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THE OPPORTUNITY TO ELIMINATE HEPATITIS C THROUGH ALTERNATIVE FINANCING MECHANISMS



Participants and organisers of a Davos side event "*An SDG Target We Can Reach: Financing Viral Hepatitis Elimination*" on 25 May 2022, jointly organised by DNDi, The Hepatitis Fund, in collaboration with the Coalition for Global Hepatitis Elimination and with support from Abbott, InTent and Roche.

The Opportunity to Eliminate **Hepatitis C** through Alternative Financing Mechanisms

Viral hepatitis (VH) is one of the leading causes of death and disability worldwide. Globally, it is the seventh biggest annual killer. It affects more than 350 million – more than HIV/AIDS, tuberculosis or malaria. (1) Fortunately, Hepatitis C (HCV) is curable thanks to the health technologies which have been developed over the past 10 years and hence, it can be eliminated. The financing gap to roll these out and eliminate HCV globally through prevention, screening, testing and treatment has been estimated at **USD 41.5 billion** between 2018 and 2030. (2)

However, not one major philanthropic funder has committed to the goal of HCV elimination and only a handful of countries, mostly high-income, are on track to achieve the World Health Assembly (WHA) elimination targets.(1) This is despite the compelling evidence that **elimination** would **avert 2.1 million HCV-related deaths globally, generate USD 46.1 billion in cumulative productivity gains and become cost-saving by 2027, with a net economic benefit of USD 22.7 billion by 2030** (2).

This discussion paper summarises the unique opportunity that international and national actors have to come together and commit to eliminate HCV and to generate historic gains from the health, social and economic impact of these

efforts. The paper offers examples of elimination programmes that have been successfully financed and implemented in low- and middle-income countries (LMICs). They illustrate how the sustainability of these programmes was secured by traditional government health financing coupled with external resources, such as catalytic funding or development aid loans. Alternative financing mechanisms that have been used for other diseases responses are also proposed as a potential way forward to finance HCV elimination efforts.

USD **41.5** billion Funding Gap

Direct Health Benefits:

10 million new infections

2.1 million deaths prevented

Indirect Economic Benefits:

USD 46.1 billion cumulative productivity gains

USD 22.7 billion net economic benefit

Source: Scott N et al. (2020) (2)

” With a person dying every 30 seconds from a hepatitis-related illness, we can’t wait to act on viral hepatitis. A hepatitis-free future is possible!

Dr Tedros Adhanom Ghebreyesus
WHO Director-General (World Hepatitis Day, 28 July 2021)

BACKGROUND

Following the inclusion of VH in the 2030 Agenda for Sustainable Development (SDG 3.3.) adopted by the UN General Assembly in 2016 calling for its combat by 2030, (3) in 2016, the 69th WHA recognized VH as a public health threat and adopted the first Global Health Sector Strategy (GHSS) on Viral Hepatitis 2016-2021. The Strategy set clear elimination targets for HCV as well as hepatitis B (HBV), including a 90% reduction in new chronic infections and a 65% reduction in mortality compared with the 2015 baseline. (4) Building on the achievements, gaps and lessons learnt at the end of the first implementation period, the new 2022–2030 GHSS on HIV, viral hepatitis and sexually transmitted infections, recently approved

by the 75th WHA, reaffirm the targets as per the 2020 baseline and recommend shared and disease-specific country actions. (5)

WHO HCV elimination targets by 2030

- 90%** reduction in incidence
- 90%** of individuals living with HCV diagnosed
- 80%** of eligible HCV population treated
- 65%** reduction in liver-related deaths

Source: WHO, Global Health Sector Strategy 2016-2021 and 2022-2030

In order to achieve the goals of the global strategy over the next eight years, new infections from HCV must be reduced from around 1,5 million new cases (20 per 100.000) in 2020 to 350,000 (5 per 100.000) by 2030; and deaths from HCV must be reduced from 290.000 (5 per 100.000) to less than 140,000 deaths (2 per 100.000). However, this requires massive expansion in the availability of prevention, diagnostic and treatment services in LMICs. (5)

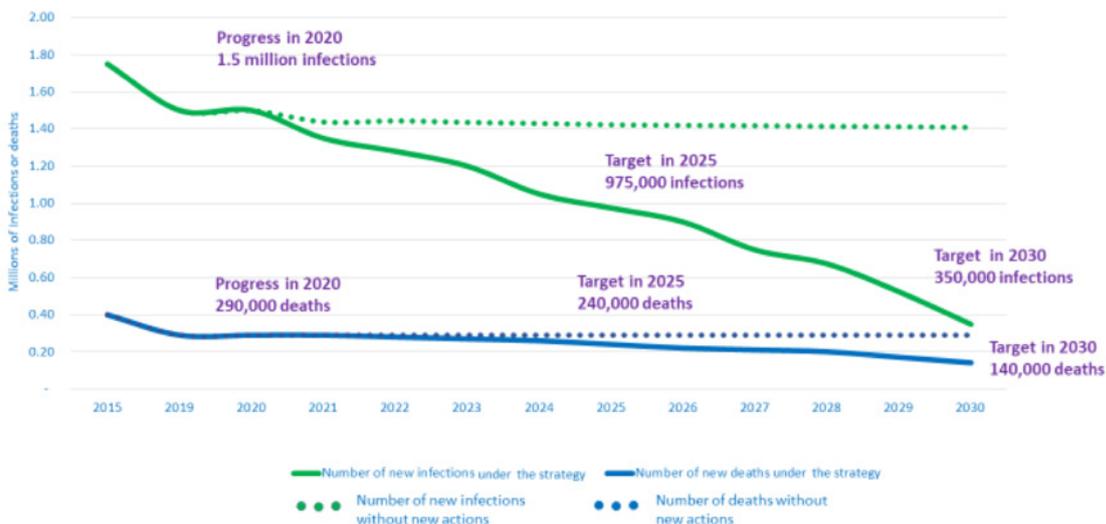


Fig. 1. HCV incidence and mortality trends from new actions implemented under new strategy vs no actions, 2020-2030, WHO Global Health Sector Strategies on HIV, viral hepatitis and sexually transmitted infections 2022-2030.

Funding as a key barrier to elimination

There remain several barriers to HCV elimination. First, despite the significant burden of the disease to people and health systems combined with clear economic gains through elimination, international investments for HCV programmes remain limited both at national and global levels. Bi- and multi-lateral donors have failed to adequately address the major funding needs for HCV. Nor have any major philanthropic funder committed to bridge the multi-billion-dollar gap despite strong cost-benefit arguments. In the absence of adequate state budgetary resources, new international funding sources must be urgently identified and secured for HCV elimination.

Second, large-scale testing and treatment are not in place in a number of LMICs due to a multitude of challenges, such as lack of adequate healthcare infrastructure, lack of coordinated screening and testing services and integrated testing programs, lack of national hepatitis programs or even guidelines. HCV treatment coverage remains low due to limited “test-and-treat” policies and price barriers for DAAs in several LMICs, often due to patents barriers.

Lastly - and often the cause of the former three barriers - is a lack of leadership and political will despite the evidence for positive returns on investment, including direct and indirect health, social and economic benefits.⁽⁶⁾ However, those countries which have taken up the challenge and led elimination program have shown significant progress in decreasing incidence and mortality (7-9) and their examples can be taken as successful models to be explored.

APPROACH TO **HCV** PREVENTION: TESTING AND TREATMENT

HCV is a blood-borne virus most commonly transmitted by using unsterilised medical equipment in healthcare settings, unscreened blood and blood products and by sharing contaminated injection equipment. HCV is a silent epidemic because the vast majority of those infected are not aware of their status, show no symptoms of the disease early-on, and therefore, do not seek treatment. Only 21% of people with chronic HCV infections are aware of their status. (10) Only 13% of diagnosed people have received treatment.

According to the WHO, elimination can be achieved by diagnosing 90% of people living with HCV and, subsequently, treating 80% of those diagnosed. (4) Elimination has been made possible by the introduction of quality-assured screening

tests coupled with cost-effective, efficacious and well-tolerated direct-acting antivirals (DAAs). The daily oral DAAs can cure HCV in over 95% of patients after an eight-to-twelve-week regimen. DAA treatment coverage needs to increase sixfold to reach the elimination targets (1). The latter includes access targets for 2.3 million people co-infected with HIV who have a higher risk of rapid progression to liver fibrosis. (11)

Access to simplified diagnostics, such as the HCV rapid self-testing tools, as well as an integrated testing for multiple diseases in the same session with appropriate linkage to care can increase testing uptake and accelerate progress towards elimination goals.

However, one of the major challenges for HCV elimination remain high patient loss to follow-up (LTFU) at key points in the care cascade. (12) In many country contexts the highest LTFU happens between confirmatory viral load testing and treatment initiation and between treatment initiation and completion. (13) That is why treatment should be immediate and free, on the same day as testing.

Key facts on **HCV** (2019)

58 million living with chronic HCV

1.5 million new infections

2.3 million co-infected with HIV

290.000 deaths

Only **21%** people were tested

Only **13%** of diagnosed people had access to treatment

Source: WHO Global Progress Report 2021

THE INVESTMENT CASE

Investing in HCV prevention and high-quality treatment will result in the alleviation of illness and death for people with HCV as well as present and future direct costs to health systems by reducing cases of liver cancer, cirrhosis and consequently, avoiding hospitalization, liver transplants or other costly treatments. (14) It will also bring long-term indirect socio-economic benefits from increased workforce participation and productivity, financial security and fundamental improvement of the quality of life for individuals and their families.(15)

At the global level, a recent model showed that **USD 41.5 billion** in testing, treatment and health care is required between 2018 and 2030 to achieve HCV elimination. According to model projections, **10 million new HCV infections** and **2.1 million HCV-related deaths** globally would be **prevented** between 2018 and 2030 compared to the 2015 baseline. In terms of indirect benefits, **the elimination strategy would generate USD 46.1 billion in cumulative productivity gains and become cost-saving by 2027, with a net economic benefit of USD 22.7 billion by 2030.**(2)

For the first time, under the new GHSS costs are aligned across diseases to avoid double-counting, building on synergies across the strategies, especially in relation to diagnostics for priority populations across HIV, viral hepatitis and sexually transmitted infections and health-strengthening actions. The costing shows considerable potential for efficiencies in shared costs across the three strategies.(5)

According to WHO estimations the total costs of the VH elimination strategy peak at USD 8 billion in 2028 due to increases in the coverage of testing and treatments for HCV and HBV, and then with impact and increased efficiencies, also thanks to cross-cutting strategy actions with other diseases, decline by 15% to USD 6.7 billion per year by 2030. Many of the benefits from the reduction in mortality accrue for several decades towards 2050.(5)

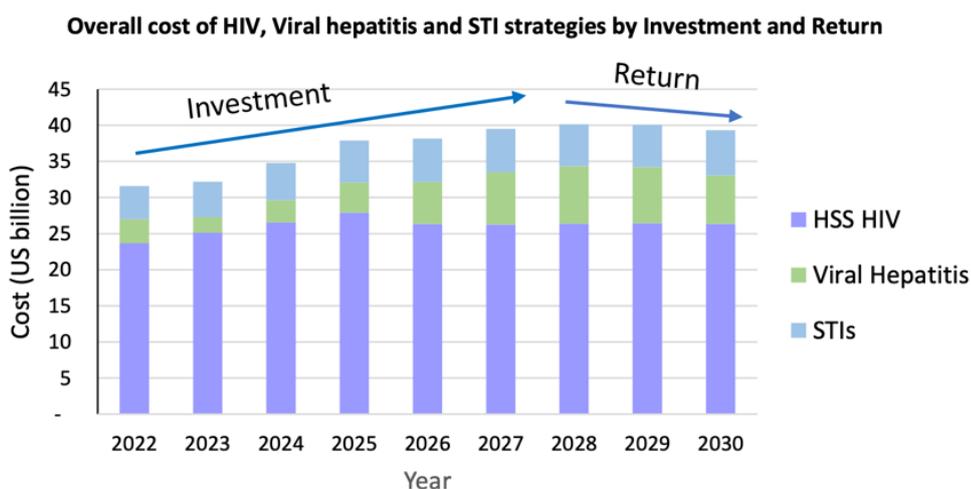


Fig. 2. Overall costing of the global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections, for the period 2022-2030, WHO Global Health Sector Strategies on HIV, viral hepatitis and sexually transmitted infections 2022-2030

There are several countries advancing faster than others toward HCV elimination, typically those that have a national hepatitis strategy in place, financial plans and strong political leadership. While less than 20 countries had national viral hepatitis strategic plans in 2012, this has increased to 124 countries by 2019. Several countries have developed investment cases in the context of disease burden and assessed funding needs to support policy development – something other countries should replicate. (16) Under the new GHSS it is envisaged that 50 countries have costed hepatitis elimination plans by 2030.(5)

The main barrier to designing, implementing and scaling up elimination programs in LMICs is the lack of adequate domestic resources or external funding. There are different mechanisms that can be used to improve implementation of national elimination HCV programs.

Local production of quality generics DAAs, as in Pakistan and Egypt with voluntary licencing (17) or compulsory licences under the Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement as in Malaysia (18), substantially help reduce treatment costs. Effective price negotiation with producers of diagnostics and treatment through volume guarantees, advance market commitments (AMC) and pooled procurement mechanisms can help lower the market price and hence, procurement costs in countries that do not have access to generic DAAs due to patent barriers. (19)

Integration of HCV programs as a way to improve financial efficiency

Integrating HCV programs into existing services or strategies or sharing costs with other areas such as HIV, harm reduction, blood safety or NCDs programs can help maximize effectiveness of public health spending as seen in **Rwanda** and in **Mongolia**.

After being one of the first low-income countries to establish a national VH control programme in 2012, **Rwanda** launched a bold five-year HCV elimination plan with strong high-level governmental endorsement in 2018. (20) It costed its elimination strategy and was able to rapidly optimise its domestic resources for HCV by integrating HCV testing and treatment services into the existing HIV response infrastructure, platforms and package of essential primary health care services covered by its health insurance scheme and by using generics DAAs. External funding from international donors helped to subsidise treatment for population categories not covered by insurance. (21)

In **Mongolia**, which has the highest incidence of liver cancer in the world, mostly due to HBV and HCV chronic infections, (22)(23) the government established the National Healthy Liver Programme 2017-2020 in order to eliminate HCV and to significantly reduce viral hepatitis-induced liver cirrhosis

and hepatocellular carcinoma.(24) With a budget of USD 20 million, allocated from the health insurance fund, health insurance coverage included screening and diagnostic tests, ultrasound as well as hepatitis B and C treatment. Liver transplantation is also subsidized by health insurance. (25)(26)

Catalytic funding as a way to kickstart national funding

Catalytic mechanisms can rapidly mobilize external resources from both the public and private sector to form new partnerships or provide seed capital to allow LMICs to fund HCV elimination programmes with a low upfront investment and reduced overall cost as seen in **Uzbekistan**. (27)

CASE STUDY: The general population elimination program (UHEP) in **Uzbekistan**

Uzbekistan used a catalytic funding mechanism developed by the Center for Disease Analysis Foundation (CDAF) designed as follows:

- CDAF provides a catalytic investment of **USD 1.6 million**, of an estimated total program budget of **USD 3.2 million**.
- The catalytic investment is used to cover upfront costs for purchasing the first round of diagnostic tests and medications.
- All participants receive free testing.
- 20% of infected persons will receive free treatment, based on income level.
- 80% of the enrolled patients purchase medications at a small markup (5%), set below catastrophic health expenditure costs. This markup subsidizes the 20% who receive free medication.
- Ongoing and future costs, including those for testing and treatment, are covered by payments from 80% of the enrolled patients.
- Total program costs, including the repayment of the upfront catalytic investment, are covered by patient payments.
- To recover the upfront catalytic investment a minimum of 55% of all patients who are diagnosed with chronic HCV and HBV need to start and adhere to treatment. (27)

This structure is sustainable only if the government is willing to set a price ceiling. That is because multiple suppliers are competing with numerous negative incentives in the system, e.g. doctors were prescribing more expensive drugs and not generics. Over half of the treated patients ended up paying for drugs at commercial prices. So, in the end the catalytic investment was not repaid, and donors had to bear all the investment risk. However, the financing ended up being catalytic in a different way. The government was convinced that it was possible to establish a national program for HCV and HBV that is simple to implement and cost-effective. As a result, the government decided to fully fund and scale-up a new 4-year programme starting in 2023 by which screening for HBV and HCV in all regions (1 million per year), PCR tests (15.000 per year) and treatment for HCV will be free and a national registry will be created. (28)

A key lesson from the Uzbekistan project was the importance of linking the external funding to government financing upon successful completion. There is a general perception that viral hepatitis elimination is complex and costly. However, this demonstration project with the Ministry of Health (MoH) and local stakeholders illustrated the ease of implementation of simplified test and treat protocols and identify suppliers who are willing to provide products at affordable prices. Similarly, the CDA Foundation is now undertaking a demonstration project in Kazakhstan that will demonstrate the use of rapid diagnostics to screen the adult population and simplified testing and treatment guidelines to eliminate HCV in the primary care setting. Again, the MoH has agreed to scale up the project nationally once successful. (28)

Results-based financing as a way to raise external funding

Another financing scheme worth exploring for use in HCV elimination is results-based financing because it ties funds to outcomes rather than inputs. It enables a more efficient allocation of donor funds by paying only against proven health interventions or results achieved. In the case of HCV, outcome payments can be linked to cured patients that have taken the final confirmation test for sustained virologic response at 12-week post-treatment (SVR12). This indicator is among one of those foreseen in a performance-linked loan currently structured by the World Bank in Egypt to partially support the implementation of a national 5-year health-system strengthening project which includes a major component for HCV testing, treatment and care services. (29) However, in many countries the biggest challenge in monitoring appears to be between treatment completion and SVR12 testing (13) and in Egypt the proportion of SVR 12 is less than the proportion of patient with known outcome in all treatment

centers. (30) Similar efforts across the testing cascade are needed to address SVR12 testing gaps or new indicators shall be considered when structuring these financing. (30)

When domestic fiscal space is constrained, an “HCV impact bond” could act as an effective option to raise upfront capital from external sources to launch or scale HCV elimination programmes while providing a good return on investment. (31) This is currently being explored in **Southeast Asia** whereby investors would provide pre-financing to implement an elimination program and be repaid only when savings generated by elimination materialize for the government. This approach would allow a return on investment of the HCV treatment, helping governments to achieve their elimination targets at limited financial risk. Investors would bear the full or part of the investment risk if the government does not realize the expected economic savings needed to repay the full pre-financing. Furthermore, a credit guarantee from donors or development aid agencies can further de-risk part or all of the investor pre-financing in case of default. If the desired impact results are achieved, investors receive their investment back plus interest. In impact bonds the outcome payer can be a government or a local public entity, or a donor – philanthropic foundations or multi- or bi-lateral agencies.

Political will and partnerships are key to scale up financing for programmes

Another model that has shown success has been demonstrated in both **Egypt** and **Georgia** and features strong political will coupled with increasing domestic health care spending and external funding, donation or subsidy.

Egypt planned and executed one of the most ambitious and successful HCV national elimination programmes to date which allowed to screen

50 million and treat 4 million people from 2014 to 2020.(7) That was possible by substantially increasing government's health care spending over the past decade (from 4.3% to 5.2%) (7), receiving technical and financial assistance by international partners such as the WHO, USAID, Centers for Disease Control and Prevention (CDC) and the World Bank, and engaging with industry partners. (32)(33) The national scheme covers the cost of screening and treatment for all HCV cases, including for those not insured, as well as screening for NCDs as an incentive to reach a wider target population. Egypt's response has been facilitated by strong Government commitment but also by effective price negotiations for screening kits, removal of patents barriers which allowed generic competition and local domestic production of generic DAAs. (34) Thanks to the cost-effectiveness of these measures which led to an impressive reduction of 91% in incidence and 40% in mortality in 2021, from the 2015 and 2018 baseline respectively (35), Egypt is predicted to reach elimination targets by 2030 or even earlier. (7) In addition in the framework of regional and South-South cooperation, Egypt aims to provide HCV testing and treatment for 1 million people in 14 African countries with high hepatitis burden with the support of WHO. (36)

Georgia, which had one of the highest burdens of HCV infection in the world, especially among people who inject drugs (PWID), has become a regional and international leader in HCV elimination efforts since 2015. Strong political commitment and collaboration between the Government, international health agencies (CDC, WHO, EASL, The Global Fund), civil society and industry partners (both pharma* and diagnostics) led to the design and successful implementation of the national HCV elimination strategy. (37) Georgia offers universal access to HCV testing and treatment cascade. Domestic budgetary resources have been secured for testing services countrywide until the elimination targets will be achieved, while DAAs became available

through a partnership agreement and donation from a pharmaceutical partner. For the long-term sustainability of the treatment funding, the government will take over the DAAs procurement once the donation will cease. Although their program is not a sustainable or scalable model for other countries, it clearly shows that with strong political commitment HCV elimination is possible. Since the launch of the HCV elimination programme, over 70% of the country's population were tested and 98% of patients who completed HCV treatment cured with SVR. (38)(8)

New external funding actors

From the discussion above, clearly we are in need of new external funding sources dedicated to HCV elimination. We have only a few examples of dedicated funds. One positive example is The Hepatitis Fund (THF) which was established in 2019 by a group of philanthropists. THF is the first and only grant-making organisation dedicated exclusively to the mission of VH elimination, to fill the gap left by major global health donors. THF is a Geneva-based foundation designed as a collective funding platform to mobilize public and private financial resources globally to accelerate action to eliminate viral hepatitis. THF raises and directs catalytic funding to programmes and initiatives that can achieve strong impact towards hepatitis elimination. THF provides grants, builds financing partnerships, provides technical support on health financing, and advocates for increased national and international funding within the Universal Health Coverage framework. While complete results from its first round of grants will be known early 2023, success stories can already be told, as THF supported work already led to the adoption of HBV birth dose in Uganda and decentralization of HCV screening in Punjab, Pakistan.(39)

*The key industry partner for DAAs in Georgia was Gilead Sciences.

CONCLUSION

HCV is curable and innovative health technologies have been developed to effectively test, cure and hence, eliminate the disease. Yet, despite the high prevalence globally and the high impact on health and social costs, HCV still significantly lacks national and international attention, bold political will and adequate resources to scale up national programmes. Any efforts to sustainably finance HCV elimination must ensure that all affected key populations have access to screening and treatment. Further, because the nature of the HCV burden differs significantly among countries, responses at country level must be tailored appropriately.

This paper has looked at case studies and financing mechanisms successfully used in Rwanda, Mongolia, Georgia, Egypt and Uzbekistan that helped reduce implementation costs for HCV elimination programmes and scale up resources. These mechanisms could be further assessed and replicated when relevant for other countries. Any financing should enable governments to gradually take on sustainable investments towards elimination which can generate revenues from co-payments or savings in health costs to self-fund programs. Support should be designed to encourage and incentivize increased and sustainable budget allocations for HCV screening and treatment programmes at the country level.

When domestic resources are limited, all sources of finance with appropriate safeguards – development, public and private – from traditional and non-traditional funders need to be considered to scale up the elimination program in a sustainable manner. In particular, the enhancement of catalytic deployment

of development assistance in mobilizing and leveraging private sector financing for SDGs should be considered, as highlighted by the Development Ministers of the Group of Seven (G7) in 2019. (40) Catalytic funding from development banks or agencies can increase interest and participation of the private sector – impact investors, high-net-worth-individuals - in the global health space that otherwise often perceives achieving health goals in many LMICs as too risky.

Results-based finance mechanisms could be considered more often because they can build institutional capacity, increase accountability to deliver and sustain results, improve effectiveness and efficiency of programs.

While innovative financing approaches targeting health outcomes - that is financing which encompasses both additional sources of non-traditional financing as well as the range of non-traditional mechanisms used to raise and deploy new funds for development - have been used successfully for other disease areas, they have been vastly underutilized to date for HCV and represent a unique opportunity to explore in HCV how new actors could come together to bridge the financing gap for elimination globally. (41)

We call on new donors and investors to join us in the effort to sustainably eliminate HCV and build stronger health systems.

CONTRIBUTORS

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Endorsed by:

