

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 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) – SDG3 ². Modelling studies suggested that reaching sufficient service coverage for five core hepatitis interventions would lead to elimination by 2030. These core interventions include (1) 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 (PWIDJ) (target coverage: 300 syringe and needle sets/PWIDJ) 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 have been uneven, a number of countries have requested the establishment of elimination criteria and guidance on the validation process. Different 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. For example, in August 2019, the Arab Republic of Egypt requested the WHO Director-General (DG) for WHO to validate elimination of HCV in the country following intensive efforts on country-wide scale-up of HCV prevention, testing and treatment. 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; and (d) be implemented efficiently. The verification process should take advantage as much as possible of data already available through routine monitoring and evaluation activities.

As of 2019, WHO has set the 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. PAHO/AMRO has also proposed an integrated framework for elimination of communicable diseases in the Americas⁴. It is therefore timely for WHO to develop a process for validation of elimination of viral hepatitis as a public health threat.

It is proposed that WHO convene an initial meeting to define the key elements of the future process that WHO will use to validate elimination of viral hepatitis as a public health threat. Impact assessment (i.e., incidence, mortality) will be the keystone of the validation process. However, to ensure sustainability and to make sure that elimination takes place according to the principles of the SDGs, it is proposed that the validation process also includes criteria for service delivery coverage of the core hepatitis interventions, as well as considering financial sustainability, equity, gender equality and human rights.

Preparation work

A 10 page “options” paper covering the main areas of validation with a series of proposed approaches for each, including questions to the participants and options to choose from. Sections would include:

- a. Overall approach and governance for the validation procedure
- b. Impact monitoring: Mortality HBV and HCV
- c. Impact monitoring: Incidence HBV
- d. Impact monitoring: Incidence HCV
- e. Service delivery coverage
- f. Equity and human rights
- g. Other considerations including sustainability

Objectives

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. Propose a practical set of hepatitis elimination criteria with respect to:
 - a. level of disaggregation (regional, national or subnational);
 - b. baseline level of endemicity;
 - c. indicators to measure (use of absolute versus relative reduction targets);
4. Define the impact indicators and levels of service delivery coverage that should be used by countries for validation;
5. Propose the key elements and methods for collecting data at country level to estimate these indicators;

6. Define the scope of the future hepatitis elimination validation process, including considerations relating to a possible differentiated approach according to population size or baseline prevalence and burden, taking into consideration issues of equity of access and population disaggregation methods.

Expected output

1. Proposed concept paper for the process for validation of hepatitis elimination in the context of other processes used by WHO (developed on the basis of the Options paper);
2. Agreement on general public health objectives for the hepatitis elimination validation process;
3. Clear guidance as to how to apply elimination criteria 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.

Technical approach

A working document (Options paper) will be drafted ahead of the meeting, including sections relevant to the objectives of the meeting. Other supporting documents will be collated and shared with meeting participants prior to the meeting.

Proposed timeline for developing the validation process, guidelines and tools

- A concept paper (with clear choices) will be prepared as an output of the meeting by April 2020, based on the Options paper that will have guided the discussion.
- Draft of validation protocol for pilot testing by 2020;
- Piloting of the validation protocol in 2-5 countries in 2020-2021;
- Finalized validation protocol by 2021;
- Validation protocol (guideline) for use in validation by 2022.

Logistical organization

- WHO Headquarters, HHS/UCN

Duration

- Three days

Dates

- 20-22 April 2020

Venue

- Domaine de Penthes, Geneva, Switzerland

Participants

WHO temporary advisers /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

Member States

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

Partners

- Funders, implementers and technical partners

WHO Secretariat

- Representative from the six Regional Offices
- WHO Headquarters technical officers involved in this area of work, including
 - Statistics
 - Immunization
 - Blood safety
 - Injection safety
 - Testing, treatment and care
 - Prevention of mother-to-child transmission of HIV, HBV and syphilis
 - Most-at-risk and vulnerable populations
 - Communication
 - 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.

