World Health Organization
European Region

Terms of Reference for the Regional Validation Committee on validation of elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus and validation of elimination of viral hepatitis B and/or C as a public health problem in the WHO European Region

I. Background

To respond to the global commitment to eliminate vertical transmission of HIV, syphilis and hepatitis B virus (HBV), and to eliminate viral hepatitis B and C as a public health problem, WHO released in 2021 the third edition of the global guidance on criteria and processes for validation of elimination of mother-to-child transmission (EMTCT) of these three diseases[1] and interim guidelines[2] for countries seeking to validate elimination of HBV and/or HCV infection as a public health problem.

The process of validation requires governance structures at national, regional, and global levels. As per WHO governance guidance[3] published in 2022, at national level, a National Validation Secretariat (NVS), and National Validation Committee (NVC) should be established and engage with the Ministry of Health, WHO Country Office, women living with HIV and/or HBV and relevant United Nations partners such as UNAIDS, UNICEF and UNFPA. At the regional level, the WHO Regional Office for Europe will host a Regional Validation Secretariat (RVS), which works in close partnership with UNAIDS, UNICEF and other relevant United Nations partners. Furthermore, the WHO Regional Office for Europe will establish and convene a Regional Validation Committee (RVC) advise WHO and the Global Validation Advisory Committee (GVAC).

[1] Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV syphilis and hepatitis B virus. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/349550). License: CC BY-NC-SA 3.0 IGO.

[2] Interim guidance for country validation of viral hepatitis elimination. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/341652). License: CC BY-NC-SA 3.0 IGO.

[3] Governance for the validation of elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus: an overview of validation structures and responsibilities at national, regional and global levels. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/362636). License: CC BY-NC-SA 3.0 IGO.

The Regional action plans for ending AIDS and the epidemics of viral hepatitis and sexually transmitted infections 2022–2030[4] have an integrated person-centered service delivery approach to the elimination of mother-to-child transmission (EMTCT) of HIV, syphilis, and hepatitis B. In The Regional Action Plans, countries of the WHO European Region have committed to triple EMTCT and to elimination of viral hepatitis B and/or C as a public health problem and WHO has committed to strengthening countries' capacities to monitor progress towards elimination and support its validation through the RVC.

Countries are encouraged to pursue elimination of triple EMTCT and viral hepatitis B and C together, however they may choose to apply separately for the following other options:

- EMTCT of HIV and/or syphilis and/or HBV
- Elimination of HCV as a public health problem;
- Elimination of HBV as a public health problem (including HBV EMTCT); and
- Elimination of both HBV and HCV together as a public health problem.

The WHO Regional Office for Europe RVC will act as an advisory group to WHO in this field.

II. Functions

The Regional Validation Committee (RVC) for validation of elimination of mother-to-child transmission (EMTCT) of HIV, syphilis and hepatitis B virus (HBV) and validation of elimination of viral hepatitis B and/or C as a public health problem, provides independent, expert advice to the WHO Regional Validation Secretariat (RVS) to support country efforts towards achieving and maintaining global validation standards for EMTCT of HIV, syphilis and HBV and elimination of viral hepatitis B and/or C as a public health problem.

In its capacity as an advisory group to WHO RVS, the RVC shall have the following functions:

1. To review national validation reports from the National Validation Committee (NVC) to determine and advise WHO on their compliance with the global criteria for validation of EMTCT of HIV, syphilis and/or HBV, and/or criteria for elimination of viral hepatitis B and/or C as a public health problem, get additional information or clarification as required, and determine eligibility for country validation assessment.

2. To coordinate with the Regional Validation Team (RVT) to support country validation assessments via in-country mission or virtual assessment using the four validation assessment tools for EMTCT (programme evaluation and assessment; data assessment and verification; laboratory evaluation and assessment; and human rights, gender equality and engagement of civil society in the EMTCT process) and/or the validation assessment tools for HBV and/or HCV elimination as a public health problem;

[4] Regional action plans for ending AIDS and the epidemics of viral hepatitis and sexually transmitted infections 2022–2030. Copenhagen: WHO Regional Office for Europe; 2023 (https://iris.who.int/handle/10665/369243). License: CC BY-NC-SA 3.0 IGO.

3. To coordinate the preparation of the regional validation assessment report to inform WHO regarding compliance with global criteria for validation of EMTCT of HIV, syphilis, and/or HBV and/or criteria for elimination of viral hepatitis B and/or C as a public health problem.

4. To advise WHO as to whether candidate countries' achievements in EMTCT of HIV, syphilis and/or HBV and/or in elimination of viral hepatitis B and/or C as a public health problem can be recommended to GVAC (through the RVS) for validation; or to issue recommendations to countries to address gaps and/or barriers to validation discovered through the country assessment process.

5. To collaborate with the RVS, NVS, NVC and Global Validation Secretariat to ensure monitoring for maintenance of validation, including review and re-evaluation of validation impact and process indicators and provide recommendations to the GVAC (through the RVS) regarding maintenance of validation of previously validated countries.

6. To monitor the current context for legal or political changes or practices that could threaten countries' ability to apply or maintain EMTCT validation or validation of elimination of HBV and/or HCV as a public health problem in the region.

7. To support capacity building of countries or NVCs where needed.

III. Composition

1. The RVC shall have up to 15 members[5] who shall serve in their personal capacities to represent the broad range of disciplines relevant to validation of EMTCT of HIV, Syphilis and HBV and validation of elimination of viral hepatitis B and/or C as a public health problem, and they should bring together expertise in the following disciplines and areas:

    a. Public health programme management: HIV, sexually transmitted infections, viral hepatitis (including HBV immunization); maternal and child health; sexual and reproductive health;
    b. Clinical management of HIV, sexually transmitted infections, and viral hepatitis;
    c. Laboratory services, including services related to quality assurance in testing for HIV, syphilis, HBV, and HCV infection;
    d. Strategic information (surveillance, monitoring, and evaluation);
    e. Engagement with communities of people living with HIV and viral hepatitis, to include at least one woman living with HIV and one woman living with HBV;

[5] Members serve as full participants and partake in the deliberations and the adoption of the recommendations of the meeting in which they are involved.

f. Gender and human rights with a focus on people at higher-risk and vulnerable groups.

2. Members of the RVC, including the Chairperson, shall be selected and appointed by WHO following an open call for experts. In the selection of the RVC members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.

3. Members of the RVC shall be appointed to serve for a period of 3 years and shall be eligible for reappointment. The Chairperson is eligible for reappointment as a member of the RVC but is only permitted to serve as Chairperson for one term. Their appointment and/or designation as Chairperson may be terminated at any time by WHO if WHO's interest so requires or, as otherwise specified in these terms of reference or letters of appointment. Where a member's appointment is terminated, WHO may appoint a replacement member.

4. The WHO Regional Office for Europe and partner organizations (UNAIDS, UNICEF, UNFPA) support the functions of the regional secretariat as observers and are not members of the RVC.

5. RVC members must respect the impartiality and independence required of WHO. In performing their work, members may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of any real, potential, or apparent conflicts of interest. To this end, proposed members/members shall be required to complete a declaration of interests form and their appointment, or continuation of their appointment, shall be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.

6. Following a determination that a proposed member's participation in the RVC would not give rise to a real, potential or apparent conflict of interest, the proposed member will be sent a letter inviting them to be a member of the RVC. Their appointment to the RVC is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, RVC members have an ongoing obligation to inform the WHO of any interests real or perceived that may give rise to a real, potential or apparent conflict of interest.

7. As contemplated in paragraph II.5 above, WHO may, from time to time, request AG members to complete a new declaration of interest form. This may be before an AG meeting or any other AG-related activity or engagement, as decided by WHO. Where WHO has made such a request, the AG member's participation in the AG activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.

8. Where a AG member is invited by WHO to travel to an in-person AG meeting, WHO shall, subject to any conflict-of-interest determination as set out in paragraph II.7 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together 'Temporary Adviser Letter). WHO shall not authorize travel by an AG member, until it receives a countersigned Temporary Adviser Letter.

9. RVC members do not receive any remuneration from WHO for any work related to the RVC. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.

IV. Operation

1. The RVC shall normally meet at least once a year. However, WHO may convene additional meetings based on country submission of national report(s). RVC meetings may be held in person or virtually.

2. AG meetings may be held in open and/or closed sessions, as decided by the Chairperson in consultation with WHO.
    a. Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views and may be attended by Observers (as defined in paragraph III.3 below).

    b. Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the AG and essential WHO Secretariat staff.

3. The quorum for RVC meetings shall be two thirds of the members.

4. WHO may, at its sole discretion, invite external individuals from time to time to attend the open sessions of an advisory group, or parts thereof, as "observers". Observers may be invited either in their personal capacity, or as representatives from a governmental institution/intergovernmental organization, or from a non-State actor. WHO will request observers invited in their personal capacity to complete a confidentiality undertaking and a declaration of interests form prior to attending a session of the advisory group. Invitations to observers attending as representatives from non-State actors will be subject to WHO internal due diligence and risk assessment including conflict of interest considerations in accordance with the Framework for engagement with non-State actors (FENSA). Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the AG at their own expense and be responsible for making all arrangements in that regard. At the invitation of the Chairperson, observers may be asked to present their personal views and/or policies of their organization. Observers will not participate in the process of adopting recommendations of the RVC.

5. The RVC may decide to establish smaller working groups (sub-groups of the RVC) to work on specific issues. Their deliberations shall take place virtually. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the RVC for review at one of its meetings.

6. RVC members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the RVC.

7. Active participation is expected from all RVC members, including in working groups, teleconferences, and interaction over email. RVC members may, in advance of RVC meetings, be requested to review meeting materials and to provide their views for consideration by the RVC.

8. Reports of each meeting and a yearly report shall be submitted by the RVC to WHO. All recommendations from the RVC are advisory to WHO, which retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the RVC.

9. The RVC shall normally make recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.

10. WHO shall determine the modes of communication by the RVC, including between WHO and the RVC members, and the RVC members among themselves.

11. RVC members shall not speak on behalf of, or represent, the RVC or WHO to any third party.

V. Secretariat

1. The WHO Regional Office shall provide the Secretariat for the RVC, including necessary scientific, technical, administrative and other support, in partnership with the Regional Offices of UNAIDS, UNICEF and UNFPA. In this regard, the RVS shall provide the RVC members in advance of each meeting with the agenda, working documents and discussion papers. Distribution of the aforesaid documents to Observers will be determined by the WHO Secretariat. The meeting agenda shall include details such as whether a meeting, or part thereof, is closed or open; and whether Observers are permitted to attend.

2. The RVS in collaboration with the RVC may appoint a Regional Validation Team (RVT) for each candidate country.

3. The RVS coordinates the RVC and RVT, provides oversight of regional and national validation processes and activities, and communicates with NVCs, GVAC secretariat.

VI. Information and documentation

1. Information and documentation to which members may gain access in performing RVC related activities shall be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. In addition, by counter signing the letter of appointment and the accompanying terms and conditions referred to in section II (6) above, RVC members undertake to abide by the confidentiality obligations contained therein and also confirm that any and all rights in the work performed by them in connection with, or as a result of their RVC-related activities shall be exclusively vested in WHO.

2. RVC members shall not quote from, circulate or use RVC documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.

3. WHO retains full control over the publication of the reports of the RVC, including deciding whether to publish them.