GOVERNANCE

MONITORING AND EVALUATION

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

2022

World Health Organization

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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

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ESSENTIAL WHO EMTCT RESOURCES

The criteria for validation established in Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus is an essential companion to the governance outlined in this document. It is available at: https://www.who.int/publications/i/item/9789240039360

Additional information on validation of EMTCT of HIV, syphilis and HBV, including updated tools and other guidance, are available on the WHO websites:

Triple elimination initiative of EMTCT of HIV, syphilis and HBV https://www.who.int/initiatives/triple-elimination-initiative-of-mother-to-child-transmission-of-hiv-syphilis-and-hepatitis-b/validation

EMTCT validation processes and tools

https://www.who.int/initiatives/triple-elimination-initiative-of-mother-to-child-transmission-of-hiv-syphilis-and-hepatitis-b/validation/process-and-tools

ABBREVIATIONS AND ACRONYMS

EMTCT	elimination of mother-to-child transmission
HBV	hepatitis B virus
HIV	human immunodeficiency virus
GVAC	Global Validation Advisory Committee
GVS	global validation secretariat
HBV	hepatitis B virus
HHS	WHO Global HIV, Hepatitis and Sexually Transmitted Infections Programmes
IOM	International Organization for Migration
NVC	national validation committee
NVS	national validation secretariat
PRG	preparatory review group
PTE	path to elimination
RVC	regional validation committee
RVS	regional validation secretariat
STI	sexually transmitted infection
TOR	terms of reference
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization

EXECUTIVE SUMMARY

Achieving validation of elimination of mother-to-child transmission (EMTCT), or vertical transmission, of HIV, syphilis and hepatitis B virus (HBV) is a tremendous accomplishment, requiring health-ministry–led accountability, rigorous data analysis, intensive programme assessment and multilevel collaboration. Maintaining validation is equally important and requires sustained, broad programme efforts to prevent new infections in infants, children and adults.

The World Health Organization (WHO) has defined EMTCT as a reduction in the number of new HIV, syphilis and HBV infections among infants and children to a level at which these infections are no longer considered a public health problem. WHO has developed criteria for validation of elimination in *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus (2021).* This governance document supplements the *Global guidance* document. Validation of elimination requires rigorous assessment at the national, regional and global levels of the impact and process indicators and the fulfilment of the four foundational requirements for (1) data quality, (2) strong programmes, (3) laboratory quality and (4) human rights, gender equality and community engagement.

Our United Nations (UN) partners provide critical support to the validation process for health system strengthening, providing comprehensive services that respect and protect the human rights of women living with HIV, syphilis or HBV and ensuring that these women are meaningfully involved in health programme planning and service delivery.

As of March 2022, 16 countries and territories have been validated for EMTCT of HIV and/or syphilis (in chronological order: Cuba, Thailand, Belarus, Armenia, Republic of Moldova, Bermuda, Anguilla, Montserrat, Cayman Islands, Antigua and Barbuda, Saint Kitts and Nevis, Malaysia, Maldives, Sri Lanka, Dominica and Oman). In 2021, Botswana has become the first country with high HIV burden to be certified for achieving the required indicators for the silver tier on the path to elimination (PTE) of HIV.

This document contains the governance guiding all structures and processes for validation. Replacing edition 1, published 15 June 2020, this revised governance document aligns with new information in the *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis, and hepatitis B virus,* which (1) includes criteria and processes for EMTCT of HBV, with specific guidance and strategies to achieve "triple elimination": (2) provides clarity, consistency and detail related to the validation process based on lessons learned from previous validation experiences; and (3) provides further details on the structure, function, composition and operation of validation processes at the national, regional and global levels.

INTRODUCTION

In 2014, *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis* was published, providing the first WHO guidance on validation for elimination of mother-to-child transmission (EMTCT), or vertical transmission.

The Global Validation Advisory Committee (GVAC) was inaugurated in 2015 to advise WHO on whether a country had met the established criteria for validation. Criteria for validation were further revised and expanded in 2017, including establishing path to elimination (PTE) criteria for countries with high burdens of HIV and congenital syphilis that have achieved substantial progress in lowering rates of mother-to-child transmission (MTCT) of HIV and lowering population case rates of HIV and congenital syphilis. A first edition of *Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis* was published in 2020 with specific guidance on the standardized structures and processes used in validation.

In 2021, EMTCT was expanded to include hepatitis B virus (HBV), and a new version of Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis, and hepatitis B virus was published with specific guidance and strategies to achieve "triple elimination".

This governance guidance further standardizes and outlines the structures, operations and responsibilities of the validation secretariats and committees in the process to validate EMTCT of HIV, syphilis and HBV at the national, regional and global levels. Consistent use of the governance structure, including following the suggested channels of communication among the various structures across the three levels, will support and optimize the validation process. This document supplements *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and HBV* and the other validation assessment tools, including the country pre-assessment tool and the four tools to assess data quality, programme strength, laboratory quality, and human rights, gender equality and community engagement. Box 1 describes important considerations prior to reading this document.

Guiding principles for validation involve the three-level national, regional and global approach and engaging relevant multisectoral stakeholders. Engaging civil society, especially communities of women living with HIV and HBV, in elimination strategies at the start of the national validation process is crucial so that issues arising around human rights, gender equality and the meaningful engagement of communities are addressed early. This will help to ensure that mitigation efforts are applied with the involvement of civil society early and throughout validation and maintenance of validation.

Box 1. Important considerations prior to reading the full document

- To fully engage with the information in this document, the reader must first be familiar with *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus (2021).*
- Throughout this document, the terms "EMTCT" and "vertical transmission" include all three infections unless otherwise indicated.
- The same structures and processes are followed whether a country is applying for validation of EMTCT or certification on the PTE (unless otherwise noted).
- For the purposes of this document and ease of reading, EMTCT validation includes PTE certification.
- When referencing "countries," the document includes any UN member states, some of which may be labelled "territories".
- Please refer to the section *Essential WHO EMTCT resources* for links to required validation guidance, tools and report templates.

GENERAL GUIDANCE ON VALIDATION FOR ALL STRUCTURES

1. The validation process consists of two components: (1) the initial country assessment and (2) the assessments for maintenance of validation. (The time intervals for assessing maintenance of validation are provided in the Global guidance document, Table 8.1, p. 50.)

2. At each of the three validation levels, there must be a validation committee. Membership criteria and expertise, roles and responsibilities and expectations for the validation committees at national, regional or global levels are the same and are listed in Box 2 and Box 3. These committees should be multidisciplinary, with a wide cross-section of experts from different subject areas critical to the validation process. The size of the committees may vary by country. At least two women living with HIV and one woman living with HBV must be included on the committees at each level of validation review. Consideration should be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance. Countries are encouraged to seek and apply for validation of elimination of all three infections; however, if applying for single or dual elimination, they may adjust membership criteria as appropriate.

Box 2. General membership criteria and expertise required for validation committees at national, regional and global levels

Individual committee members should collectively have expertise and experience in the following areas:

- engagement with communities of people living with HIV and HBV to include at least two women living with HIV (WLHIV) and one woman living with HBV (required);
- prevention of HIV and other sexually transmitted infections (STIs), specifically syphilis and HBV;
- hepatitis B immunization programmes and services;
- epidemiology, monitoring and evaluation, and disease surveillance;
- human rights, with a focus on higher-risk and vulnerable groups, such as migrants and displaced persons;
- management of public health programmes;
- laboratory services, including services related to quality assurance in testing for HIV, syphilis and HBV infection;
- maternal and child health care in the public and private sectors;
- social and behavioural sciences.

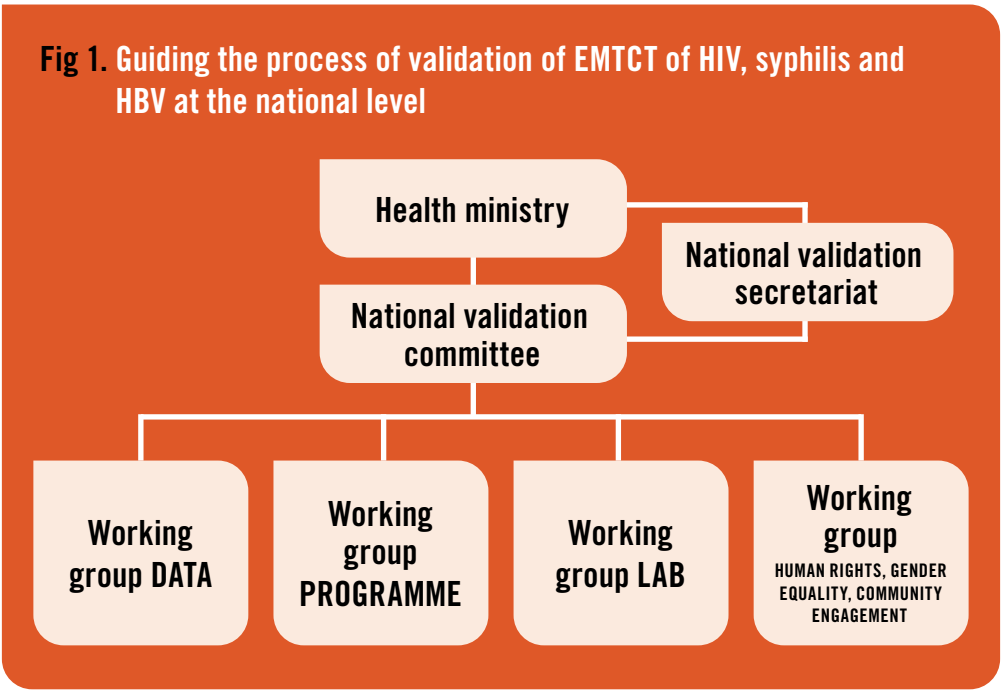
3. The committees should be able to act independently when reviewing and assessing whether a country has achieved or maintained the elimination targets. Committee members at all levels should serve as independent experts and not represent government or nongovernmental entities in their position. The roles, responsibilities and expectations for members of validation committees are included in Box 3.

Box 3. Roles and expectations of members of validation committees

- Assess countries' efforts toward elimination without bias.
- Be willing to sign a confidentiality agreement and commit to keeping all information confidential. Information and discussions during validation reviews should not be shared with persons or entities outside the committee. Confidentiality statements will be renewed annually. Committee members may be asked to resign from the committee if they breach confidentiality.
- Declare any real or perceived conflicts of interest by completing a declarations of interest (DOI) form before engagement in any country assessment or other committee activity. These statements should be renewed annually by the respective WHO secretariats.
- Have time to review validation information in detail without financial remuneration from health ministries or WHO.
- Serve, for the duration of the initial validation exercises and, if feasible, through the maintenance period as per the specific standard operating procedures for the relevant committee.

VALIDATION STRUCTURE AT THE NATIONAL LEVEL

Fig 1. Guiding the process of validation of EMTCT of HIV, syphilis and HBV at the national level



4. At the national level, the following bodies (where applicable) are integral in the validation process (Fig. 1):
   - The health ministry
   - The WHO country office (If there is no WHO country office, the WHO regional office should be consulted.)
   - The national validation secretariat (NVS) hosted by the WHO country or regional office
   - The national validation committee (NVC)
   - Relevant UN partners, such as the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA) and the International Organization for Migration (IOM)
   - Other implementing partners involved in the efforts to achieve EMTCT.

HEALTH MINISTRY

5. The health ministry is critical in initiating all EMTCT activities in the country. The ministry establishes the roadmap towards elimination. Once the ministry believes they are ready to be validated, they submit the validation request to the WHO country office. If the country has no WHO country office, the request should be submitted to the regional validation secretariat (RVS). The request should declare for which of the three infections the ministry is seeking validation of elimination.

6. The health ministry constitutes and convenes the NVC with the appropriate expertise for validation of its national efforts to achieve EMTCT. The health ministry ensures that the NVC can rigorously, independently and transparently investigate and document, through the national validation report, its national EMTCT data and all foundational requirements for validation. The health ministry approves the final report before it is sent to the RVS.

NATIONAL VALIDATION SECRETARIAT (NVS)

7. The WHO country office hosts the NVS, which works in close partnership with counterparts from UN agencies as needed. Where there is no WHO country office, the NVS is hosted by the responsible WHO office or regional office.

8. The NVS, in concert with the health ministry, serves as the first point of contact with national stakeholders. Together with relevant UN and non-UN implementing partners, it provides logistical and technical support to the NVC for assessing the programmes for EMTCT and ensuring the accuracy of the national validation report.

9. The NVS organizes an orientation meeting on the validation process with the health ministry, the NVC, UN partners and other relevant implementing partners. This meeting provides an overview of the validation process and orients all stakeholders to the global criteria for validation, assessment tools and timelines.

10. Through the NVS, the health ministry submits to the RVS the final national validation report and the subsequent maintenance of validation reports to the RVS.

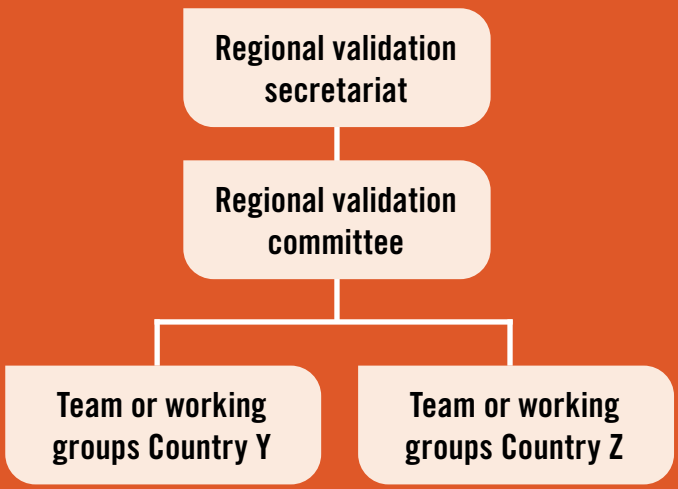
NATIONAL VALIDATION COMMITTEE (NVC)

11. The primary responsibility of the NVC is to present evidence, in the national validation report, that a country has met the global validation criteria. Following the initial orientation meeting, the NVC is responsible for drafting a roadmap for the validation process detailing the committee's activities, roles and responsibilities, and timelines. Working groups or a national validation team (NVT) can be established to support the gathering of evidence and the subsequent development of the national validation report. An NVC chair and co-chair should be selected in consultation with the NVS.

12. The responsibilities of the NVC include:
    - conducting national assessments for validation, including collecting evidence from desk reviews and in-country missions using the four validation tools: (1) data and surveillance systems, (2) programmes and services, (3) laboratory and (4) human rights, gender equality and community engagement;
    - ensuring that all issues raised by the NVC are communicated to the health ministry through the NVS;
    - submitting the national validation report to the NVS for initial review. Several rounds of edits can take place and should be agreed upon between the NVC and NVS before the final report is submitted to the health ministry for final approval;
    - working on a continuing basis with the NVS, RVS and RVC during the regional validation assessment, including revising the national validation report and providing responses to any requests for clarifications and/or additional information, as needed;
    - submitting the final national validation report to the NVS; please see national validation report template at: https://www.who.int/initiatives/triple-elimination-initiative-of-mother-to-child-transmission-of-hiv-syphilis-and-hepatitis-b/validation/process-and-tools

VALIDATION STRUCTURE AT THE REGIONAL LEVEL

Fig 2. Guiding the process of validation of EMTCT of HIV, syphilis and HBV at the regional level



13. The regional validation process verifies the content, validity and quality of the national validation report. At the regional level, the following entities have an important role in the validation process: (Fig. 2)
    - the regional validation secretariat
    - the regional validation committee.

REGIONAL VALIDATION SECRETARIAT (RVS)

14. The WHO regional office, under the auspices of the regional director and coordinated by programmatic offices, hosts the RVS, which works in close partnership with counterparts from UN agencies.

15. The RVS has the overall responsibility of supporting the process of validation in a country and is responsible for communications between the national, regional and global levels.

16. The RVS is responsible for establishing, convening and orienting the RVC to the validation criteria, process and assessment tools.

17. The RVS determines the terms of reference (TORs) for the RVC and is responsible for orienting the RVC to the TORs.

18. The RVS defines the detailed operational practices at the regional level, including the evaluation approach and methods, and the organization of an in-country mission or virtual validation assessment. In keeping with the objectives of EMTCT validation, to ensure the efficient use of both human and financial resources (as has been done throughout the COVID-19 pandemic and other natural disasters), a virtual or hybrid validation assessment of countries is permitted. The RVS will determine the assessment method and advise the global validation secretariat (GVS) accordingly. A virtual assessment of EMTCT achievements follows a process similar to the in-country validation procedures. It is conducted by the RVC (or an optional regional validation team [RVT] if the RVC permits) under the guidance of the RVS. Although there are no established specific global norms or standards for conducting virtual validations, the RVS may elect to set regional standards and procedures that uphold the integrity of the validation process.

19. The main responsibilities of the RVS include:
    - establishing RVC agendas and workplan in collaboration with the chair;
    - providing coordination, communication, administrative and logistical support for the RVC and their validation assessment activities, including in-country missions or virtual validation assessments;
    - reviewing national EMTCT reports submitted by a candidate country to ensure the achievement of the required targets in compliance with global validation criteria and processes;
    - assembling and reviewing the materials for review at the RVC meeting; this includes the national validation report and any other documents received at the regional level for review;
    - collaborating with the country to ensure that reports on the maintenance of validation are completed at the designated time intervals and that the reports address the recommendations made by the RVC and GVAC;
    - submitting regional validation reports or maintenance of validation reports from the RVC to the GVS;
    - communicating requests for clarifications and additional information from the GVS through the health ministry to the relevant stakeholders and receiving responses from the NVS and/or RVC;
    - participating in the global preparatory review group (PRG) process in advance of a GVAC review (please see paragraph 31, first bullet under "Validation/maintenance of validation processes");
    - summarizing via a PowerPoint presentation the information contained in the regional validation report submitted to the GVS for GVAC review; this can be done by the WHO regional advisor and/or a WHO country representative;
    - presenting regional updates to the GVS on countries in the application pipeline.;
    - reviewing and providing feedback to the GVS on the validation assessment tools and national and regional report templates;
    - collaborating with the GVS to identify and build capacity for countries in the prevalidation period and maintaining a workplan to include supporting countries in the pipeline for validation.

REGIONAL VALIDATION COMMITTEE (RVC)

20. The RVC is a standing committee of expert members (see Box 2) established and convened by the RVS to independently assess whether its countries have achieved or maintained the validation of EMTCT.

21. The RVC may decide to establish teams or working groups of independent experts to rigorously validate the data and information presented in the national validation report.

22. RVCs, with the approval and support of the RVS, may conduct validation assessments either in country, virtually or a hybrid of both.

23. The main responsibilities of the RVC include:
    - reviewing the national validation report, developing the regional validation report and advising the RVS on whether countries have achieved or maintained the criteria for validation of EMTCT and can be officially recommended for review at the global level;
    - liaising with the RVS to request and receive additional information and clarifications from the NVC and revising the regional validation report accordingly;
    - reviewing maintenance of validation reports at the designed maintenance time intervals: see chapter 8 of *Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus* at https://apps.who.int/iris/handle/10665/349550.

24. To become fully operational, the RVC, with the support of the RVS, will
    - define the roles and responsibilities of RVC members in accordance with regional preferences and individual areas of expertise, in line with global guidance;
    - decide on internal work processes, including nominating a chair or co-chair; and
    - decide whether to create working groups or teams to assess the four areas required for validation review. The RVC, through the RVS, can request and retain consultants or other sources of expertise to conduct validation assessments as in-country or virtual country missions to support the development of its regional validation report.

25. The regional validation report will strictly follow the report template. (Please see Regional Validation Report template at: https://www.who.int/initiatives/triple-elimination-initiative-of-mother-to-child-transmission-of-hiv-syphilis-and-hepatitis-b/validation/process-and-tools.)

26. If the RVC does not recommend a candidate country for validation, the country will not progress to global review. Instead, the RVS will communicate issues raised by the RVC to the health ministry and will work together with the NVS and the NVC to address the identified issues. An updated national validation report may then be resubmitted for reconsideration of validation at the regional level.

27. For countries that have been successfully validated, the RVC will review subsequent maintenance of validation reports and decide whether the candidate country has maintained validation and has responded adequately to prior recommendations made by the RVC and GVAC (for example, describing progress made since the last review). If the RVC advises that the country has met the criteria for maintenance of validation, the RVS will forward the maintenance report and the RVC meeting report to the GVS within three months of the review date.

VALIDATION STRUCTURE AT THE GLOBAL LEVEL

28. At the global level, the following entities are involved in the validation process:

- the Global Validation Secretariat (GVS)
- the Global Validation Advisory Committee (GVAC)
- relevant UN partners, such as UNAIDS, UNICEF, UNFPA and the IOM.

29. The global validation process verifies that the country has met the conditions for validation based on the criteria for each of the critical components outlined in the *Global guidance* document.

GLOBAL VALIDATION SECRETARIAT

30. WHO headquarters hosts the GVS. The GVS is staffed by the members of the department of Global HIV, Hepatitis and Sexually Transmitted Infections Programmes (HHS) and other relevant departments within WHO. Relevant UN counterparts at the global level will partner with the GVS as necessary to support the validation process.

31. The responsibilities of the GVS include:

Operations

- coordinating the development and revision of the guidance for the validation criteria, processes and assessment tools to ensure that the validation process is consistent across countries and regions and is aligned with the global guidance;
- collaborating with RVSs to identify and build capacity for countries in the pre-validation process and maintaining a workplan to include what is needed to support regions and countries in the pipeline for validation;
- establishing, convening, coordinating and providing logistical support for the proper functioning of the GVAC;
- scheduling GVAC meetings, including the annual and quarterly web-based and/or in-person meetings for validation reviews and GVAC business;
- appointing the GVAC chair and co-chair; the director of HHS will make these appointments;
- maintaining membership of the GVAC by coordinating the selection of GVAC members through a WHO-approved, standardized process for recruitment into advisory committees;
- coordinating all activities of the GVAC, including the provision of administrative and logistical support to the GVAC in its review of regional validation reports and other documents; these documents must be submitted to the GVAC no less than four weeks prior to the review date;
- setting GVAC meeting agendas in consultation with the GVAC chair and co-chair;
- submitting final decision letters, including recommendations and validation certificates, through the signatory process at WHO. All correspondence to countries will be emailed and sent in hard copy via certified mail to the regional offices, which will forward them to the health ministry.
- maintaining and archiving, through SharePoint, all documents related to past validation reviews and up-to-date information on validated countries.

Validation/maintenance of validation processes

- establishing a Preparatory Review Group. Once the GVS has conducted a preliminary review of the regional validation report and deemed that the report includes all required information for the GVAC review, the PRG will be convened. The PRG consists of a subset of GVAC members who conduct the expert subject matter reviews and hold discussions prior to the full GVAC review. Regional advisors and WHO country advisors will be asked to join the review call and be ready to respond to any requests for clarifications or to provide additional information needed by the PRG. If additional information or clarifications are needed, the GVS will expedite the request for information and ensure that the information is received before the greater GVAC meeting.
- conveying any requests from the PRG or the GVAC for clarifications or additional information to the NVC via the RVS;
- assembling and finalizing recommendations received from the GVAC during the validation reviews.

32. The GVS has the authority to exclude documents from GVAC review that have not previously been submitted to and reviewed at the regional level during the regional validation or maintenance process (for example, shadow reports). The GVS sets and adheres to strict deadlines for submitting documents for initial or maintenance of validation reviews at the global level.

33. All documents to be reviewed must be submitted to the GVS at least six weeks prior to the scheduled GVAC review date.

34. If documents are received after the deadline date submission, the validation or maintenance review will be moved (if possible) to the next GVAC meeting date, or an ad hoc meeting, if determined feasible by the GVS, will be scheduled by the GVS in consultation with the GVAC chair and co-chair.

35. Following a validation or maintenance of validation review, the GVS will circulate draft GVAC meeting notes and draft recommendations made during the meeting to GVAC members for input. All responses will be due back to the GVS no later than three weeks after the documents are shared. The GVS seeks WHO approval on any recommendations made and finalizes validation documents. All records of GVAC meetings will be made available to the GVAC.

GLOBAL VALIDATION ADVISORY COMMITTEE (GVAC)

36. The GVAC is an independent advisory body that provides technical advice and supports oversight for the validation and maintenance of the validation process. Its main responsibility is to determine whether countries' efforts towards achieving the EMTCT meet the global validation criteria and standards.

37. As with all WHO headquarters advisory bodies, all recommendations from the GVAC are advisory to WHO, which retains full control over any subsequent decisions or actions regarding any recommendations, proposals, policy issues or other matters considered by the GVAC.

38. The GVAC advises WHO through the GVS on the validation of EMTCT by making their own independent evaluations through a thorough primary review of the regional validation report and discussions in GVAC meetings. (National validation reports will be available but are not regarded as the primary document for review.)

39. The main activities and responsibilities of the GVAC include:

- Reviewing regional validation and maintenance of validation reports and other related documents previously reviewed by the RVC;
- A subset of GVAC members participates in a PRG on a rotating basis for each validation/maintenance review prior to presenting their expert opinion on a component of the RVC report to the GVAC.
- Preparing for and participating in annual and quarterly meetings to review countries for validation or maintenance of validation. GVAC business meetings may be scheduled as needed. The GVAC's annual meeting will be scheduled in or around September of each year. The annual meeting will be used to review validation reports, share expertise and ideas on capacity building across disciplines, and review ongoing lessons learned from the validation and maintenance processes.

40. The GVAC will discuss and aim to reach consensus on whether a country has achieved the global criteria for validation or maintenance of validation. If a consensus cannot be reached, a formal vote will be held as outlined in the GVAC standard operating procedures. All dissenting and minority opinions will be recorded in the minutes of the meeting.

41. Once WHO has accepted the GVAC recommendation for validation, the Director-General signs a certificate recognizing the country's achievement of elimination. The certificate and recommendations for follow-up actions are sent with a letter from the Associate Director-General to the WHO regional office for transmission to the country.

42. A synopsis of validation processes and responsibilities at national, regional, and global levels are found in Fig. 3.

43. Countries that have been validated as having achieved EMTCT will be assessed at regular, defined intervals for maintenance of validation. (Fig 4). For more detailed information and maintenance reviews, see chapter 8 in *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus.*

44. Schedules for maintenance reviews will be set out in the decision letter sent by WHO following validation or maintenance of validation. Considering the multiple validation combinations possible for single, dual or triple elimination, countries may seek further clarification on timelines for review through the GVS.

Fig 3. Process for validation of EMTCT including the responsibilities of the health ministry, committees and secretariats at the national, regional and global levels

Health ministry

1. The health ministry sends a request for validation to the WHO country office or national validation secretariat (NVS).
2. The health ministry establishes the national validation committee (NVC) for collecting the evidence and reporting on efforts to achieve EMTCT. It may also create a team or working groups to be responsible for data collection and preparation of the final report.

National validation committee/ and secretariat (NVC/NVS)

3. The NVC conducts a preliminary assessment.
4. The NVC writes the national validation report.
5. The national validation secretariat applies for validation and submits the validation report to the WHO regional director or regional validation secretariat.

Regional validation committee/ and secretariat (RVC/RVS)

6. The WHO regional director or regional validation secretariat establishes and convenes a regional validation committee. Any of these entities can create a regional team or working groups.
7. The assigned regional validation body undertakes a desk review of the elements in the national validation report and conducts the regional validation assessment (via in-country mission or virtual assessment).
8. The regional validation team, working group or committee submits the regional validation report to the regional validation secretariat.

Global Validation Advisory Committee and secretariat (GVAC/GVS)

9. The regional validation secretariat submits the regional validation report to the global validation secretariat, which reviews the report before sending it to the Global Validation Advisory Committee.
10. The Global Validation Advisory Committee reviews the regional report and advises WHO whether the country has reached elimination targets and should be validated and provides, if necessary, a list of recommendations to sustain EMTCT criteria.
11. Once WHO has accepted the GVAC recommendation for validation, the Director-General signs a certificate recognizing the country's achievement of elimination. The certificate and recommendations for follow-up actions are sent with a letter from the Associate Director-General to the WHO regional office for transmission to the country.

45. After the GVAC has reviewed a country for maintenance of validation twice, the GVS, on the advice of the GVAC, may decide to transfer countries to the RVC for continued maintenance reviews. It is assumed that the RVC will follow the same schedule and timelines as the GVAC. RVCs may, through the RVS and GVS, request a consultation with a GVAC member to enhance their understanding of previous GVAC maintenance reviews. The RVC will inform the GVS through the RVS whether countries continue to maintain validation. GVS notification should occur no later than three months after RVC approval of maintenance of validation. If there are significant changes in the national health system, human rights situation, or not meeting the global criteria for EMTCT of HIV, syphilis or HBV, observed by the RVC, the monitoring report on maintenance of EMTCT of HIV and syphilis should be referred back to the GVS for review and follow-up with the GVAC.

Fig 4. Process for maintenance of validation of EMTCT of HIV, syphilis and HBV

Health ministry

1. The health ministry works with the NVC to provide evidence of the national efforts to maintain EMTCT.
2. The health ministry reports on the requested indicators using the UNAIDS Global AIDS Monitoring (GAM) system, if applicable.

National validation committee (NVC)

3. The NVC prepares the maintenance of validation report every 3 years after initial validation (or every 4 years where applicable) for EMTCT of HIV and syphilis and every 5 years for EMTCT of HBV. The NVS submits the monitoring report to the RVS.

Regional validation secretariat/ Regional validation committee (RVS/RVC)

4. The RVS sends the monitoring report to the RVC.
5. The RVC conducts a desk review 0f the maintenance of validation report,
6. In case of requests for additional information, the RVC, through the RVS, works with the NVC and the health ministry to obtain the information.
7. The RVC submits the final report to the RVS and advises on the status of maintenance of validation.

Global validation secretariat/Global validaton advisory committee (GVS/GVAC)

8. The GVS monitors the required cycles for maintenance status across validated countries.
9. The GVS reviews the maintenance of validation report and sends it to the GVAC for review.
10. The GVAC reviews the maintenance of validation report and advises WHO on whether validation targets have been maintained.
11. The GVS notifies the health ministry on maintenance of validation and informs the RVS and NVS.

DEFERRAL OF VALIDATION

46. At the global level, the GVAC may advise WHO to defer validation or maintenance of validation pending the receipt of additional information from the country. In some cases, the GVAC co-chairs may choose to discuss the decision directly with the RVC co-chairs. The communication between the GVAC and the RVC will be facilitated by the GVS and the RVS.

47. If the GVAC advises WHO to defer validation pending clarifications or requests for additional information requested by the GVAC, the GVS will submit the requests to the RVS, which will then communicate with the RVC and NVC in the candidate country to ensure a rapid turnaround for responding to the requested clarifications. Once all requested information has been received, the GVAC will meet to assess whether the country can be validated. A country may not appeal the decision to defer validation. The GVS will work with the RVS to submit any additional information or clarifications and schedule a GVAC meeting to review and revote as soon as possible.

VALIDATION SUSPENSION

48. The GVAC may advise WHO to suspend a country if the country no longer meets the global targets. This includes human rights violations in the context of EMTCT that have been observed in the prior review and are worsening, or progress toward mitigating these violations is not shown.

49. Following a vote for suspension, the country will be placed in a three-year probationary period. In this period, the country will report yearly to the RVS on EMTCT indicators and any relevant human rights issues that led to the suspension.

50. If the country still does not meet the criteria to maintain validation at the end of the three-year probationary period, the GVAC may advise WHO to revoke validation. The GVS will notify the health ministry, the NVS and the RVS of the revocation through an official letter from WHO headquarters.

MECHANISM FOR APPEALS

51. An appeals mechanism has been established for candidate countries who do not agree with the WHO decision to suspend validation. In case of an appeal, the candidate country may, working in collaboration with the NVS, NVC, RVS and RVC, request that the GVAC re-evaluate the decision.

GROUNDS FOR APPEALING A VALIDATION DECISION

52. The only grounds for appealing a WHO decision are that the GVAC has made one or more significant errors in reviewing the regional report or misinterpreted information presented therein.
    - Applicants must demonstrate that this error was based on the regional validation report that was reviewed by the RVC and RVS.
    - The appeal may include a rebuttal or elaboration on information already in the report.

SUBMISSION OF A VALIDATION APPEAL

53. The health ministry must submit a request for appeal to the GVS through the RVS and the NVS. The letter of appeal must detail the reason for the appeal and outline the areas in which the country believes the elements for validation were either missed or misinterpreted in the RVC report.

54. The timeline for appeal is as follows:
    - The health ministry must submit a letter requesting appeal to the GVS within three months from the date of receiving the written notice that WHO has suspended the validation or maintenance of validation of EMTCT.
    - Once an official request for appeal is received by the GVS, the GVAC will review the appeal and advise WHO on validation.

AFTERWORD

This governance guidance document will be refined and updated regularly based on the experience of evaluating countries for EMTCT validation at national, regional and global levels or with any revisions in the criteria and processes for validation.

The GVS may seek legal counsel from the WHO Quality Norms and Standards (QNS) office and other WHO departments regarding matters related to the governance of the validation process. The WHO QNS department has the ultimate authority to amend or change this governance document.

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