

MEETING REPORT

FINANCING PREVENTION, TESTING AND TREATMENT
OF HEPATITIS IN THE CONTEXT OF UNIVERSAL
HEALTH COVERAGE

**REPORT FROM A SATELLITE
MEETING AT THE REPLENISHMENT
CONFERENCE OF THE GLOBAL
FUND TO FIGHT AIDS,
TUBERCULOSIS AND MALARIA**

MARCH 2020



MEETING REPORT

FINANCING PREVENTION, TESTING AND TREATMENT
OF HEPATITIS IN THE CONTEXT OF UNIVERSAL
HEALTH COVERAGE

**REPORT FROM A SATELLITE
MEETING AT THE REPLENISHMENT
CONFERENCE OF THE GLOBAL
FUND TO FIGHT AIDS,
TUBERCULOSIS AND MALARIA**

MARCH 2020

Financing prevention, testing and treatment of hepatitis in the context of Universal Health Coverage: report from a satellite meeting at the Replenishment Conference of the Global Fund to Fight AIDS, Tuberculosis and Malaria, October 2019

ISBN 978-92-4-000268-5 (electronic version)

ISBN 978-92-4-000269-2 (print version)

© World Health Organization 2020

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Financing prevention, testing and treatment of hepatitis in the context of Universal Health Coverage: report from a satellite meeting at the Replenishment Conference of the Global Fund to Fight AIDS, Tuberculosis and Malaria, October 2019. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

This publication contains the report of the side event that was held at the 2019 conference for the replenishment of the Global Fund to Fight AIDS, Tuberculosis and Malaria in Lyon, France, on 8 October 2019 and does not necessarily represent the decisions or policies of WHO.

Printed in Switzerland

Introduction

Globally, WHO estimates that 257 million people were living with chronic HBV infection, and 71 million people with chronic HCV infection in 2015. Most viral hepatitis deaths are due to cirrhosis and hepatocellular carcinoma secondary to chronic HBV and HCV infections. Unlike tuberculosis (TB), malaria and HIV, the number of deaths due to viral hepatitis is still increasing over time.¹ Among the 36.7 million persons living with HIV in 2015, an estimated 2.7 million had chronic HBV infection and 2.3 million had been infected with HCV.² Liver disease is a major cause of morbidity and mortality among those living with HIV and viral hepatitis.³

The viral hepatitis B and C epidemics can be addressed through effective, high-impact, affordable, cost-effective interventions that can often be integrated with HIV, TB and other chronic disease interventions. In 2016, the World Health Assembly endorsed the Global Health Sector Strategy (GHSS) on viral hepatitis that called for elimination of hepatitis as a public health threat by 2030.⁴ Viral hepatitis elimination is defined as a 90% reduction in incidence and a 65% reduction in mortality, compared to the 2015 baseline. To eliminate viral hepatitis as a public health threat, the GHSS focuses on five core interventions that need to be implemented at a sufficient level of service coverage. Four core interventions address prevention – three-doses hepatitis B vaccination for infants, prevention of mother-to-child transmission of HBV, blood and injection safety, and comprehensive harm reduction services for people who inject drugs (PWID). The fifth core intervention is providing access to HBV and HCV testing and treatment.⁵ However, progress since 2016 is insufficient. While the number of countries with national plans keeps increasing, few of these plans are funded⁶ and not all include the recommended set of core interventions. Efforts to achieve global viral hepatitis elimination need to be delivered through a public health approach,

Today, the global mortality from viral hepatitis exceeds that of HIV, TB or malaria, and is likely to exceed the toll from those three diseases combined by 2040.

Viral hepatitis elimination meets all criteria for inclusion in the UHC framework.

However, today, start-up funding is essential.

Countries that have made major progress towards viral hepatitis elimination using their own funds, such as Egypt, Georgia and Mongolia, all started with external catalytic funding.

including through strategic integration with HIV, TB and other programmes and services. Ultimately, viral hepatitis prevention and treatment needs to be integrated in Universal Health Coverage (UHC) and at the level of primary health care (PHC). However, within the current funding landscape and global response, catalytic investment is required to jumpstart planning and management of hepatitis activities, optimize procurement of commodities, and monitoring and evaluation (M&E) of viral hepatitis programmes.

A side event was held at the 2019 conference for the replenishment of the Global Fund to Fight AIDS, Tuberculosis and Malaria in Lyon, France, on 8 October 2019 to consider the effective use of global health resources. The meeting underscored the potential public health impact of expanding viral hepatitis elimination programming through strategic integration, including integration with existing efforts to eliminate AIDS and TB. Conclusions outlined here call for the integration of the viral hepatitis response within programmes funded by the Global Fund and other funding agencies under a broader logic of UHC, as well as the establishment of catalytic funding for setting up and implementing national hepatitis plans.

A major opportunity to prevent new infections and deaths

Today, the global mortality from viral hepatitis exceeds that of HIV, TB or malaria,⁷ and is likely to exceed the toll from those three diseases combined by 2040, under the current status quo.⁸ Scaling up the five core interventions of the GHSS on viral hepatitis to sufficient coverage could lead to elimination. Of these, three intervention areas (universal hepatitis B immunization, prevention of mother-to-child transmission of HBV, blood and injection safety) are mostly on track, apart from birth dose vaccine delivery in Africa. Major gaps exist today in two intervention areas: harm reduction for PWID as well as testing and treatment for HBV and HCV.⁹ Increased efforts to address these gaps will be crucial to achieve the mortality and incidence targets of the GHSS for viral hepatitis elimination.

¹ Global hepatitis report. Geneva: World Health Organization; 2017 (<http://apps.who.int/iris/bitstream/10665/255016/1/9789241565455-eng.pdf?ua=1>, 24 October 2019).

² Ibid. 1.

³ Easterbrook P, Sands A, Harmanci H. Challenges and priorities in the management of HIV/HBV and HIV/HCV coinfection in resource-limited settings. *Semin Liver Dis.* 2012;32(2):147-57.

⁴ WHO global health sector strategy on viral hepatitis. Geneva: World Health Organization; 2016 (http://www.who.int/hepatitis/strategy2016-2021/Draft_global_health_sector_strategy_viral_hepatitis_13nov.pdf?ua=1, accessed 16 March 2016).

⁵ Consolidated strategic information guidelines for viral hepatitis. Geneva: World Health organization; 2019 (<https://apps.who.int/iris/bitstream/handle/10665/310912/9789241515191-eng.pdf?ua=1>, accessed 30 January 2020).

⁶ Progress report on HIV, viral hepatitis and sexually transmitted infections, WHO 2019. (<https://apps.who.int/iris/bitstream/handle/10665/324797/WHO-CDS-HIV-19.7-eng.pdf?ua=1>, accessed 30 January 2020).

⁷ Ibid 1.

⁸ Foreman et al. Forecasting life expectancy, years of life lost, and all-cause and cause-specific mortality for 250 causes of death: reference and alternative scenarios for 2016–40 for 195 countries and territories. *Lancet* 2018. [https://doi.org/10.1016/S0140-6736\(18\)31694-5](https://doi.org/10.1016/S0140-6736(18)31694-5).

⁹ Ibid. 1.

High impact, affordable and cost-effective interventions

Failure to close the coverage gaps would be a major missed opportunity, since these interventions are effective, affordable, high-impact and cost-effective. The effectiveness and cost-effectiveness of harm reduction interventions, notably needle and syringe programming (NSP) and opioid substitution therapy (OST) for PWID, has been documented in many settings.^{10,11,12} These interventions are highly effective for HCV as well as HIV prevention. WHO recommends HBV, HCV and HIV testing and treatment interventions for PWID.¹³ Nevertheless, global coverage and quality of harm reduction services remains low. In the broader community, testing and treatment for HBV and HCV is also highly effective and would represent a 0.5% to 1.5% increase of the UHC price tag at the current cost of commodities within an ambitious elimination scenario.¹⁴ Their impact is high, as a 1.5% increase in the UHC price tag would lead to a 5% decrease in mortality and a 10% increase in healthy life years. Testing and treatment for HBV and HCV are also highly cost-effective. The incremental cost-effectiveness ratio is under one GDP per capita per DALY in most cases, and often cost saving (WHO data submitted for publication).

¹⁰ Abdul-Quader AS, Feelemyer J, Modi S, Stein ES, Briceno A, Semaan S, Horvath T, Kennedy GE, Des Jarlais DC. Effectiveness of structural-level needle/syringe programs to reduce HCV and HIV infection among people who inject drugs: a systematic review. *AIDS Behav.* 2013 Nov;17(9):2878-92.

¹¹ Platt L, Minozzi S, Reed J, Vickerman P, Hagan H, French C, Jordan A, Degenhardt L, Hope V, Hutchinson S, Maher L, Palmateer N, Taylor A, Bruneau J, Hickman M. Needle syringe programmes and opioid substitution therapy for preventing hepatitis C transmission in people who inject drugs. *Cochrane Database Syst Rev.* 2017 Sep 18;9:CD012021.

¹² MacArthur GJ, Minozzi S, Martin N, Vickerman P, Deren S, Bruneau J, Degenhardt L, Hickman M. Opiate substitution treatment and HIV transmission in people who inject drugs: systematic review and meta-analysis. *BMJ.* 2012 Oct 3;345:e5945.

¹³ WHO. Consolidated Guidelines on HIV prevention, diagnosis and care for key populations. 2016 Update.

¹⁴ Tordrup D, Hutin Y, Stenberg K, Lauer JA, Hutton DW, Toy M, et al. Additional resource needs for viral hepatitis elimination through universal health coverage: projections in 67 low-income and middle-income countries, 2016-30. *Lancet Glob Health.* 2019;7(9):e11180-e8.

Optimized procurement and economies of scale can reduce costs further

The cost of WHO pre-qualified testing and treatment commodities has fallen considerably in recent years. In 2019, the best market price for HBV treatment was 23 USD per year.¹⁵ The HBV DNA test, critical to long-term monitoring, can be procured at an estimated unit cost of 20 USD. The large-scale procurement of diagnostic and treatment commodities for HIV can serve as basis to push for parity in viral load testing costs across disease areas. For HCV, the best market price for curative treatments was 60 USD per cure in 2019. In India, Pakistan and Egypt, lower prices are available on the national markets. The HCV RNA test which confirms HCV chronic infection and cure, was 9.80 USD per test amounting to around 20 USD for diagnostic assessment and test for cure per patient.¹⁶ Unfortunately, people in low-and-middle income countries (LMICs) lack access to the best prices due to ineffective forecasting, low demand, fragmented procurement, diverse patent landscape, licensing status and high in-country mark-up.

The price of these commodities could fall even further with appropriate forecasting, optimized pooled procurement and increased volumes. Concerted action by major donors, lenders and purchasers could provide a strong signal to the market that would lead to further price reductions. In particular, the impact of existing investments in HIV and TB diagnostics (point of care nucleic acid tests) in the context of Global Fund supported programmes could be substantially enhanced by expanding their use to viral hepatitis.¹⁷ Large-scale procurement of testing and treatment commodities by major purchasers would also provide an incentive to WHO pre-qualification that would increase the documentation of quality.

¹⁷ Analysis by CHAI estimates that 69% of 120 countries use less than 25% of their current GeneXpert installed base capacity for TB testing, based on 2017 Cepheid TB sales data. *Ibid* 16.

Missed opportunities in integration

Integration of viral hepatitis elimination efforts with existing prevention and health services could have a significant impact on public health, particularly for harm reduction interventions among PWID. Moreover, improvement of infection control in health-care settings, particularly safe and appropriate use of injections, is highly relevant for both HCV and HIV prevention.

Viral hepatitis prevention, testing and treatment interventions can be added to services already reaching different communities and patient groups, including in HIV and TB treatment services, maternal and child health clinics, primary health care or harm reduction and drug dependence treatment services. Meaningful partnerships with communities affected by HIV and TB could be replicated for viral hepatitis to enhance the impact of the response design and delivery. The programmatic synergies also extend to M&E.¹⁸ The global M&E framework for hepatitis B¹⁹ is a cascade of care that is identical in concept to the HIV cascade.²⁰ The M&E framework for hepatitis C is a cascade of cure²¹ that is identical in concept to TB.²² Also, harm reduction indicators are already available, but underused.²³

¹⁸ Monitoring and evaluation for viral hepatitis B and C: recommended indicators and framework, WHO 2016.

¹⁹ *Ibid* 5.

²⁰ Consolidated strategic information guidelines for HIV in the health sector. Geneva: World Health Organization; 2015 (<http://who.int/hiv/pub/guidelines/strategic-informationguidelines/en/>, accessed 27 December 2015).

²¹ *Ibid* 5.

²² Guide to monitoring and evaluation for collaborative TB/HIV activities. Geneva: World Health Organization; 2015 (https://apps.who.int/iris/bitstream/handle/10665/150627/9789241508278_eng.pdf?sequence=1, accessed 30 January 2020).

²³ UNAIDS: Key population atlas. <http://kpatlas.unaids.org/dashboard>.

Need for startup funds

Viral hepatitis elimination meets all criteria for inclusion in the UHC framework, including in HIV, TB and primary health care prevention, testing and treatment programmes. Elimination targets can be integrated in health systems with an M&E framework that can document progress. Economic analyses, along with expected market dynamics in case of optimized bulk procurement, suggest that in the long-term, health systems that apply UHC principles should be able to finance hepatitis elimination in LMICs. However, today, start-up funding is essential for situation analysis, planning, management, M&E, and establishment of optimized schemes to procure large quantities of quality assured commodities. Countries that have made major progress towards viral hepatitis elimination using their own funds, such as Egypt, Georgia and Mongolia, all started with external catalytic funding.

Way forward

Due to the availability of affordable diagnostics and treatments for HBV and HCV, recognised and evidence-based prevention interventions, and the prospects for further innovations towards an HBV cure, enhanced investments made today could have a major impact on global health within a short period of time. Immediate action towards integration can be taken by global health donors to reap the fruit of existing synergies and increase the impact of their investments.

Firstly, global health investors supporting HIV, TB and harm reduction programmes may want to review their policies to include and/or expand support for the following activities:

- Procurement of quality assured medicines and diagnostics for HBV and HCV within the mandate of co-infection, to achieve the elimination of HBV and HCV among people living with HIV and among key populations at risk of HIV, and beyond.

- Inclusion of HCV testing and treatment within all programmes that reach out to key populations and other populations at risk with testing and treatment for TB or HIV, and within opioid substitution therapy and needle and syringe programmes.
- Support to improved prevention services, including safe and appropriate use of injections and harm reduction services, as a comprehensive public health approach to HIV, TB and viral hepatitis, together with evidence-based drug dependency treatment.
- Inclusion of interventions for the prevention of mother-to-child transmission of HBV to similar interventions targeting HIV and syphilis transmission.
- Assistance to procurement for countries that want to buy hepatitis medicines at lower price using their own funds, ensuring that optimized procurement mechanisms in place for HIV are being used for HBV or HCV as well.
- Optimization of the use of structural investments in diagnostics systems rolled out for other programmes such as point-of-care nucleic acid tests for HIV and TB.
- Integration of viral hepatitis M&E systems with other donor and lender M&E programmes for HIV and TB.
- Integration of professional trainings given for viral hepatitis, HIV and TB.
- Meaningful involvement of the communities affected by viral hepatitis in co-infection and harm reduction service design, at the country coordinating mechanisms level and the global level, to enhance the impact of programmes.²⁴

Secondly, while the bulk of viral hepatitis elimination should be financed through national health systems, catalytic funding is required to kick-start viral hepatitis elimination

services within the UHC delivery streams. Given the current national health financing landscape in most low- and middle-income countries, external seed funding is essential to design and implement effective national plans by supporting policy development, targeted start-up costs, epidemiological assessment, detailed planning, specialized technical management and implementation capabilities, and appropriate budgeting.²⁵

²⁴ Taaffe, J. and D. Wilson (2018). "Mobilising a global response to hepatitis: Lessons learned from the HIV movement." *Global Public Health* 13(4): 473-488.

²⁵ Wilson D., World Hepatitis Summit Intervention, Sao Paulo 2017. Accessed on 20 January 2020 on <https://youtu.be/j6tsfdlo-Cc?t=2216>

Side-Event convened by:

International Coalition to Eliminate HBV (ICE-HBV)

Co-Chairs:

Prof François Dabis, Director of the French National AIDS and Viral Hepatitis Research Agency, France
Charles Gore, Executive Director of the Medicines Patent Pool, Switzerland

Speakers & Presentations:

Prof Benjamin Cowie, Physician and Epidemiologist, Director of the WHO Collaborating Centre for Viral Hepatitis, Doherty Institute, Australia – *The State of the Viral Hepatitis Epidemic – Success and Challenges*

Dr Mehlika Toy, Epidemiologist and decision scientist, Asia Liver Centre, Stanford, USA – *Viral hepatitis elimination – the price tag and the potential impact of innovative collaborations*

Dr Yvan Hutin, Team Lead ad interim, Global Hepatitis Programme of WHO, Switzerland – *Universal Health Coverage: integrated services delivery for HIV & hepatitis*

Dr Christian Ramers, Senior Clinical Advisor on Viral Hepatitis, Clinton Health Access Initiative, USA – *Leveraging rapidly falling commodity costs to improve clinical outcomes among people living with HIV and key populations through elimination of viral hepatitis*

Ms Jessica Hicks, Head of Programmes, World Hepatitis Alliance, United Kingdom – *Involving the affected community and civil society in innovative financing strategies*

Prof Massimo Levrero, Professor of Medicine at the University Claude Bernard Lyon, France and Board member, International Coalition to Eliminate HBV – *Collaborative biomedical innovations for viral hepatitis elimination*

Partners:

- Barcelona Institute for Global Health (IS Global)
- CDA Foundation
- Clinton Health Access Initiative (CHAI)
- Coalition to Eradicate Viral Hepatitis in Asia Pacific (CEVHAP)
- Coalition for Global Hepatitis Elimination
- EndHep2030
- Forum for Collaborative Health
- France Recherche Nord & Sud SIDA-HIV & Hépatites (ANRS)
- German Center for Infection Research (DZIF)
- Hepatitis B Foundation
- Medicines Patent Pool
- Peter Doherty Institute for Infection and Immunity
- World Health Organization
- World Hepatitis Alliance

For more information, contact:

World Health Organization
Global HIV, Hepatitis and Sexually Transmitted Infections Programmes
20, avenue Appia
1211 Geneva
Switzerland

E-mail: hiv-aids@who.int
www.who.int/hiv
www.who.int/hepatitis/en/

