

Defining a WHO process to validate elimination of viral hepatitis as a public health threat

Concept Note

Background

In 2016, the World Health Assembly adopted the Global Health Sector Strategy (GHSS) on Viral Hepatitis, 2016-2021. The GHSS calls for elimination of viral hepatitis as a public health threat (defined as a reduction of 90% in incidence and 65% in mortality, compared with the 2015 baseline)¹. This target is aligned with similar 2030 elimination targets for HIV and sexually transmitted infections (STIs) and linked to the public health elimination focus of the health-specific Sustainable Development Goals (SDGs) – SDG3². Modelling studies suggested that reaching sufficient service coverage for five core hepatitis interventions would lead to elimination by 2030. These core interventions include (i) infant vaccination with hepatitis B vaccine (target coverage: 90%), (2) prevention of mother-to-child transmission of hepatitis B virus (HBV) (target coverage:90%), (3) blood and injection safety (target coverage:100%), (4) harm reduction for persons who inject drugs (PWIDs) (target coverage: 300 syringe and needle sets/PWID) and (5) HBV and HCV testing and treatment (target coverage: 90% of diagnosis and 80% of treatment, respectively)¹. While the GHSS defines service coverage targets and impact targets globally, work remains to be done before these indicators can routinely be measured and monitored in regions and countries and validated by WHO in practice (e.g., specify baseline, the nature of the reduction in absolute or relative terms, the means of verification etc.).

While progress on the GHSS on Viral Hepatitis has been uneven, WHO has recognized the need for, and a number of countries have requested, the establishment of elimination criteria and guidance on the validation process. This is consistent with the intention of WHO to set global criteria and where possible standardize validation processes across the range of diseases WHO has targeted for elimination. Certain countries have requested work on validation of hepatitis C virus (HCV) elimination, and others on triple elimination of mother-to-child transmission of HIV, HBV and syphilis. In line with the GHSS and country requests WHO proposes to develop a framework for country validation of elimination of viral hepatitis (focus on HBV and HCV) infection as public health threats. The framework would aim to (a) be useful from a public health perspective; (b) contribute to building national capacity; (c) provide guidance on how to address different country contexts, including differences between countries according to their baseline level of endemicity; (d) be implemented efficiently; and motivate countries to take action on hepatitis elimination. The verification process should take advantage as much as possible of existing processes and data already available through routine monitoring & evaluation activities.

As of 2019, WHO has set goals for eradication of three diseases, elimination of 13 diseases and control for one³ and generic guidelines for disease certification/validation/verification have been developed. The WHO Regional Office for the Americas (AMRO) and the Pan American Health Organization (PAHO) have also proposed an integrated framework for elimination of communicable diseases in the Americas⁴. WHO is in the process of developing global guidance on multidisease elimination in countries. It is therefore timely for WHO to develop a process for validation of elimination of viral hepatitis as a public health threat.

WHO proposed to convene an initial meeting “Defining a WHO process to validate elimination of viral hepatitis as a public health threat” to be held 20-22 April 2020 to define the key elements of such a process. Impact assessment (i.e., incidence, mortality) will be the keystone of the validation process. However, recognising the challenges in obtaining reliable impact data, it is proposed that the validation process also includes criteria for service delivery coverage of the core hepatitis interventions, consistent with the GHSS. Furthermore, to ensure that the validation process will take into consideration the sustainability of elimination and that elimination takes place according to the principles of the SDGs, the validation process will also aim to address implementation considerations, such as financial sustainability, equity, gender equality, ethics and human rights.

As a result of the COVID-19 pandemic, invited participants were informed of the postponement of the meeting to end of June 2020, and subsequently in April that the initial meeting at the end of June would be virtual with a planned second meeting shortly thereafter. Over the last two months, preparations for this June meeting, including the background papers have continued. In particular, substantial progress has been made in the area of elimination of mother-to-child transmission of hepatitis B (HBV EMTCT).

We now plan to host this first meeting virtually on **29 and 30 June as two half-days from 13:00 to 17.30 CET**, to accommodate different time zones. This first meeting will focus on two main areas: a) to provide background to and overview of the proposed validation process; b) specific focus on the HBV EMTCT component of the validation process. A follow meeting(s) will be held to discuss other elements of the validation process, including impact criteria, service coverage criteria for the other four core interventions, implementation considerations and governance. Although this meeting will provide an important ‘steer’ on the EMTCT component of the validation process, it will not be until the last meeting that final recommendations will be formulated and submitted.

Part 1: Defining a WHO process to validate elimination of viral hepatitis as a public health threat, with a focus on HBV EMTCT

Day 1 (29 June) will focus on the objectives, background, rationale and overall process for development of the validation of elimination criteria for HBV and HCV, including the methodology, lessons learned from other disease elimination programmes and their validation processes, and presentation of a background paper on country preparedness to assess and

meet elimination validation criteria.

Day 2 (30 June) will focus on HBV EMTCT, with draft criteria and governance process for validation of HBV EMTCT, and approaches to measuring impact for discussion.

Part 2: We anticipate a second virtual meeting to be scheduled soon thereafter to address all other aspects of the hepatitis B and C validation of elimination criteria and governance process. A third virtual or face-to-face meeting may be considered if additional time and discussion is required to the full scope of the validation process.

Preparatory work

A series of background papers have been developed to inform this initial end of June validation of elimination meeting. These include the following:

1. An overall guidance framework document for elimination of viral hepatitis as a public health threat. This will be the main guidance document that will be further developed following the end June phase 1 meeting, and then guide discussions during the second meeting.
2. A draft guidance document specifically relating to HBV EMTCT to inform discussions on options and approaches at the June 2020 meeting. This content will guide the planned update to the existing “Orange book” - Guidance on criteria and processes for validation of EMTCT of HIV and syphilis, to potentially include hepatitis B, but also the overall viral hepatitis elimination guidance document.
3. Country preparedness for validation of elimination, with a mapping of availability of existing indicators at country level for 15 priority countries. This document will help to inform assessment of the feasibility of using certain criteria and processes in countries, particularly those with a high hepatitis disease burden.
4. Impact assessment methods for estimating HBV incidence.

Objectives of first meeting (29–30 June): Part 1

1. Review the various certification, verification and validation processes and definitions used by WHO in the field of elimination or eradication of communicable and non-communicable diseases;
2. Define the general public health objectives of a possible viral hepatitis elimination future validation process at country level;
3. Define the impact indicators and levels of service delivery programme coverage that should be used by countries for validation of HBV EMTCT;
4. Define the governance process at national, regional and global level for validation of elimination or path to elimination of HBV EMTCT.
5. Propose the key elements and methods for collecting data at country level to estimate these indicators.

Expected output (29–30 June): Part 1

1. Updated draft guidance following the meeting specifically relating to HBV EMTCT
2. An updated overall guidance framework document for elimination of viral hepatitis as a public health threat that incorporates the June meeting consensus on HBV EMTCT, in the context of overall validation process for viral hepatitis elimination.
3. Clear guidance as to how to apply elimination criteria for HBV EMTCT in terms of:
 - a. Indicators and definitions used for validation process;
 - b. Use of absolute or relative indicators and metrics;
 - c. Geographic level of disaggregation;
 - d. Management of countries with low endemicity at baseline or missing data;
 - e. Path towards elimination with milestones and conditions of maintenance; and
 - f. Governance body and procedures.
4. List of service coverage and impact indicators to be used for validation;
5. Outline of the process to collect data in view of the estimation of elimination indicators;
6. Framework for a possible tiered approach to validation according to utilitarian criteria, including potentially population size or baseline burden.
7. Identification of a set of countries to pilot the validation process.

Proposed timeline for developing the validation process, guidelines and tools

- Initial virtual meeting with a focus on HBV EMTCT at end of June 2020 (Part 1). An overall draft guidance framework document for elimination of viral hepatitis will be revised and expanded as an output of the meeting by end of July 2020.
- Second virtual or in person meeting around Sept 2020 (Part 2) on overall validation of elimination of viral hepatitis
- Draft of validation protocol for pilot testing by end 2020
- Piloting of the validation protocol in 2-5 countries in 2021
- Finalized validation protocol by 2021
- Validation protocol (guideline) for use in validation by 2022.

Logistical organization

- WHO Headquarters, HHS/UCN, supported by all WHO Regional Offices

Duration and Dates

- Two half days from 13:00 to 17:30 CET
- 29-30 June 2020 – part 1
- TBD – part 2

Venue

- Virtual

Participants

- A technical meeting of experts to participate by invitation
- All meeting participants will be invited to participate in Part 1 and Part 2 (and Part 3 if an additional meeting is required) meetings to ensure the two Experts in modelling

Invited technical experts

- Experts in monitoring and evaluation
- Experts in modelling
- Experience in validation for other infectious diseases
- Experts in UHC
- Experts in clinical and service delivery HIV/hepatitis/STIs
- Civil society, representatives of the most affected population groups

National programmes of Member States

- Countries that have achieved major progress towards elimination
- Focus countries of strategic importance that have not initiated a scaled-up elimination plan
- Countries with high disease burden

Partners

- Implementing and technical partners

WHO Secretariat

- Representatives from the six Regional Offices
- Representatives from selected WHO Country Offices
- WHO Headquarters technical officers involved in this area of work, including
 - Hepatitis policy and programming
 - Immunization
 - Testing, treatment and care
 - Prevention of mother-to-child transmission of HIV, HBV and syphilis
 - Most-at-risk and vulnerable populations
 - Ethics
- IARC, Lyon

References

¹ World Health Organization. Global health sector strategy on HIV 2016-2021. Towards ending AIDS. World Health Organization; 2016.

² Hutin Y, Low-Beer D, Bergeri I, Hess S, Garcia-Calleja JM, Hayashi C, et al. Viral hepatitis strategic information to achieve elimination by 2030: key elements for HIV program managers. JMIR public health and surveillance. 2017;3(4):e91

³ As of 2019, there are 3 diseases (polio, dracunculiasis, yaws) targeted for eradication, 13 diseases (yellow fever, CRS, trachoma, lymphatic filariasis, hepatitis, measles, rubella, neonatal tetanus, onchocerciasis, leprosy, malaria, Chagas, HIV, syphilis) targeted for elimination and one targeted for control (hepatitis in SEAR/WPR) by the WHA.

⁴ Pan American Health Organization. An integrated, Sustainable Framework to Elimination of Communicable Diseases in the Americas. Concept Note. Washington, DC. 2019.