studies, reports and interviewed global experts including epidemiologists, clinicians, community advocates, public health experts and policymakers, to inform the framework and identify countries that have achieved viral elimination targets. Only papers published in English were reviewed. The final reference list was generated on the basis of originality and relevance to the broad scope of this review.

Introduction

In 2016, the World Health Assembly adopted the WHO Global Health Sector Strategy (GHSS) on Viral Hepatitis 2016–2021,(1) which provided a roadmap for the elimination of hepatitis B and hepatitis C and outlined clear elimination targets, including an 80% reduction in new chronic infections and a 65% reduction in mortality compared to 2015 levels. While 194 countries have endorsed the strategy, far fewer have developed national plans for viral hepatitis elimination,(2) with a minority adopting a public health approach to eliminating viral hepatitis. In many countries the major barriers to a comprehensive response are leadership and political will, exacerbated by competing priorities and scarce resources,(1) particularly in high-endemicity areas.(3) A recent *Lancet Gastroenterology* & *Hepatology* Commission – focusing on 'Accelerating the elimination of viral hepatitis'(3) – identified 20 heavily burdened countries that account for over 75% of the global burden of viral hepatitis and highlighted the need for these countries to mobilise domestic funding to address it. The Commission outlined innovative financing models to support country-level elimination programmes, and called for the development of an investment case for viral hepatitis to demonstrate the feasibility of elimination and quantify its health, social, and economic benefits.

With an estimated 71 million people living with the hepatitis C infection, at current rates hepatitis C will account for 0.84 million deaths annually by 2040 due to cirrhosis and liver cancer.(4) However, new treatments known as direct-acting antivirals (DAAs) have revolutionised hepatitis C care, with cure rates of over 95% following 8–12 weeks of once-daily well-tolerated tablets, providing a unique opportunity to eliminate hepatitis C as a global public health threat. Since DAAs became available in 2013,(5) they have been shown to reduce the risk of liver failure and liver cancer (6, 7) and improve patients' quality of life.(8, 9) A full course of generic DAAs can now be purchased for less than US\$100 in multiple countries,(10) but are cost-effective even at a much higher cost across a range of

low, middle, and high-income country settings.(11, 12, 13) Nonetheless, globally, treatment coverage remains low, with an estimated 1·5 million people initiating DAA-based treatment by 2016, leaving the majority of people living with hepatitis C infection untreated.(14) Emerging data on the productivity losses associated with hepatitis C, and conversely the improvements in productivity post-cure (15-17), will help quantify the broader economic losses attributable to hepatitis C (18, 19). A recent WHO costing exercise (20) estimated that a total cost of \$16·0 billion was needed for hepatitis C testing and treatment costs, in addition to \$20·5 billion for programme costs to implement the elimination of hepatitis by 2030 among 67 countries. Identifying sources of investment and building the economic case for countries to invest in national hepatitis C-related activities will be critical to achieving global elimination targets.

In 2011, to capitalise on strong political commitment, an investment approach for an effective response to HIV/AIDS was published, and was seen as a major turning point in the HIV epidemic.(21) It demonstrated how major efficiency gains could be realised through the rapid scale-up of HIV/AIDS prevention, treatment, and care programs, by harnessing social mobilisation, increasing synergies between programme elements, and promoting the benefits of treatment as prevention. A comparable, strategic approach to investment in prevention, testing and treatment activities for hepatitis B and hepatitis C elimination is needed.

A global investment framework for viral hepatitis elimination

Building on the work of the WHO GHSS on viral hepatitis (2016),(1) we developed a strategic investment framework (**Figure 1**) for the global elimination of hepatitis B and hepatitis C by 2030. While these diseases have different epidemic characteristics, they share many similarities in health system requirements and approaches for effective disease control,(3) including interventions to prevent infections (safety of blood supply, safety of health care-associated injections) and testing

and treatment programmes that are delivered through common platforms (population-based, community-level, heath centre, primary, secondary, tertiary-level hospitals) and workforces (specialists, doctors and nurses).(22) The framework adopts a public health and health systems strengthening approach to identify national and international activities that would support country-level implementation of viral hepatitis elimination strategies across diverse settings. For the purposes of this paper, we focus on hepatitis C elimination to demonstrate how policymakers and others can use this framework to support and justify investment in hepatitis C activities.

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An investment framework for hepatitis C elimination

Firstly, the framework identifies the importance of using multiple financing mechanisms to encourage investment from domestic, private sector and international sources and enable policymakers and financiers to galvanise support for action. Secondly, the framework identifies activities that countries and international agencies can implement, along with critical enablers to allow the effective implementation of hepatitis C programmes at scale. Finally, the framework outlines the economic benefits of achieving hepatitis C elimination, including direct, indirect and cross-sectoral economic benefits, and the broader benefits that investment can provide through health systems strengthening. To demonstrate the impact of the investment framework, we modelled two investment scenarios for hepatitis C: elimination – where investments in activities were scaled up to meet the WHO 2030 diagnosis and treatment elimination targets, and progress where more modest investments in activities were made to implement current WHO screening guidelines. The models estimate the impact, cost, cost-effectiveness and economic benefits over time of both scenarios at a global and WHO regional level. Uniquely, the models estimate the economic productivity losses associated with hepatitis C infection due to absenteeism and presenteeism. A detailed model description and additional findings are explored in the accompanying modelling paper.(23)

Financing hepatitis C elimination activities

Hepatitis C elimination will require considerable leadership, political will, and financial investment. Global financing mechanisms, such as the Global Fund, (24) Gavi, (25) and Unitaid, (26) have successfully brought together elements of the financing value chain to mobilise, pool and invest in or "replenish" health programmes.(27) As of July 2018, the Global Fund had disbursed more than \$38 billion (24) for HIV/AIDS, tuberculosis, malaria, and health systems. However, its recent global strategy 2017–2022 did not mention hepatitis C.(28) More directly, Unitaid (26) has invested \$60 million since 2013 in programmes that aim to develop better, simpler, point-of-care diagnostic tools and support countries to negotiate gain access to cheap hepatitis C medicines, and integrate hepatitis C testing and treatment into HIV programmes.(29) However, in the current context of shrinking aid budgets and reduced development assistance for health, (30) significant new funding to support a global response to hepatitis C elimination is unlikely. For most countries, funding for hepatitis C programmes will be reliant on domestic and innovative financing sources and blended finance instruments to sustain and scale up health programmes.(27) Domestic sources already account for most of the funding for the development of country-level responses to hepatitis C,(3) highlighting the need for clear strategies to enable countries to support intervention scale-up and delineate stakeholder responsibility, accountability, and funding models.

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In 2016, a report (31) on innovative financing of hepatitis B and hepatitis C prevention and treatment in low and middle-income countries (LMICs) outlined how a combination of funding mechanisms, adapted to the context of the country, payers and patients, will be needed to accurately target country-specific challenges. It promoted public-private partnerships with a focus on non-infrastructural interventions and a shared value approach to enable countries to partner with pharmaceutical and diagnostic companies where there are clear synergies between public health programmes and companies' commercial activities. In 2018, the United Nations Secretary-

General launched the Strategy for Financing the 2030 Agenda for Sustainable Development, (32) which identified actions to support countries to accelerate financing the Sustainable Development Goals (SDGs), including aligning global economic policies and financial systems with the 2030 Agenda; enhancing sustainable financing strategies and investments at the regional and country levels; and seizing the potential of financial innovations, new technologies and digitisation to provide inclusive and more equitable access to finance.

Positioning national hepatitis C responses within a framework of universal health care (UHC) and the broader SDGs (1) can enable policymakers to leverage the roll-out of UHC for investment in hepatitis C programmes while facilitating prevention, diagnosis and early management of other major health conditions, including liver cancer, hepatitis B, HIV, tuberculosis, and other chronic diseases such as diabetes and hypertension.(33) Many of the strategies and infrastructure required for hepatitis C elimination can be effectively added to existing HIV (and potentially tuberculosis and other UHC) programmes at little additional cost,(34) with examples of this currently underway in Georgia (35), Rwanda (36), and Ukraine (37). Multiple policy and economic mechanisms can be utilised to improve the affordability of hepatitis C elimination. **Table 1** summarises theses and describes how these mechanisms have been utilised to finance various health-related issues, with reference to countries where these approaches have been implemented successfully.

Key elimination activities

Our investment framework identifies *national* and *international* activities that would support the elimination of hepatitis C, along with critical enablers to allow hepatitis C programmes to be

implemented effectively at scale (Table 2). These were framed to address existing challenges that underpin the lack of investment and action in many countries, which are often interlinked and have cascading impacts that perpetuate each other in a negatively reinforced cycle (Figure 2). For example, many LMICs with a growing hepatitis C disease burden lack a formally costed hepatitis C elimination programme. This can arise from a lack of awareness among policymakers about the burden of hepatitis C-related disease and potential benefits of prioritization of hepatitis C elimination. This lack of awareness of the disease burden is often driven by inadequate data and weak surveillance systems. These in turn reduce governments' capacity to prioritize resource allocation for national viral hepatitis elimination action plans and limited public sector-optimized procurement of medicines or diagnostics. Countries then have fragmented procurement, rather than national pooled procurement; this can lead to a high mark-up in drug prices from pharmaceutical companies, and the perception that DAAs are expensive. This in turn prevents national programme managers from investing and consequently they miss valuable opportunities to appropriately invest in hepatitis C elimination and maximise the return on investment. **Table 2** details the national and international activities and key enablers of hepatitis C elimination, tools to support the implementation of these activities, and countries that are successfully implementing activities. National activities include purchased commodities and programmes that have a direct effect on reducing hepatitis C transmission, morbidity, and mortality. These should be informed by surveillance data and local epidemiology and scaled up according to the size of the affected population. Supporting governments to develop national plans and local investment case will help to raise the profile of hepatitis C elimination and build political commitment through global, regional, national and local forums to catalyse action and financing. Strengthening and integrating viral hepatitis surveillance and monitoring systems within national information systems can aid

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national and local governments assess the nature of the epidemic, the true burden of disease and

attributable cost to the country. This enables improvement of resource allocation for services and

workforce training. A roadmap for such an approach can be found in the WHO viral hepatitis C continuum of care monitoring and evaluation framework.(38) In many settings, the effectiveness of viral hepatitis programmes is limited by poor health infrastructure, including low laboratory capacity and a lack of reliable supply chains for vaccines, medicines and diagnostics.(39) Investing in health systems strengthening approaches that deliver public programmes that address multiple diseases, with emphasis on task-shifting and task-sharing,(40, 41) will increase cost-efficiency and ensure sustainability.(20) Promoting standardisation, simplification and decentralisation of health services to reach and actively involve those populations most affected will help drive demand and ensure population coverage. Supporting community sector advocacy and civil society engagement to highlight inadequate hepatitis C funding and demand access to testing and treatment will help support all *National activities* for HCV elimination.

Despite major reductions in the cost of hepatitis C treatments over the past few years, (10, 42) the high costs of treatment and diagnostics mean that many countries cannot support the scale-up of testing and treatment programmes needed to achieve elimination. Countries should explore Trade Related Aspects of Intellectual Property Rights (TRIPS) flexibilities and licensing agreements and be encouraged to employ voluntary licenses that allow production and supply of generic antiviral medicines, currently available to 112 LMICs (home to 65.4% of the people living with hepatitis C).(43) Licensees of the Medicines Patent Pool and Gilead may sell outside the 112 countries if no granted patent is being infringed. This includes cases in which a compulsory licence is issued (44) by a government authority to make use of a patent during the patent term without the authorization of the patent holder to address a public heath need. For example, compulsory licenses can allow local production or importation of generic products (31) from other countries for the domestic market without the consent of the patent holder, and against royalty payments; however, this has only been used twice for hepatitis products.(45) Direct negotiations with pharmaceutical and diagnostic

companies has enabled reduced prices in Australia,(46) and Egypt (47, 48) and others. Ensuring hepatitis C medicines and diagnostics are included in the national Essential Medicines List (EML),(49) and Essential In Vitro Diagnostics List,(50) will be critical as many countries continue to expand their UHC packages.

International activities are implemented by development and related agencies that impact on global policy engagement and are designed to create the necessary environment for countries to achieve elimination and encourage financial investment. Helping countries to identify and support priority activities promotes prioritisation of activities based on an understanding of the in-country epidemiology and context. This will be important because local technical expertise and capacity may be lacking. Georgia's technical advisory group, composed of local and international hepatitis C experts to enable country ownership, has adopted a multi-stakeholder participatory approach to develop strategies, objectives, and actions to help Georgia eliminate hepatitis C.(35, 51) Promoting simplified clinical pathways and models of care that are integrated across related diseases and platforms, including HIV, tuberculosis, and viral hepatitis, will help to reduce overall costs of programmes and increase programme coverage.

Key enablers can facilitate the rapid scale-up of national hepatitis elimination activities and can be classified into three categories. Social enablers make environments conducive to supporting the uptake of hepatitis C elimination activities. For example, harnessing opportunities for publicity through World Hepatitis Day, conferences, and other high-level meetings to increase the profile of viral hepatitis elimination and advocating directly to government to reprioritize budgets to scale up hepatitis C activities. Policy enablers support the scale-up of hepatitis activities and investment approaches by providing a regulatory environment (laws, policies, and guidelines) to attract investment, strengthen coordination with other health programmes, and identify opportunities for

health systems strengthening and cost-savings. For example, the integration of hepatitis C activities into UHC country packages enables hepatitis C drugs to be listed on the national Essential Medicines List and supports pooled procurement. *Program enablers* can enhance quality, coverage, and impact of hepatitis C elimination activities through a public health approach,(39, 43) for example, ensuring clinical testing and treatment guidelines and legislation can support universal access to hepatitis C testing and treatment.

The return on investment

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Beyond life-threatening complications, individuals infected with hepatitis C experience a reduction in quality of life, decreased health and wellbeing, and substantial social stigma. (73) This can reduce workforce participation and personal financial security,(17) and lead to direct costs to health systems. Most of these healthcare costs typically occur 10-20 years after initial infection with the onset of cirrhosis and liver cancer, which can be very costly and challenging to manage. (95) To gain support and traction from financers, a strong investment case is essential for country elimination programmes. Epidemic and economic models have been used to support investment cases by quantifying the impact, resource requirements, and return on investment of changes in viral hepatitis disease control strategies. (69, 58, 96) However, much of the current work on viral hepatitis elimination explores the cost-effectiveness of scaling up hepatitis C treatment by only taking into account direct costs. Many of these analyses underestimate the current cost of chronic viral hepatitis to the community because they do not consider decreased workforce participation and/or reduced quality of life among people living with hepatitis.(15-17) Analyses that do not include indirect economic productivity losses (15-19) fail to capture the longer-term economic benefits of increased workforce participation among people who are cured and will not suffer premature death and those who never become infected in the first place. Advancements in diagnostics and the discovery of a cure for hepatitis C mean that major gains are now possible over short time horizons, provided investment can be catalysed.

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To demonstrate the utility of the Investment Framework, we produced model-based epidemic and economic projections to assess the impact of two investment strategies for hepatitis C: an "elimination strategy" and a "progress strategy". In the elimination strategy, efforts were scaled up to meet the WHO 2030 elimination targets of having 90% of people with hepatitis C diagnosed and 80% of diagnosed patients on treatment by 2030. In the progress strategy, a more modest

investment in hepatitis C testing and treatment was modelled to assess cost-effectiveness of increased investments in hepatitis C without achieving elimination targets. The status quo and the two investment scenarios were assessed for each of the WHO's six world regions; a detailed model description and additional findings are explored in the accompanying modelling paper.(23)

Epidemiological impact of investment in hepatitis C

Based on current estimates of total people living with hepatitis C across the six WHO regions, the application of the elimination strategy would substantially reduce the overall number of people living with hepatitis C. The model projected that if hepatitis C testing and treatment were scaled up according to the elimination scenario, an 85% (95% Credible Interval (CI) 70–92%) reduction in annual hepatitis C incidence and a 47% (95% CI 27–63%) reduction in annual hepatitis C-related mortality could be achieved by 2030, relative to 2015.

Compared to the status quo, this was estimated to prevent a cumulative 2.1 (95%CI 1.3–3.2) million hepatitis C-related deaths and 10 (95%CI 4–14) million new hepatitis C infections globally between 2018-2030, and to substantially reduce the overall number of people living with hepatitis C. In the progress scenario, minimal impact was made on incidence. This was due to the high prevalence among risk populations, which meant that reinfection rates were high enough to negate the benefits of treatment among populations such as people who inject drugs. In the status quo, progress and elimination scenarios, 6%, 57% and 70% (respectively) of the global adult population were tested by 2030.

Economic impact of investment in hepatitis C

The cumulative cost of the elimination scenario was \$41.5 billion (\$33.1–48.7 billion) between 2018 and 2030 (\$23.4 billion more than the status-quo), with a peak in annual investment of \$4.8 billion (\$3.2–5.7 billion) globally in 2019. By 2025, both the progress and elimination scenarios had

incremental cost-effectiveness ratios of under \$2,000 per disability-adjusted life year (DALY) averted, reducing to \$842 (\$514–1,613) and \$885 (\$654–1,189) per DALY averted respectively by 2030. This does not include indirect economic benefits. The indirect economic benefits from scaling up hepatitis C programmes continued to grow over time as a result of the cumulative morbidity and mortality averted, leading to a larger and more productive workforce. The elimination scenario produced a cumulative economic productivity gain of \$46.1 billion (\$35.9–53.8 billion) between 2018 and 2030 (by reducing cumulative productivity losses from \$273.8 billion in the status quo scenario to \$227.7 billion). When the cumulative \$46.1 billion in productivity gains from elimination were considered alongside the additional \$23.4 billion investment required compared to the status quo scenario, hepatitis C elimination was estimated to become cost-saving by 2027 and lead to a net global economic benefit of \$22.7 billion (\$17.1–27.9 billion) by 2030.(23)

<u>Cross-sectoral economic benefits of hepatitis C elimination and synergies with other development</u> <u>sectors</u>

Achieving the SDG target for UHC requires global investment in infrastructure, and many countries have already commenced major investments in health.(97) Integrating hepatitis C services within these investment approaches and systems can significantly reduce costs compared to implementing disease-specific programmes. The simplicity and safety of hepatitis C treatment means that most services can be delivered through the primary care sector in many countries, making integration highly achievable, and a recent costing study estimated that adding viral hepatitis elimination activities (B and C) to UHC would only increase the total costs of UHC by 1.5%.(20) This is an important consideration, because the human resource costs associated with testing, treatment and cure can be more than double the commodity costs in many settings, and adequate human resources may already exist and be financed in current health systems.(20) When the model projections were re-run without additional human resource costs, the investment to eliminate

hepatitis C became cost-saving almost immediately (2019), compared to 2027 with 50% of staff costs or 2030 with 100% of staff costs included. Procuring drugs at generic pricings was critical, with elimination estimated to take until 2030 or 2037 to become cost-saving if drugs were \$1,000 or \$5,000 respectively in high-income countries. This highlights the importance of continued global efforts to universally reduce drug costs.(23).

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Discussion

Eliminating the public health threat of hepatitis C is technically achievable. The challenge to eliminate hepatitis C as a public health threat by 2030 is not that the targets are too ambitious to be achieved, but that most countries globally are not investing sufficient funds and political effort to achieve these targets. This investment framework provides a clear pathway for achieving the financing mechanisms and activities required to reach viral hepatitis elimination and highlights the substantial long-term health and financial benefits of meeting the 2030 elimination targets. Countries should identify their specific challenges as highlighted in Figure 3, and - using this investment framework and the accompanying modelling paper (23) - can begin to build political commitment with the development of a national hepatitis plan that includes an investment case for hepatitis C elimination. While it may not be realistic for all LMICs with high hepatitis C prevalence to mobilise significant amounts of domestic funding in the short term, there are cost-neutral and lowcost strategies that can build momentum and support for elimination (Figure 3). For countries with lower hepatitis C prevalence and limited funding for hepatitis C treatment programmes, the productivity gains and cost savings demonstrated in our models will be less. However these countries can make considerable advances in hepatitis C elimination, at low cost, by adopting synergistic and cost-sharing strategies such as the integration of hepatitis C services into existing health programmes, such as HIV and tuberculosis programmes, which have existing infrastructure, including skilled workforce and robust surveillance systems.

All countries, regardless of hepatitis C prevalence and burden, can leverage the expansion of UHC to ensure hepatitis C services (testing and treatment) are included in their minimum package of health services, which will substantially reduce costs.(20) Our models demonstrated that \$41.5 billion is required between 2018 and 2030 to achieve global elimination, but that this is likely to be recovered in cost savings by 2027, beyond which considerable additional economic returns are possible. Rapidly reducing new infections and death from hepatitis C will also have a profound benefit on future disease burden, (98) while generating major savings in healthcare costs associated with managing severe liver disease and other health-related consequences of viral hepatitis. Unlike in other diseases, highly effective treatments that cure hepatitis C disease enable the prevention of deaths and new infections without ongoing costs as indicated in Figure 3. Moreover, early investment can lead to substantially greater long-term economic benefits,(43, 57, 69) and as the costs of diagnostics and treatment decline through advocacy, international support, private partnerships and community mobilization, these benefits will increase.(10)

Most countries will need to increase their domestic financing and create fiscal space to invest in hepatitis elimination programmes. As such, greater emphasis will need to be placed on the economic benefits of hepatitis programmes, as outlined in this paper. Investment plans to support national policies are needed to ensure evidence-informed decision-making regarding which interventions will provide the greatest public health returns. If domestic efforts to provide funding are unsuccessful, new streams of finance – including innovative financing mechanisms – to support national programmes should be explored (see **Figure 1**).

While this paper presents an investment framework for global hepatitis C elimination, similar global economic modelling has been demonstrated for hepatitis B (99) that identified how scaling up

coverage vaccination (to 90% of infants), birth-dose vaccination (to 80% of neonates), use of peripartum antivirals (to 80% of hepatitis B e antigen-positive mothers), and population-wide testing and treatment (to 80% of eligible people) could achieve hepatitis B elimination by 2030. Similarly, positioning hepatitis B elimination activities within countries' UHC packages will help to ensure sustainable funding for vaccines, diagnostics and medicines. China was an early adopter of a health system strengthening approach to rapidly scale up hepatitis B immunisation to reach population coverage.(100) The country negotiated local manufacturing for treatments and vaccines that have significantly reduced prices and guaranteed supply while generating a new revenue stream. Such investments have also stimulated national drug and vaccine production, ensuring sustainability of the programme and the development of new in-country industries and technology markets.

Conclusion

Any elimination activity requires resourcing and significant investment at a country level, as identified in the GHSS strategy on viral hepatitis. Identifying sources of investment and building the economic case for countries to invest in national hepatitis C-related activities will be critical to achieving global elimination targets. The investment framework presented herein outlines national and international activities that will enable reductions in hepatitis C incidence and mortality and identifies potential sources of funding and tools to help countries build the economic case for investing in national elimination activities. This is the first global investment framework that has demonstrated a substantial economic benefit of investing in hepatitis C elimination and demonstrates how such investments would become cost-saving by 2027. Leveraging global support and political will for the expansion of UHC, and ensuring hepatitis services are integrated into these substantial new investments, will enable new funding sources for viral hepatitis elimination activities as well as health systems' strengthening opportunities. Encouragingly, in September 2019 the United National General Assembly included viral hepatitis in its political declaration on universal healthcare

demonstrating commitment by heads of state, political and health leaders and policymakers globally to begin integrating hepatitis B and hepatitis C elimination programmes into UHC country programmes. (101) Countries should utilise the investment case and existing evidence to raise the profile of viral hepatitis elimination and build political commitment through global, regional, national and local forums that engage affected communities, healthcare professionals and other key stakeholders.

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Table 1. Mechanisms to improve financing for HCV elimination activities						
Financing Mechanisms	Approaches to support HCV elimination	Examples				
Government health expenditure	Increase overall Government health expenditure and increased budget allocation for Hepatitis C activities Development of HCV national plan & investment case to estimate size of the population living hepatitis C and overall costs to the community and government	Australia (46), Egypt (47-48), Scotland (58) African Union (31) countries committed to allocate at least 15% of their annual budget to improve the health sector in their country.				
Health insurance and Universal Health Coverage	Increase access and use by making health services more affordable, through voluntary or mandatory health insurance and universal health coverage schemes	Thailand (66), South Africa (64)				
Influencing market forces to reduce costs of commodities	Effective price negotiations with pharmaceutical manufacturers for hepatitis treatment and diagnostics Local Production of generics Volume or tiered pricing Medicines patent pool	Australia (46), Mercosur countries (94), Pakistan (71), India (44), Malaysia (90, 91) Affordable Medicines Facility – malaria (AMFm) (63), a pilot project funded by UNITAID and hosted by the Global Fund that negotiates price reductions of malaria treatments with manufacturers and provides a subsidy to buyers, through a co-				
	Compulsory licences / Patent challenges	payment. Argentina, Brazil, China, Morocco, the Russian Federation, Ukraine and Médecins du Monde are currently challenging the patent applications for sofosbuvir (31).				
Maximising effectiveness of public health spending	Synergistic action creates opportunities to finance substantial improvements in HCV care without further straining health sector budgets via integration of viral hepatitis into existing services and UHC Adopting an investment case approach to guide investments for maximum impact Reallocation of existing funds towards hepatitis	Debt2Health initiative (67)- initiative of the Global Fund that helps channel the resources of developing countries away from debt repayment and toward lifesaving investments in health.				
Innovations and efficiencies over time	Dried blood sampling to reduce diagnostics costs Non-specialist care, including task sharing and task-shifting Financial Transaction Tax	Australia (57), Scotland (58) UNITAID (27) has raised US\$2 billion from a €1 levy on air tickets leaving France. This 'air levy' now been applied in 15 countries globally.				
Private-Public Partnerships (PPP)	Formal risk management mechanism – where public authorities partner with the private sector to provide services. PPP's aims to share the risks and costs of investment, while enhancing the development of innovation through partnerships.	The Gavi Matching Fund (25) is a public-private funding mechanism designed to incentivise private sector investments in immunisation. RED (28, 67)- is a brand created to engage business and consumer power in the fight against AIDS in Africa. Branded products and services when purchased, activate corporate giving to the Global Fund. RED				

		has generated over US\$600 million in
		funds.
International donors'-	Provision of effective treatment through development	UNITAID (29) is partnering with FIND to
development assistance for	assistance for health	support the development of better,
health		simpler, point-of-care diagnostic tools for
	Low-cost diagnostics	HCV and introduce HCV testing and
		treatment into HIV programs in seven countries.
Sharing costs with other	Harm reduction costs	Portugal (76), Pakistan, Rwanda (36),
strategies	Trainin reduction costs	Brazil (61), Georgia (35)
strategies	Immunisation and blood safety	Committee of the control of the cont
		Pan American Health Organization (PAHO)
	Coinfection with HIV and service delivery	Revolving Fund for vaccines (31) - for 35
	de messer man and service de men,	years, the Revolving Fund of PAHO has
		helped Member States, pool their national
		resources to procure high-quality life-
		saving vaccines and related products at the
		lowest price.
Dedicated hepatitis fund	Create a global viral hepatitis fund to leverage resources and	EndHEP2030 Fund (31)- is the only grant-
	cultivate synergies through innovative public–private	making organization dedicated exclusively
	partnerships, and catalyse action on viral hepatitis.	to the mission of ending viral hepatitis
	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.	
Pooled financing	Bringing together development and commercial actors to	Global Procurement Fund (GPRO) (31)-
	pool financing and offer opportunities to scale up blended	works with participating countries to pool
	finance models	orders from member countries and uses
		international competitive bidding to purchase products at negotiated prices.
		GPRO only works with manufacturers that
		have freedom to operate – either with a
		license from the originator-companies or
		those with a license from the Medicines
		Patent Pool.
Results-based financing	Seeks to create market incentives to achieve critical social	Since 2014, the Global Fund has
	outcomes by only paying when results are achieved. Two	implemented a Results Based Financing
	main types: Performance-based financing targets the supply	model in Rwanda (36), called 'National
	side, whereas conditional cash transfers target the demand	Strategy Financing' to incentivize results
	side of a given market.	and efficiency.
Social Impact Bonds (SIB)	SIBs and DIBs draw on elements of impact investing and	Global Fund (25) supports a social impact
and Development Impact	public-private partnerships and allow outcome funders to	bond to address HIV in adolescent girls and
· ·	pay directly for the achievement of outcomes rather than for	young women in South Africa.
Bonds (DIBs)	inputs. Investors provide the upfront risk capital and play a	The International Finance Facility for
	critical role in helping improve service delivery by bringing	Immunization uses donor pledges to issue
	private sector discipline into practice.	vaccine bonds to raise money for Gavi
	Processor also processor	Alliance.

Challenges to hepatitis C elimination	Activities to support investment in hepatitis C elimination	Tools	Country Examples
Low-quality surveillance systems and a lack of reliable cause-specific mortality data for liver cancer and liver failure.(33) A lack of quality data means the true economic	National – Strengthen surveillance systems and monitor progress towards viral hepatitis elimination: Integrate hepatitis C indicators into national health information systems to assess hepatitis burden Develop national plan and investment case Monitor hepatitis C service access, uptake, and quality	WHO hepatitis C continuum of care monitoring and evaluation framework (38)	Australia (55-57) Georgia (35, 51) Scotland (58) Rwanda (36, 59)
 impact of viral hepatitis – including healthcare costs, reduced quality of life, workforce participation and productivity – is substantially underestimated.(34, 35) As a consequence, insufficient resources are allocated to the issue.(63) 	 International – Set and monitor global targets to encourage countries to strengthen in-country surveillance systems: Advocate for the inclusion of hepatitis indicators into existing surveillance systems – e.g. HIV surveillance systems Provide technical assistance to develop national plan and national targets Provide country support for the development of investment case and financial investment monitoring Provide country support for health information systems strengthening using strategic information tools 	WHO – Country Health statistics and information systems (60)	Rwanda (36) Brazil (61)
A lack of awareness among policymakers & limited political will to prioritise hepatitis C elimination Often driven by inadequate data and weak surveillance systems,(2) competing health priorities, and limited health budgets.(1) Compounded by a lack of awareness in the	National – Develop a national viral hepatitis elimination plan and local investment case: Mobilise political commitment Identify key actors to optimise resource allocation & financing mechanisms Develop country-specific targets and monitoring activities Ensure supportive laws, policies and guidelines	 World Hepatitis Day events and campaigns Policy reports and briefing meetings with policymakers National meetings, conferences, and other high- level political forums 	Scotland (58) Australia (46) Egypt (48, 62)

general population and at-risk communities, who consequently fail to demand action from their governments (63)	 International – Develop a global investment case: Raise the profile of hepatitis C elimination among policymakers and financiers Garner political support, e.g. by demonstrating the economic benefits of viral hepatitis elimination Attract global donor investments through evidence-based advocacy 	•	Let's end hepC policy dashboard ¹	South Africa (64, (65) Rwanda (36, 59) Thailand (66)
Limited funding, donor support and investment	National – Investment and financing for sustainability:	•	Optima hepatitis C ²	Brazil (61)
 in hepatitis C elimination activities Limited funding from global donors such as the Global Fund (67) and the Bill & Melinda Gates Foundation.(68) Countries need to generate domestic revenue for elimination activities 	 Demonstrate cost-effectiveness (11, 69) and health benefits (56, 57) of hepatitis C elimination Mobilise domestic resources by leveraging private investment and innovative financing models (31) Advocate for inclusion of viral hepatitis activities in UHC packages and broader health financing approaches. Support research and innovation towards optimised hepatitis C service delivery and elimination activities.(27) 	•	Cost-effectiveness calculator ³ National Viral Hepatitis Programme Financing Strategy Template ⁴	Rwanda (36) Pakistan (70, 71)
	International – Develop international guidelines and tools to identify and	•	Optima hepatitis C ²	South Africa (64)
	 support priority activities and stimulate investment: Support cost-effectiveness evaluations for hepatitis C programme activities Identify and provide funding for priority activities Facilitate investment in research and innovation Promote innovative financing models to generate government revenue, attract private investment, and secure donor funds for priority activities 	•	Cost-effectiveness calculator ³ Cost-effectiveness analysis registry database ⁵	Thailand (66)

¹ 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). www.letsendhepc.com

² The Burnet Institute 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. (<u>www.ocds.co/hcv</u>)

³ Harvard Medical School, with support from WHO and UNITAID, has developed a Hep C Calculator that allows the adaption of cost-effectiveness models to country-specific epidemics. (http://tool.hepccalculator.org/)

⁴ World Hepatitis Alliance, National Viral Hepatitis Programme Financing Strategy Template. (https://www.hepatitisfinance.org/investment-case/)

⁵ Center for the Evaluation of Value and Risk in Health analyses the benefits, risks and costs of strategies to improve health and healthcare (<u>www.cearegistry.org</u>)

	Advocate for inclusion of hepatitis C services in UHC and broader health financing approaches		
Low awareness of hepatitis C treatment within affected communities & the impact of stigma Only 20% of the estimated 71 million persons living with hepatitis C are aware of their infection.(72) Widespread stigma and discrimination,(73) combined with a lack of understanding that	 National – Raise awareness of hepatitis C to reduce stigma and increase community demand for testing and treatment: Encourage community sector advocacy and civil society engagement to highlight inadequate hepatitis C funding Ensure local epidemiology and surveillance data to inform national hepatitis plans; promote community-focused activities Enable community-led reform of restrictive/stigmatising laws, policies and guidelines (e.g. criminalisation of syringe possession and drug use (75)) 	World Hepatitis Day events and awareness campaigns	Brazil (61) Scotland (58) Portugal (76) France (77)
hepatitis C is now easily curable, contributes to low testing and treatment coverage.(55) Non-evidence-based restrictive and discriminatory policies and legislation, such as liver-disease stage restrictions and restrictions based on recent drug and/or alcohol use,(74) perpetuate stigmatisation of key risk populations and prevent people from accessing treatment.	 International – Raise the profile of hepatitis C, support awareness-raising activities and advocate on behalf of affected communities: Advocate for community sector support and funding, including civil society, hepatitis C councils and affected populations Ensure international testing and treatment guidelines (78-81-) support simplified clinical pathways and community-focused responses 	No Hep C advocacy tool ⁶	Rwanda (36) Pakistan (71) Egypt (82)
 Siloed health programmes & poor health infrastructure Limited laboratory capacity Lack of reliable supply chains and quality assurance programmes for vaccines, medicines and diagnostics.(39) Inadequate capacity and skills of the health workforce, limit the effectiveness of viral hepatitis programmes.(39, 43) 	 National – Implement cost-effective public health systems and strengthen health infrastructure Standardise, simplify and decentralise health services for sustainability, cost-efficiency and reach of key-affected populations (1) Coordinate donors towards adopting streamlined policies and guidelines facilitating health system strengthening opportunities and non-siloed program management and delivery Offer training and quality assurance programs for blood safety and infection prevention, laboratory practices, and supply chain management (87) Develop policies and training programs for task-sharing and task-shifting (40, 41) 	 Global Health Sector Strategy on Viral Hepatitis 2016-2020 (1) WHO Model Essential Medicines List (49) WHO Model Essential In Vitro Diagnostics List (50) Hepatitis testing, treatment and care guidelines (78, 81) Injection safety and blood 	Rwanda (36) Ukraine (37) Georgia (35)

⁶ NoHep.org developed a toolkit for patient organisations, NGOs and individuals working in the field of viral hepatitis to support national advocacy efforts. (http://www.nohep.org/)

Over-reliance on centralized specialist services or tertiary hospitals, particularly in LMICs,(83, 84) despite clear evidence of the effectiveness of primary care systems for viral hepatitis service delivery.(11, 85, 86)	Strengthen national hepatitis procurement and supply management systems (e.g. through integration into broader national systems or local production pathways)	safety policies (88)	
	International – Develop global policies and guidelines that facilitate health system strengthening and non-siloed approaches to programme management and delivery: • Support non-siloed programme funding, enabling integration across related diseases and platforms (e.g. HIV, hepatitis C, TB and vaccination programmes)	WHO global guidelines on task shifting (89)	South Africa (64) Thailand (66) Egypt (47, 48)
	 Review international testing and treatment guidelines (83-86) for simplified clinical pathways and service delivery models Support hepatitis procurement and supply management systems 		
 Limited access to affordable prevention, diagnostics and medicines Despite major reductions in the cost of treatments over the past few years, (10) major 	National – Negotiate access to affordable diagnostics, prevention and medicines to ensure population coverage and equitable access to treatments: Negotiate prices with pharmaceutical companies Include hepatitis C drugs on national Essential Medicines List and Essential In	Medicines Law & Policy legal and policy analysis hub ⁷	Egypt (47, 48) Rwanda (36) Malaysia (90, 91)
 discrepancies in prices exist across low, middle and high-income countries.(10, 92) Many countries are missing opportunities to access cheaper medicines through voluntary licenses that allow production and supply of 	 Include nepatitis C drugs on national Essential Medicines List and Essential in Vitro Diagnostics List Use TRIPS flexibilities and patent challenges Simplify clinical guidelines for cost reduction and testing and treatment decentralisation Comprehensive prevention / harm reduction service packages 		

⁷ 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. (www.medicineslawandpolicy.org)

gene	eric antiviral medicines to 112 LMICs.(43)	International – Fund and facilitate access to affordable prevention,	•	International policies and	Mercosur
 Acce 	ess to affordable diagnostics is a key barrier	diagnostics and medicines and invest in new technologies		guidelines, e.g. WHO	countries (94)
for n	many countries, with diagnostics often costing	Support generic competition to drive prices down		Essential In Vitro Diagnostics	(Argentina, Brazil,
more	re than treatment in LMICs, where poor	Promote mechanisms for affordable medicines acquisition		List (50) and Essential	Paraguay and
labo	oratory capacity and access to reliable and	Accelerate regulatory approval for WHO (or equivalent) prequalified products		Medicines List (93)	Uruguay)
low-	-cost diagnostics prevent rapid scale-up of	Capacity-building for regulatory authorities' pre-market assessments and	•	Joint price negotiations	
testi	ing and treatment programmes.(6, 87)	registration of new medicines and diagnostics			
		Encourage private investment funding through innovative blended financing			
		models for low-cost prevention, medicines, and diagnostics' research and			
		development			



FINANCING SOURCE



DOMESTIC FUNDING



PRIVATE SECTOR



INTERNATIONAL FUNDERS AND ORGANIZATIONS

- Government health expenditure
- Health insurance
- Taxing commodities
- Maximising effectiveness of public health spending
- Private-Public Partnerships
- · Pooled financing
- · Results-based financing
- Innovative blended financing models
- International donor investments
- Cost-sharing strategies
- Social impact bonds and development bonds
- Dedicated hepatitis fund





KEY ENABLERS

- Political commitment and advocacy
- · Community mobilisation
- Supportive laws, policies and guidelines
- Community-based approaches
- · Skilled workforces
- Medicines and equipment
- Research and innovation
- Universal Health Coverage



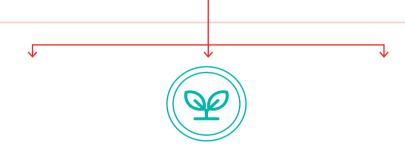
NATIONAL ACTIVITIES

- National hepatitis plan and local investment case
- Investment and financing for sustainability
- · Surveillance and monitoring
- Awareness raising and stigma reduction
- Prevention, testing and treatment
- Health systems strengthening



INTERNATIONAL ACTIVITIES

- Global investment case
- Set and monitor global targets
- International guidelines, guidance and tools
- Facilitate access to affordable prevention, diagnostics and medicines
- Identify and support priority activities
- · Invest in new technologies



RETURN ON INVESTMENT



DIRECT ECONOMIC BENEFITS

- Healthcare cost savings
- Disability-adjusted life years averted
- Quality-adjusted life years gained



INDIRECT ECONOMIC BENEFITS

- Workforce and leisure productivity
- Household security
- National and regional security



CROSS - SECTORAL ECONOMIC BENEFITS

- Sustainable Development Goals
- Stronger health systems
- Stronger partnerships and financial mechanisms

Figure 2. Identified challenges to investment in HCV elimination

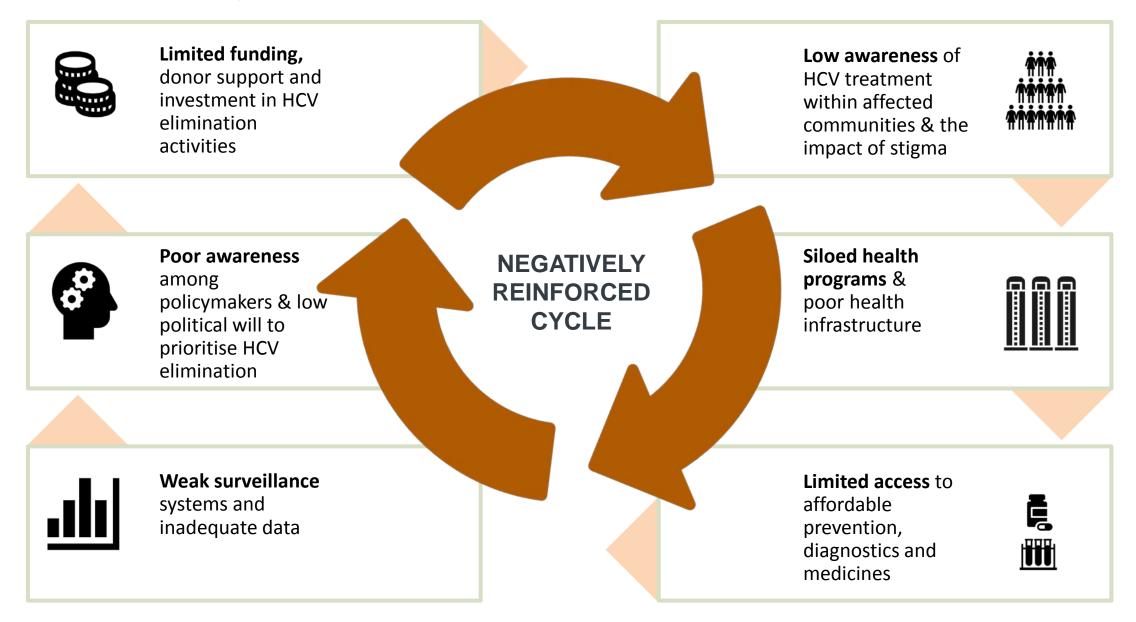


Figure 3. Pathways to scale HCV elimination activities



RAPID SCALE-UP

Interventions where the government is committing significant new HCV resources

RESULTS

- Reprioritize government budgets to scale up HCV activities
- Financing for sustainability

 innovative financing to
 ensure ongoing HCV

 funding
- Increase the efficiency and effectiveness of HCV programs – targeting new infections



SCALE-UP

Interventions where only limited new HCV resources are available

RESULTS

- Health system strengthening
- Investing in low-cost strategies that increase access to HCV activities
- Investment in research and innovation to improve effectiveness and costeffectiveness
- Revising guidelines to support task-shifting and program scale up



COST NEUTRAL

Interventions where no new HCV resources are available

RESULTS

- Political commitment & community mobilisation
- National Hepatitis Plan
- Policy change, law reform and guidelines to support HCV elimination
- Price negotiations with manufacturers and use of flexibilities in patent law for low-cost HCV medicines and diagnostics
- Ensuring efficiency of existing resource utilisation and data-driven responses