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# VALIDATION OF ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION OF HIV AND SYPHILIS

AN OVERVIEW OF VALIDATION STRUCTURES AND RESPONSIBILITIES AT NATIONAL, REGIONAL AND GLOBAL LEVELS

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World Health Organization

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Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis: an overview of validation structures and responsibilities at national, regional and global levels

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# ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **EMTCT** | elimination of mother-to-child transmission |
| **GVS** | Global Validation Secretariat |
| **GVAC** | Global Validation Advisory Committee |
| **MTCT** | mother-to-child transmission |
| **NVC** | national validation committee |
| **NVS** | national validation secretariat |
| **PMTCT** | prevention of mother-to-child transmission |
| **PTE** | path to elimination |
| **RVC** | regional validation committee |
| **RVS** | regional validation secretariat |
| **UNAIDS** | Joint United Nations Programme on HIV/AIDS |
| **UNFPA** | United Nations Population Fund |
| **UNICEF** | United Nations Children's Fund |

# EXECUTIVE SUMMARY

WHO has defined elimination of mother-to-child transmission of HIV and syphilis (EMTCT) as a reduction in the number of new HIV and syphilis infections among infants to a level at which they are no longer a public health problem. WHO defines these levels as the impact criteria for country validation of EMTCT for the two infections. Prevention of mother-to-child transmission (PMTCT) of HIV includes preventing primary HIV infection in women and girls of childbearing age, identifying HIV infection as early as possible before or during pregnancy and postpartum, providing the pregnant and post partum women and their families living with HIV antiretroviral therapy immediately on diagnosis and continuing antiretroviral therapy through the pregnancy and breastfeeding periods. Women are then encouraged to continue antiretroviral therapy for life. PMTCT of syphilis includes early detection of maternal syphilis and immediate treatment with a minimum of one injection of 2.4 million units of benzathine penicillin G intramuscularly at least four weeks before delivery. Partner testing and treatment is strongly recommended to prevent syphilis reinfection during pregnancy.

WHO published the first edition of the *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis* in 2014. In 2017, WHO published the second edition, which included a tiered set of criteria (bronze, silver and gold) to recognize countries with high background prevalence of HIV and syphilis for their tremendous achievements in PMTCT, termed the path to elimination (PTE). As of January 2020, 14 countries had been validated for EMTCT of HIV and/or syphilis. At least five countries in the WHO African Region are projected to be eligible to apply for PTE during 2020–2022. This guidance provides a basic overview of the national, regional and global validation structures and processes needed to assess countries for achieving the criteria required for WHO to validate that a country has achieved EMTCT of HIV and syphilis and the PTE. The purpose and intent of this governance guidance is to provide clarity, consistency and detail related to the structure, function, composition and operational duties of validation committees at national, regional and global levels as an extension to what is provided in the *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis*. In addition, this publication describes the standardized methods for country programme review and validation of EMTCT of HIV and syphilis and PTE at these levels.

In April 2019, an external evaluation was carried out in the form of stakeholder interviews to gather information on experiences, views and perceptions of the process of country assessment and validation of EMTCT of HIV and syphilis with the intent to develop and formalize this first governance document. Findings from the assessment were reviewed at an in-person focused meeting of a subset of Global Validation Advisory Committee (GVAC) members and WHO regional advisors. Summary discussions from this focused meeting were presented at the face-to-face full GVAC meeting in June 2019. Additional input on the draft document was obtained via email from GVAC members during June–August 2019 and submitted to WHO regional advisors and GVAC members for final approval in November 2019.

This governance guidance publication details the agreed upon governance structures that cover national, regional and global activities. Between the publication of this governance guidance in 2020 and the planned third edition of *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis*, the governance structures and processes in this publication serve as the most current methods to be applied to the country review and validation process. Revisions to this publication are expected to be incorporated periodically (every 2–4 years). At the time of the development of this governance document, the criteria and processes for country validation of EMTCT of hepatitis B were in development. Specific governance for the processes related to validating countries for EMTCT of hepatitis B will be forthcoming in a subsequent revision of this guidance.

# INTRODUCTION

1. In 2014, the first edition of *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis* was published. In 2015, the Global Validation Advisory Committee (GVAC) was established to objectively evaluate whether countries have achieved the elimination of the mother-to-child transmission (EMTCT) of HIV and syphilis. The second edition was released in 2017 and included expanded guidance on governance, processes and criteria. Further, the criteria and guidance for countries with a high burden of HIV and syphilis that have made significant progress in lowering mother-to-child transmission (MTCT) rates were added and termed path to elimination (PTE).

2. This governance guidance provides further detail on the standardized structure and processes used to validate EMTCT of HIV and syphilis. This publication serves alongside and as a supplement to the *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis (global EMTCT guidance)*, the four country assessment tools on EMTCT of HIV and syphilis and the pre-assessment tool on EMTCT of HIV and syphilis and PTE. In the interim between the publication of this governance guidance in 2020 and the planned third edition of the *global EMTCT guidance elimination of mother-to-child transmission of HIV and syphilis*, the governance structures and processes in this publication serve as the most current methods to be applied to the country review and validation process.

3. This publication was developed from a pre-existing but unpublished draft governance guidance outline on EMTCT of HIV and syphilis developed in tandem with the first edition of the global EMTCT guidance. In April 2019, an external evaluation was carried out to gather additional information and views on, experiences and perceptions of the process for validation of EMTCT of HIV and syphilis. A draft governance document was produced that compiled recommendations from this stakeholder interview process and added to the pre-existing draft governance. A global meeting was then convened on 11–12 June 2019 with members of the Global Validation Secretariat (GVS), regional validation secretariats (RVSs), GVAC and implementing partners to review the findings and propose changes to the current governance structure as generally described in the second edition of the global EMTCT guidance to improve the clarity, consistency and efficiency of the validation process. Recommendations from that meeting are included in this governance guidance publication.

4. This publication describes the overall governance of validation and, as such, standardizes and outlines the structures, operations and responsibilities of the validation committees and secretariats involved in the process of validation of EMTCT of HIV and syphilis and PTE at the national, regional and global levels. Consistent use of the governance structure including the lines of communication is anticipated to support and simplify the validation process.

5. Guiding principles for the process of validation of EMTCT of HIV and syphilis or PTE involve aligning with relevant national and global strategies and engaging relevant stakeholders in a multisectoral approach. Engaging civil society and the community of women living with HIV at the start of the national validation process will facilitate a meaningful contribution of the community to the validation process.

6. The validation process consists of two main segments: (1) country assessment for validation of EMTCT of HIV and syphilis and PTE; and (2) maintenance of validation of EMTCT or PTE of HIV and syphilis.

## VALIDATION STRUCTURE AT THE NATIONAL LEVEL

7. At the national level the following entities, if available in the country, have an important role in the validation process: the health ministry, the WHO country office, the national validation secretariat (NVS), the national validation committee (NVC), civil society, the community of women living with HIV and relevant United Nations partners such as UNAIDS, UNICEF and UNFPA. Other implementing partners that are involved in the efforts to achieve EMTCT of HIV and syphilis can also be included.

## HEALTH MINISTRY

8. The health ministry initiates the validation process by submitting the validation request to the WHO country office, which informs the RVS, hosted at the WHO regional office, of the country's intent. If the country has no WHO country office, the request should be submitted directly to the RVS.

9. The health ministry establishes an NVC, which gathers the evidence at the country level and prepares the national validation report.

10. The health ministry constitutes the NVC with the appropriate expertise for validation of its national efforts to achieve EMTCT of HIV and syphilis or PTE.

11. The health ministry convenes and leads the NVC, which functions as an extension of health ministry efforts to rigorously, independently and transparently document its national.

12. The health ministry ensures that country data for EMTCT indicators are entered annually into the UNAIDS Global AIDS Monitoring System (GAM)

## NATIONAL VALIDATION SECRETARIAT (NVS)

13. The WHO country office hosts the NVS, which works in close partnership with UNAIDS, UNICEF and UNFPA. The NVS serves as the first point of contact with national stakeholders. It provides technical support, together with relevant United Nations partners, to the country and the NVC for assessing the programme for EMTCT of HIV and syphilis and preparing the national validation report.

14. The WHO country office serves as an intermediary between the regional level and the NVC. If the country does not have a WHO country office, a relevant United Nations partner can liaise between the NVC and RVS.

15. The NVS submits the final national validation report and the monitoring reports for maintenance of validation status to the RVS for review and approval.

16. The NVS organizes a kick-off meeting at the initiation of the validation process with the health ministry, NVC (including civil society), United Nations partners and relevant implementing partners, with support from the RVS, to review the overall validation process and to orient or train all stakeholders with respect to the global criteria and processes, tools, requirements and timelines.

## NATIONAL VALIDATION COMMITTEE (NVC)

17. The NVC provides the evidence in the report that a country has met the global criteria for validation of EMTCT of HIV and syphilis or PTE of HIV and syphilis. Annex 1 provides sample terms of reference for the NVC. The main responsibilities of the NVC include:

    - coordinating the national assessment and validation process at the national level, that is, coordinating the collection of the evidence from the in-country mission and ensuring effective communication with the health ministry and NVS;
    - preparing the national validation assessment report[1] on EMTCT of HIV and syphilis or PTE using the four validation assessment tools: (1) data and surveillance systems, (2) programme evaluation and assessment, (3) laboratory assessment and (4) human rights, gender equality and community engagement;
    - submitting the national validation report to the health ministry and NVS for initial review;
    - coordinating the in-country mission or virtual assessment (when applicable) for regional validation;
    - working with the NVS, the RVS and the regional validation committee (RVC) during the regional validation assessment;
    - revising the national validation report and providing responses to the requests for clarifications and recommendations from the in-country validation mission and the RVC;
    - submitting the final national validation report to the health ministry and NVS.

18. Each NVC may receive technical support from the WHO country office and other United Nations implementing or funding partners (hosted in the NVS) for preparing the national validation report. Each United Nations agency country office can determine the optimal communication practices with the health ministry and the NVC. If the country does not have a WHO country office, the country may submit validation requests directly to the RVS.

1 The template for the national validation report is available from: https://www.who.int/reproductivehealth/publications/rtis/9789241505888/en.

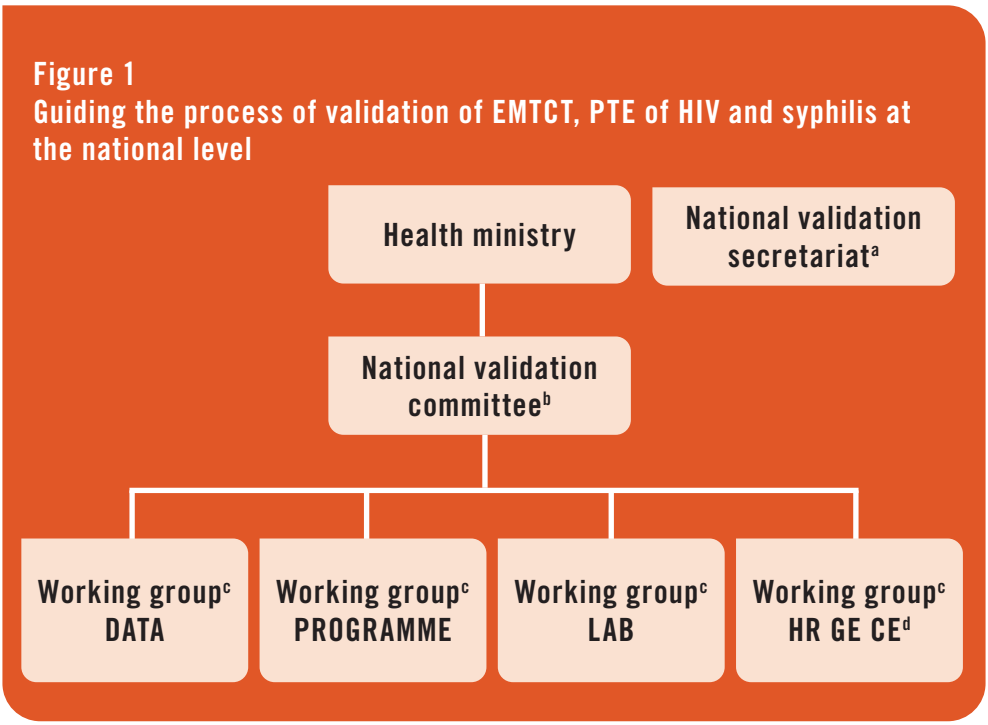
19. The primary responsibility of the NVC is to prepare and submit the national validation report according to the global EMTCT guidance and the report template. The NVC remains fully active for the duration of the validation process.

20. The NVC drafts a roadmap for the validation process following the initial kick-off meeting detailing the activities, roles and responsibilities, data collection, sequence of events and timelines.

21. The NVC decides on the internal work processes and nominates a chairperson, co-chair and technical secretariat to organize meetings and to support the writing of the national validation report.

22. The NVC decides to create working groups as required and/or retain consultants or other sources of expertise to support the development of its national validation report. Figure 1 presents a guide to the organization and governance at the national level.

**Figure 1**
**Guiding the process of validation of EMTCT, PTE of HIV and syphilis at the national level**




[a] Including the WHO country office and United Nations partners.
[b] Including United Nations partners and the community.
[c] Including input from the community.
[d] Human rights, gender equality and community engagement.

## MEMBERSHIP OF NATIONAL VALIDATION COMMITTEE

23. The NVC is a multidisciplinary team with a wide cross-section of professionals from various services and programmes and representation from people living with HIV, including at least one woman living with HIV. The health ministry is encouraged to give priority to practical experience, personal integrity, gender balance and geographical diversity in selecting NVC members. Including multiple disciplines in the NVC helps to ensure an all-inclusive, transparent and collaborative review of the efforts to achieve EMTCT of HIV and syphilis or PTE in the country. The WHO country office, other United Nations partners (UNAIDS, UNICEF and UNFPA) and other relevant non–United Nations implementing partners can provide advice and support to the health ministry in selecting national stakeholders. United Nations and non-United Nations implementing partners may also serve on the NVC as determined by the health ministry.

24. The NVC should include expertise in the following disciplines (this is a suggested minimal list of expertise):

- clinical expertise in HIV and sexually transmitted infections. Viral hepatitis and immunization experts should be included if the country is considering EMTCT of hepatitis B;
- the community of people living with HIV, including at least one woman living with HIV (required);
- epidemiology, monitoring and evaluation;
- human rights, with a focus on higher-risk and vulnerable groups;
- public health programmes: HIV and sexually transmitted infection programme management (viral hepatitis and immunization programmes if the country is considering EMTCT of hepatitis B);
- laboratory services;
- maternal and child health care;
- private sector maternal and child health care; and
- social and behavioural sciences.

25. The national validation committee (NVC) may include the following stakeholders in the efforts to evaluate EMTCT of HIV and syphilis and PTE:

- national government representatives;
- civil society and women living with HIV;
- United Nations partners if involved in efforts to achieve EMTCT in the country;
- other relevant implementing non–United Nations partners;
- foundations, academic institutions and professional associations; and
- nongovernmental organizations serving in the community or country.

26. The NVC decides who will be responsible for writing the national validation report. NVC members should have the technical expertise to contribute to the national validation report and to review the regional validation report.

27. NVC members must be committed to allocate time and energy to review the data in detail for the national validation of EMTCT of HIV and syphilis and PTE of HIV and syphilis without financial remuneration from the health ministry or WHO.

28. Each NVC member must sign a confidentiality and conflict-of-interest statement before engagement in a country assessment. This should be renewed yearly during the time the NVC is involved in country assessment.

29. The size of the NVC will vary by country. However, efforts should be made to ensure that the NVC is unbiased and has the technical expertise as described in the NVC membership section.

30. NVC members remain fully active on the NVC for the duration of the validation process.

## VALIDATION STRUCTURE AT THE REGIONAL LEVEL

31. At the regional level, the following entities play an important role: the RVS, hosted by the WHO regional office, and the RVC. (Figure 2 presents a guide to the organization and governance at the regional level).

32. The regional validation process is intended to validate and verify the content and quality of the national validation report. The RVC and the RVS work together to assign regional support for the country validation or to provide feedback to the national teams (NVC and NVS) regarding the need for further review and action. The RVS and RVC should support the process and ensure that RVC members have a full understanding of the performance and practices of the country for the target and service indicator criteria contained within the four assessment tools.

33. In keeping with the objectives of the EMTCT validation, while ensuring the efficient use of both human and financial resources, a "virtual" validation assessment of countries is permitted. The RVS will assess and approve the request for a virtual validation before implementation. The virtual assessment of EMTCT achievements follows a similar process as the in-country validation missions. It is conducted by the RVC under the supervision of the RVS. Although there are no specific global criteria for conducting virtual validations, the RVS may set regional criteria. As is the case for all validations, whether conducted in country or virtually, the regional assessment must have verified and described in the regional validation report that a country has achieved the required criteria by demonstrating the following:

    - a robust monitoring and surveillance system capable of identifying maternal and infant cases of HIV and syphilis as well as monitoring service coverage;
    - sufficient information on the laboratory services and network to ensure reliable and accurate HIV and syphilis diagnosis among both adults and exposed infants;

- sufficient information to understand the basic organization and functioning of health services and programmes related to EMTCT; and
- evidence to understand the impact of human rights, gender equality and community engagement on the implementation of the EMTCT strategy.

## REGIONAL VALIDATION SECRETARIAT (RVS)

34. The RVS has the overall responsibility for the process of validation of country efforts to achieve EMTCT of HIV and syphilis and PTE criteria and works together with the RVC. The WHO regional office (programmatic offices) hosts the RVS, which works in close partnership with UNAIDS, UNICEF and other relevant United Nations partners.

35. The RVS serves as the focal point for communication between the national (health ministry, NVC and NVS), regional (RVC), global (GVAC and GVS) and United Nations partners.

36. The main roles and responsibilities of the RVS include:

- establishing and convening the RVC;
- coordinating regional validation processes and activities;
- ensuring the coherence of and compliance with global validation criteria and processes;
- providing coordination, communication, administrative and logistic support for the RVC and the assessment activities, including in-country visits;
- approving and submitting regional validation reports from the RVC to the GVS;
- processing any appeals to the validation process if raised by the health ministry in the candidate country;
- communicating the decision of the GVS and GVAC regarding validation or maintenance of validation to the NVS;
- communicating requests for clarifications and additional information from the GVAC with the relevant stakeholders (RVC, NVC, NVS and health ministry) and receiving responses from the NVC, NVS and/or RVC;
- collaborating with the country to ensure that reports on maintenance of validation are completed every two years and that the report addresses the recommendations made by the RVC and GVAC;
- coordinating the presentation of country maintenance of validation reports (submitted by the country to the RVS) to GVAC. The report can be presented by the WHO regional advisor and/or a WHO country representative.
- presenting regional mid-term planning for candidate countries in the pipeline for consideration of validation for EMTCT of HIV and syphilis or PTE to the GVS and GVAC.

## REGIONAL VALIDATION COMMITTEE (RVC)

37. The RVS facilitates establishment and convenes the RVC. Each region is encouraged to establish a standing RVC to gain experience in the validation process and to ensure capacity-building at the regional level. When the RVC becomes fully operational and capable over time, it may play an increasingly important role in the maintenance of validation process as outlined below. If the region opts not to convene an RVC, the RVS will fulfil the roles of the RVC.

38. The standing RVC oversees the validation processes in the region and decides to establish teams or working groups to be dedicated to the validation process for a specific country. Annex 2 provides sample terms of reference for the RVC.

39. The RVC has the main responsibility to advise the RVS as to whether countries have achieved the criteria for validation of EMTCT or PTE of HIV and syphilis and can be recommended for review by the GVS and the GVAC.

40. The RVC is responsible for submitting a complete and accurate regional validation report to the RVS, which is then submitted to the GVS.

41. The main activities and responsibilities of the RVC include:

- reviewing national validation reports from the NVCs to determine compliance with the global criteria for validation of EMTCT or PTE of HIV and syphilis through expert desk review and in-country mission or virtual validation assessment using the four validation assessment tools;
- working with the NVCs to assist country efforts to prepare and complete validation activities;
- preparing the regional validation report to inform national and global partners regarding compliance with global criteria for validation of EMTCT or PTE of HIV and syphilis and submitting it to the RVS;
- liaising with the RVS to provide updates about validation activities and assisting the RVS in communicating between national, regional and global partners as required;
- collaborating with the RVS, NVS and NVC to ensure the monitoring for maintenance of validation, including re-evaluation of impact and process indicators every two years; and
- reviewing and providing feedback to the RVS and GVS on the validation assessment tools.

42. To become fully operational, the RVC, with the support of the RVS, will:

- define the roles and responsibilities within the RVC in accordance with regional preferences and individual areas of expertise;
- decide on internal work processes and nominate a chair, co-chair and secretary;
- determine detailed operational practices including: evaluation approach and methods, organization of in-country missions or virtual validation assessment and communicating with the NVS, NVC and global partners;

- decide to create working groups or retain consultants or other sources of expertise to conduct in-country missions or virtual validation assessments and to support the development of its regional validation report.

43. The regional validation report will:

- provide an overall description of the process of country review performed by the regional validation working groups;
- describe general programming within the four evaluation areas covered by the validation tools;
- review the nationally reported data demonstrating achievement of the criteria required for validation of EMTCT or PTE of HIV and syphilis;
- recommend whether the programmes for achieving EMTCT of HIV and syphilis or PTE of HIV and syphilis have achieved the global validation criteria based on a review of the national validation report and country assessment;
- provide recommendations to strengthen and improve the programmes and activities for EMTCT of HIV and syphilis in the country.

44. If the RVC does not recommend a candidate country for validation, the national and regional reports will not be sent to the GVS for validation review. Instead, the health ministry is requested to work together with the NVC and RVC to address the identified issues and then submit an updated national validation report for reconsideration of validation.

45. With respect to maintenance of the validation process, the RVC will review and approve the national monitoring reports and send them to the RVS for review and approval.

46. The maintenance of validation responsibility can be transferred to the RVC, at the discretion of the GVS and GVAC, after two rounds of review for maintenance of validation at the global level. From then on, the RVC will advise the RVS on maintenance of validation status and the RVS will request endorsement from the GVS.

47. However, in case of any unforeseen changes in the national health system or human rights situation observed by the NVC or RVC that could affect the processes of maintaining EMTCT of HIV and syphilis, the monitoring report on maintenance of EMTCT of HIV and syphilis can be submitted to the GVS for review and follow-up with the GVAC, if needed.

## MEMBERSHIP OF THE REGIONAL VALIDATION COMMITTEE (RVC)

48. Membership of the RVC includes independent experts in the region engaged in efforts to achieve EMTCT of HIV and syphilis, including civil society and the community of women living with HIV.

49. The WHO regional director, with strong input from the RVS, selects the required members of the RVC, ensuring that it collectively includes expertise in the following disciplines:

- clinical expertise in HIV and sexually transmitted infections (viral hepatitis and immunization experts should be included if countries in the region will be evaluated for EMTCT of hepatitis B);

- the community of people living with HIV, including at least one woman living with HIV;
- epidemiology and monitoring and evaluation; and
- human rights, with a focus on people at higher risk.

50. The WHO regional director, in close collaboration with the RVS, selects experts for the RVC (according to their internal processes for selecting advisory committee members) and may include:

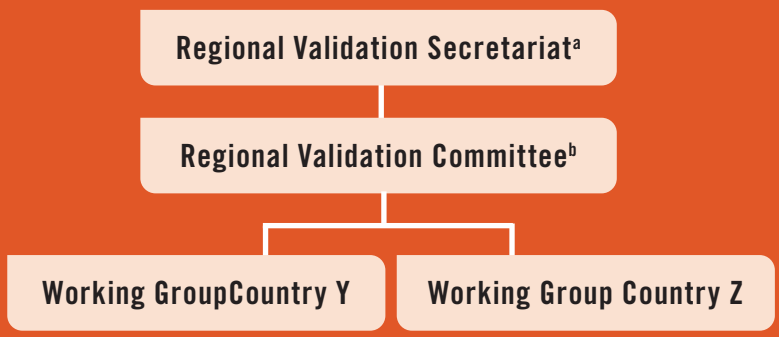
- representatives from marginalized and vulnerable groups;
- laboratory scientists;
- maternal and child health experts;
- experts from public health programmes: HIV, sexually transmitted infection and hepatitis B programme management;
- private sector maternal and child health experts; and
- social and behavioural scientists.

51. If the RVC has any knowledge gaps, it could decide to include technical advisory groups, expert committees or other bodies that are active at the regional level.

52. The RVC should be viewed as an advisory body with the technical and/or practical experience, personal integrity, gender balance and geographical diversity critical to the success of an international assessment. Its size will vary by region.

53. RVC members must have the time, interest and capability to review data in detail for the national validation of EMTCT or PTE of HIV and syphilis without financial remuneration from WHO.

**Figure 2**
**Coordination of the regional assessment of country achievement of EMTCT PTE of HIV and syphilis.**




[a] Inclusive of WHO regional office and United Nations partners.
[b] Inclusive of United Nations partners and the community.

54. RVC members must sign a WHO confidentiality and conflict-of-interest statement. Specifically, members should not have any salary bonuses or other supplementary elements of compensation tied to efforts to validate EMTCT of HIV and syphilis or PTE.

55. In case of conflict of interest, because of previous engagements, contractual issues or other conflicts, RVC members must be excused from the specific country validation vote (They may contribute to the process but may not vote).

## VALIDATION STRUCTURE AT THE GLOBAL LEVEL

### GLOBAL VALIDATION SECRETARIAT (GVS)

56. WHO headquarters hosts the GVS, staffed by the Department of Global Programmes of HIV, Hepatitis, and STI. The mission is to provide coordination, leadership and oversight of the validation process at the global level. The GVS works in close partnership with other relevant departments and United Nations partners. Since January 2020, the GVS has been coordinated entirely within the new Department of HIV, Hepatitis and STI. This includes the Director, relevant focal points on HIV and syphilis and consultants assigned to the coordination of the GVAC.

57. The GVS is responsible for establishing and coordinating the functioning of the GVAC, communicating with the RVSs and providing official recognition letters and recommendations from the GVAC to countries (health ministries) that achieve and/or maintain the validation of EMTCT of HIV and syphilis or PTE of HIV and syphilis.

58. Specifically, the GVS:

- informs the RVS about the outcome of the validation assessment by the GVAC;
- directly notifies the region or a candidate country (health ministry) through a letter from WHO and ensures that the health ministry receives clear explanations and/or suggestions for improvement if the candidate country did not meet the global validation criteria;
- reviews and considers any recommendations provided by regional partners for improving the validation processes in the country; and
- provides guidance for ongoing monitoring and evaluation of EMTCT and maintenance of validation impact and process indicators.

59. The main roles and responsibilities of the GVS include:

- developing and revising guidance on the validation processes and criteria and the use of the validation assessment tools to ensure consistency across countries;
- developing the validation assessment tools, ensuring the periodic review of the tools and providing updates as necessary;
- coordinating the activities of the GVAC and providing administrative and logistic support to the GVAC in its review of validation reports, decisions on applications (calculating and maintaining voting records) and validation appeals;

- conveying any requests for clarifications or additional information to the RVSs by email;
- facilitating communication of information from national and regional levels to the GVAC;
- organizing GVAC meetings to discuss and conduct voting for country validation of EMTCT or PTE and maintenance of validation;
- establishing a functional website with up-to-date information, on countries in the pipeline for EMTCT or PTE validation, report templates and assessment tools;
- serving as the final arbiter in the event of a health ministry appeal; and
- maintaining membership of the GVAC by identifying and selecting GVAC members through a WHO-approved standardized process for recruitment to committees.

60. The GVS retains the right to intervene if the GVAC is requesting data or information not directly related to the validation criteria or deviating from the validation process.

61. The GVS identifies possible conflicts of interest from GVAC members and adjudicates if recusal for a vote on the validation is needed. GVAC members who are also members of NVCs or RVCs for a country under GVAC review may recuse themselves from the voting process.

62. The GVS reserves the right to exclude the review of documentation submitted to the GVAC that has not been reviewed by NVCs or RVCs.

63. The GVS may seek legal counsel from the WHO legal office regarding matters related to the governance of this process.

64. The GVS reserves the right to override or defer the decision for validation or maintenance of validation if additional concerns arise during the country, regional or global review process.

65. The GVS assumes responsibility for the following operations.

- The GVS posts and announces open GVAC positions and facilitates the identification of new GVAC members through a WHO-approved standardized process for recruitment to committees, which ensures that the GVAC includes independent, gender-balanced members from all WHO regions and has the expertise as described under membership.
- The GVS schedules and conducts the annual face-to-face meeting. The GVS is responsible for supporting travel for GVAC voting members, setting the agenda in accordance with the GVAC co-chairs and for facilitating communication around the meeting with the GVAC, partners and external observers.
- The GVS sets an annual schedule with quarterly web-based meetings for reviewing country applications for validation and maintenance of validation of EMTCT of HIV and syphilis or PTE.
- The GVS sets strict deadline dates for submitting documents related to validation or maintenance of validation. The documents will be due one month before the fixed

web-based meeting date. The GVS will review documents for the first week to identify any clarifications or missing data before submitting to the GVAC. The GVAC will then have at least three weeks to review country documents before the web-based meeting. Validation reports submitted after the deadline will automatically be designated for the next scheduled web-based meeting.

- The GVS schedules ad hoc GVAC business web-based meetings as needed.
- The GVS documents (through meeting notes) the results and conclusions from GVAC validation and business meetings. The GVS circulates the meeting notes to the GVAC members for comments and then posts them on SharePoint.
- The GVS ensures a quorum for GVAC validation, coordinates the GVAC voting for validation and/or maintenance of validation and archives the related validation documents on SharePoint.
- The GVS facilitates the communication between the GVAC and the RVSs for requesting additional or missing information or clarifications on any part of the validation reports, both for initial or maintenance of validation reviews by the GVAC.
- The GVS collaborates with RVSs to identify countries in the pre-validation process and maintains a work plan to include countries in the pipeline for validation.
- The GVS schedules web-based meetings for country reviews for maintenance of validation every two years following initial validation of EMTCT or PTE, including follow-up on any GVAC recommendations made at the time of initial validation or most recent maintenance of validation.
- The GVS builds a library of regional and national validation reports, notes for the record from the validation meetings, letters and recommendations to the health ministries and copies of validation certificates.
- The GVS organizes the receipt of annual confidentiality agreements and declaration-of-interest statements from GVAC members.
- The GVS circulates draft letters and recommendations from GVAC for country validation or maintenance of validation of EMTCT of HIV and syphilis or PTE for review by the RVS, WHO governing bodies and WHO legal teams for review and input.
- The GVS circulates draft country validation letters and recommendations to the GVAC, with review and input of edits and comments before final submission. A two-week turnaround for GVAC input on draft letters will be expected.
- The GVS submits final letters and certificates of validation signed by the WHO Director General to health ministry staff in countries where EMTCT of HIV and syphilis or PTE has been validated and maintained. These letters will be accompanied by recommendations to the countries from the GVAC to ensure that the validation is maintained.
- The GVS sends final letters of validation and maintenance of validation for EMTCT of HIV and syphilis and PTE to regional offices or country health ministries through email, with a copy to the WHO regional advisors if it is sent directly to the health ministry.

## GLOBAL VALIDATION ADVISORY COMMITTEE (GVAC)

66. The GVAC is an independent advisory body that provides technical assistance and supports oversight of the validation process. Its main responsibility is to determine whether countries' efforts towards achieving EMTCT or PTE of HIV and syphilis and meet the global validation criteria.

67. The GVAC advises WHO through the GVS on the validation of EMTCT or PTE of HIV and syphilis by making their own independent evaluation through a thorough review of the regional validation reports and through discussion in GVAC meetings.

68. The main roles and responsibilities of the GVAC include the following:

- The GVAC reviews and evaluates the national and regional validation reports to ensure compliance with the global criteria for validation of EMTCT of HIV and syphilis.
- After review of national and regional validation reports and internal discussion, the GVAC delivers a formal vote on whether a country has achieved the required criteria for validation of EMTCT or PTE;
- The GVAC reviews and evaluates RVC reports for maintenance of validation. After the GVAC has reviewed a country for maintenance of validation for two cycles of two years each, the GVAC and GVS can decide whether the RVC may conduct further maintenance reviews moving forward.
- If the RVC is assigned sole review for maintenance of validation of EMTCT or PTE, the GVAC will only be informed of the decision. The GVAC will review maintenance of validation only of countries that the RVC was unable to validate for maintenance or for those that have not adequately addressed previous GVAC recommendations.
- The GVAC endorses RVC recommendations and provides any additional recommendations not made by the RVC to countries on their performance in achieving criteria for EMTCT of HIV and syphilis or PTE.
- The GVAC provides clear guidance and recommendations should EMTCT of HIV and syphilis or PTE not be validated. This may include requests for clarification and additional information, which will be sent to the country through the RVS.
- The GVAC reviews supporting guidance documents for validation of EMTCT of HIV and syphilis and recommends updates, as needed, to the *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis*, the governance document on EMTCT of HIV and syphilis and validation tools, including NVC and RVC report templates.

69. The GVAC will have a face-to-face meeting scheduled annually. Further, the GVAC will meet virtually every quarter (or every two months as needed) to review countries for validation or maintenance of validation. Ad hoc business calls will be scheduled as needed.

70. The main activities of the GVAC for country validation review include the following:

- The GVAC receives the national and regional validation reports from the GVS at least three weeks before the validation review for EMTCT or PTE of HIV and syphilis. The GVAC will only review the documents already reviewed by the RVC. Thus, the GVAC will not review documents that have not been reviewed by the RVC, including shadow reports and any other documents presented or available after the RVC has reviewed a country.
- The GVAC critically reviews the validation reports to ensure consistency and compliance with the global validation criteria for EMTCT of HIV and syphilis or PTE.
- The GVAC forwards questions and requests for clarification to the regional offices through the GVS.
- Selected GVAC members will evaluate and present specific components of the validation report to the GVAC in the validation meeting and determine whether the country has met the global validation criteria. For a small country with low HIV and syphilis prevalence, where line listing of cases is allowed, two independent GVAC members will be asked to review the cases and determine whether infant cases are due to programme failures.
- The GVAC discusses the findings of the regional validation report and determines whether the country has met the global validation criteria during one of their meetings.
- The GVAC votes formally on a country's status for validation and maintenance of validation of EMTCT of HIV and syphilis or PTE.

71. GVAC members have four options when casting a vote (Table 1)

**Table 1.** GVAC Options for Voting for Validation of EMTCT/PTE or Maintenance of EMTCT/PTE

1. Validate or maintain validation without recommendations
2. Validate or maintain validation with recommendations
3. Defer validation or maintenance of validation pending responses to requests for clarification from the RVS/country
4. Do not validate or maintain validation. Provide recommendations with timelines for re-review

72. A quorum (two thirds of the voting membership of the GVAC) must be present during meetings on country validation and maintenance of validation (virtual or face-to-face) to accept a final vote from the validation meeting. If a quorum is confirmed by the end of the meeting, a majority vote of at least 75% of the participating members must be obtained for the meeting to declare validation. In circumstances related to an unexpected absence of one or two GVAC members who previously confirmed attendance, the GVS, in discussion with the GVAC co-chairs, may override this calculation. The meeting minutes will include details of GVAC participation. Please see Table 2 regarding this calculation of quorum and majority vote based on current GVAC voting membership.

**Table 2.** Reference for GVAC voting for validation or maintenance of EMTCT of HIV and syphilis or PTE

| A: Example total number of GVAC members | B: Quorum: number of GVAC members needed (%) to accept a vote from a validation meeting<br>Quorum defined as at least 67% of the GVAC members present | C: Minimum number of votes (%) needed to establish a majority vote from a validation meeting. Majority vote is defined as at least 75% of quorum |
|---|---|---|
| 18 | 18 (100%) | 14 (77%) |
| 18 | 17 (94%) | 13 (76%) |
| 18 | 16 (89%) | 12 (75%) |
| 18 | 15 (83%) | 11 (80%) |
| 18 | 14 (78%) | 11 (78%) |
| 18 | 13 (72%) | 10 (77%) |
| 18 | 12 (67%) (minimum) | 9 (75%) |

**73.** If a quorum is not obtained during a GVAC meeting for validation or maintenance of validation of EMTCT or PTE of HIV and syphilis, the GVAC co-chairs in discussion with the GVS may request that excused absent GVAC members vote by ballot if these GVAC members have declared that they have reviewed the national and regional validation reports, the meeting recordings and notes and feel comfortable delivering a vote.

**74.** The GVAC advises the GVS on the validation status and whether there are requests for information or clarification if a deferral vote is undertaken. The GVAC will provide clear recommendations for improvement if validation is not achieved. (The next section outlines a process for deferring GVAC validation pending additional information from the country). In some cases, the GVAC co-chairs may need to communicate directly with the RVC co-chairs to discuss certain issues, and the RVS will facilitate this.

**75.** Country validation of EMTCT of HIV and syphilis or maintenance of validation may be deferred or suspended following a majority GVAC vote to defer or suspend validation. This may occur if a country no longer meets the criteria for EMTCT of HIV and syphilis or if human rights violations are observed and considered to warrant suspension. The next section outlines a process for suspending validation pending country achievement of the criteria for EMTCT of HIV and syphilis.

## MEMBERSHIP OF THE GLOBAL VALIDATION ADVISORY COMMITTEE (GVAC)

**76.** GVAC members should have expertise in EMTCT of HIV, and syphilis, and should be capable of critically reviewing and evaluating regional validation reports.

**77.** The GVAC membership will comprise 18–25 independent members (not part of the United Nations System and with no reported conflicts of interest), including two women living

with HIV. The GVS will appoint the chair and co-chair. The GVAC members may be involved in regional validation missions and RVCs. Terms of reference for the GVAC are provided in Annex 3.

78. The GVAC includes experts that collectively represent, the following disciplines:

- clinical expertise in HIV and sexually transmitted infections (hepatitis B experts, including immunization, should be empanelled when the GVAC is evaluating countries for EMTCT of hepatitis B);
- the community of people living with HIV, including at least two women living with HIV;
- epidemiologists and experts in programme and data monitoring and evaluation;
- human rights, with a focus on at-risk and vulnerable groups;
- laboratory science;
- maternal and child health experts;
- public health programmes: HIV and AIDS and sexually transmitted infection programme management;
- private sector maternal and child health experts;
- social and behavioural sciences; and
- private sector management.

79. The GVAC is an advisory body with the technical experience, personal integrity, gender balance and geographical diversity, especially from low- and middle-income countries, to assess whether the criteria for achieving EMTCT of HIV and syphilis have been met.

80. The GVAC will include at least one representative from each WHO region. In regions with a (standing) RVC, the WHO regional office may designate a representative from the RVC to serve as an expert to the GVAC to ensure direct linkage between the global and regional levels.

81. GVAC members may be nominated by an RVS, United Nations partners, the GVS, other GVAC members or other outside agencies but must follow the WHO-approved processes for selecting voluntary committee members. Once an open position and specialty is identified, an open nomination period of two weeks will take place. This will enable other GVAC members and regional advisors to recommend new members. The GVS will ensure that each candidate does not have any conflicts of interest and is willing to sign the confidentiality agreement. The GVS will then invite the candidate to join the GVAC.

82. GVAC members must respect the impartiality and independence of their position on the GVAC. In performing their work, they may not seek or accept instructions from any government or agency or from any authority external to WHO. They must be free of real, potential or apparent conflicts of interest. To this end, proposed members and active members will be subject to WHO's policy on conflicts of interest and will be required to complete a declaration-of-interests form.

83. The expected duration of GVAC membership is three years. Members may choose to leave before three years for any reason and specifically if they are unable to meet the requirements of membership for the duration of the three-year period. Members may request two renewals of three years each (nine years total). Renewals beyond nine years are possible and will be decided on a case-by-case basis by the GVS. Efforts will be made to stagger the rotation of members to ensure a consistent level of experience, institutional memory and expertise in the GVAC.

84. The GVAC is composed of voting members (independent experts). Non-voting observers attend GVAC meetings and can include partners engaged in global efforts to achieve EMTCT of HIV and syphilis such as UNAIDS, UNICEF, UNFPA and invited observers from outside organizations that are involved in aspects of validation reviews. Community and other relevant observers can be invited (by the GVS) to participate in the yearly face to face GVAC meeting.

85. GVAC members must have the time, interest and capability to review national and regional validation reports in detail without financial reimbursement from WHO. Participating in the activities is estimated to entail 28–32 hours per person per year. In addition, the GVAC holds one face-to-face meeting for a minimum of 2.5 days per year.

86. GVAC members must sign a WHO confidentiality and conflict-of-interest declaration. Specifically, members should not have any salary bonuses or other supplementary elements of their compensation tied to the performance or validation of local initiatives for achieving EMTCT of HIV and syphilis.

87. The GVS may terminate membership of the GVAC for any reason, including but not limited to:

- failure to attend three consecutive GVAC calls or meetings without excuse from the GVS;
- change in affiliation resulting in a conflict of interest; and
- lack of professionalism involving, for example, a breach of confidentiality.

88. In case of conflict of interest, because of prior participation in a country validation, contractual issues or other conflicts, GVAC members must recuse themselves from the specific country validation vote. They may however, contribute to the country review process.

# PROCESSES FOR COUNTRY VALIDATION OF EMTCT OF HIV AND SYPHILIS

## GOVERNANCE AND COORDINATION OF THE VALIDATION OF EMTCT OF HIV AND SYPHILIS

89. The complexity of the validation process with the various actors at three levels can be reduced by adhering to the suggested processes, sequence of events and communication lines. Consistency across countries is important to the sustainability and credibility of the validation process. This section outlines common processes in detail, with flowcharts depicting the sequence of events and the roles of various actors.

Figures 3 and 4 summarize the main activities per level and depict the responsibilities across actors in the validation and maintenance processes.

**Figure 3**
**Overview of responsibilities of the committees at the national, regional and global levels**

| | |
|---|---|
| **National validation secretariat (NVS)** | **National validation committee (NVC)**<br>• Develops the roadmap for country validation work processes<br>• Coordinates preparation of and collects the evidence for the national validation report<br>• Coordinates the in-country mission and submits the final national validation report to the NVS<br>• Prepares the monitoring report for maintaining validation status |
| **Regional validation secretariat (RVS)** | **Regional validation commmittee (RVC)**<br>• Reviews the national validation report<br>• Conducts country assessment (in-country mission or virtual assessment),<br>• Prepares the regional validation report and submits it to the RVS<br>• Reviews the monitoring report for maintenance of validation and submits it to the RVS for review and approval |
| **Global Validation Secretariat (GVS)** | **Global Validation Advisory Committee (GVAC)**<br>• Reviews the regional validation report<br>• Advises the GVS with respect to the vote for validation or maintenance of the validation of EMTCT of HIV and syphilis or PTE<br>• Provides recommendations on maintaining validation where required<br>• Advises on the guidance, tools and processes |

## Figure 4
## Governance and coordination of the process of validation and maintenance of validation for EMTCT of HIV and syphilis and PTE

### National level

- The health ministry initiates validation with a request to the National Validation Secretariat (NVS) hosted by the WHO county office
- The health ministry establishes the National Validation Committee (NVC)
- The NVC collects data and prepares the national validation report
- The NVC sends the national validation report to the NVS, which sends to the Regional Validation Secretariat (RVS) for review and approval
- The NVC works with the Regional Validation Committee (RVC) on in-country missions and on recommendations from the Global Validation Advisory Committee (GVAC)
- The NVC prepares the monitoring report for maintenance of validation, sends to the NVS, which sends it to the RVS for approval

### Regional level

- The WHO regional office hosts the RVS
- The WHO regional office appoints the RVC
- The RVC reviews the national validation report
- The RVC coordinates with the NVS and NVC and conducts an in-country or virtual mission
- The RVC approves national and regional validation reports
- The RVC sends both validation reports to the RVS for submission to the Global Validation Secretariat (GVS)
- The RVC reviews monitoring reports for maintenance of validation and advises the RVS on the required continuity of country performance of validation criteria

### Global level

- The The GVS produces guidance and tools for the validation process
- The The GVS facilitates the communication between the Global Validation Advisory Committee (GVAC), the RVS and the RVC and the health ministry
- The The GVS coordinates the GVAC
- The The GVS sends national and regional validation reports to the GVAC
- The The GVS notifies the health ministry, NVS, and RVS regarding GVAC voting and recommendations for EMTCT validation and Path to Elimination (PTE).
- The The GVS monitors maintenance of validation (every two years)
- The The GVS endorses and documents the RVS decision on maintenance of validation and informs the GVAC

### Global Validation Advisory Comittee (GVAC)

- The GVAC provides advice on validation standards, tools and processes
- The GVAC reviews national and regional validation reports to ensure consistency and compliance with EMTCT and PTE criteria
- The GVAC reviews Provides independent advice through a formal vote to the GVS regarding validation and maintenance of validation of countries for EMTCT and PTE
- The GVAC provides independent recommendations to the GVS and RVS regarding country monitoring and evaluation improvements

## PROCESS FOR VALIDATION OF EMTCT OF HIV AND SYPHILIS

90. Figure 5 provides a concise overview of the primary responsibilities of the national, regional and global committees with a directional flow of activities within the process for validation of EMTCT and PTE of HIV and syphilis.

**Figure 5**
**Process for validation of EMTCT or PTE of HIV and syphilis, including the responsibilities of the health ministry, committees and secretariats at the national, regional and global levels**

| | |
|---|---|
| **Health ministry** | • The health ministry sends a request for validation to the WHO country office or NVS<br>• The WHO country office or NVS informs the regional validation secretariat<br>• The health ministry establishes the NVC for collecting the evidence and reporting on efforts to achieve EMTCT of HIV and syphilis |
| **National Validation Committee (NVC) and secretariat (NVS)** | • The NVS organizes a kick-off meeting at the national level with the RVS, the NVC and the health ministry<br>• The NVC prepares the national validation report and submits it to the health ministry and NVS for approval<br>• The NVS submits the initial validation report to the RVS |
| **Regional Validation Committee (RVC) and Secretariat (RVS)** | • The RVS/Regional Director establishes and convenes the RVC<br>• The RVC reviews the national validation report by desk review and conducts country assessment in collaboration with the NVC (via in-country mission or virtual assessment)<br>• In case of requests for additional information, the RVC works with the NVC and health ministry to obtain<br>• The RVC prepares and submits the regional validation report to the RVS<br>• The RVS submits the national and regional validation reports to the GVS |
| **Global Validation Advisory Committee (GVAC) and Secretariat (GVS)** | • The GVS reviews the validation reports and sends them to the GVAC<br>• The GVAC discusses the components of the validation reports and provides a formal vote<br>• In case of requests for additional information by the GVAC, the GVS communicates with the RVS, which coordinates with the RVC, the NVC and the health ministry to obtain<br>• The GVAC advises the GVS on the status of validation or maintainance of validation for the candidate country<br>• The GVS notifies the health ministry of the GVAC decision on validation after informing the RVS and the NVS |

## PROCESS FOR MAINTENANCE OF VALIDATION OF EMTCT OF HIV AND SYPHILIS

91. Countries that have been validated for achieving EMTCT or PTE of HIV and syphilis will be assessed every two years for maintenance of validation. To be assessed for maintenance of validation, countries are asked to submit a brief report to the RVS that includes the following information:

    1. Executive summary
    2. Brief description of changes, **if any**, in the health systems since validation
    3. Brief description of changes, **if any**, to the programmes for achieving EMTCT of HIV and syphilis since validation
    4. Key findings for the two years after the last validation review
        - Provide data for the required impact and process indicators (include numerator and denominator data) using the data tables in the validation report template
        - Systems and data sources used for the impact and process data on achieving EMTCT of HIV and syphilis (report only if the data sources are different from those reported in the original national validation report)
        - Potential risks to sustaining EMTCT or PTE of HIV and syphilis (report only if there are potential risks)
    5. Provide a response to all GVAC recommendations made at the time of validation
    6. The regional representative in cooperation with the country will prepare a slide set and present it to the GVAC. The GVAC will follow the same procedure for voting as for validation (quorum and majority) and can reach one of the following conclusions:
        - maintain validation without recommendations;
        - maintain validation with recommendations;
        - defer maintenance of validation pending requests for clarification from the RVS; and
        - do not maintain validation.
    7. Countries that were validated using the criteria for small countries or those with low HIV and syphilis prevalence can continue to pool data (up to four years) but must present a line listing of all cases of infants exposed to and infected with HIV and syphilis. The RVC and/or GVAC will decide on whether individual infant cases should count within the calculation of the infant case rate.

Figure 6 describes and summarizes the process for maintenance of validation of EMTCT of HIV and syphilis.

## Figure 6
## Process for maintenance of validation of EMTCT of HIV and syphilis

| | |
|---|---|
| **Health ministry** | • The health ministry convenes the NVC for collecting the evidence of national efforts to maintain EMTCT of HIV and syphilis<br>• The health ministry reports on the requested indicators with the UNAIDS Global AIDS Monitoring system (GAM) |
| **National Validation Committee (NVC)** | • The NVC prepares the maintenance of validation report every two years after validation of EMTCT of HIV and syphilis<br>• The NVS submits the monitoring report to the RVS |
| **Regional Validation Committee (RVC)** | • The RVS sends the monitoring report to the RVC<br>• The RVC reviews the maintenance of validation report by desk review<br>• In case of requests for additional information, the RVC works with the NVC and the health ministry to obtain<br>• The RVC submits the final report to the RVS and advises on the status of maintenance of validation<br>• The RVS submits the monitoring report to the GVS |
| **Global Validation Advisory Committee (GVAC)** | • The GVS keeps track of the two-year cycle of maintenance status across validated countries<br>• The GVS reviews the individual maintenance of validation report and sends it to the GVAC for review<br>• The GVAC reviews the maintenance of validation report and takes a formal vote<br>• The GVAC advises the GVS on maintenance of the validation of the country<br>• The GVS notifies the health ministry on maintenance of validation and informs the RVS and NVS |

## PROCESS FOR DEFERRING VALIDATION

### PROCESS FOR REQUESTING CLARIFICATION

92. If the majority of GVAC members vote for deferral pending clarifications or request for additional information, the GVAC will provide a list to the GVS. The GVS will compile these requests for clarification alongside preliminary recommendations to the RVS, which will be communicated to the RVC and NVC in candidate countries to ensure validation (or maintenance of validation).

93. As decided by the GVAC, some of the recommendations may need to be implemented before a re-vote is considered. Following a vote for deferral, requests for clarification will be communicated as outlined in Figure 7.

The GVAC will reconvene to review the country and regional responses to the requests for clarifications, and a repeat vote will be carried out.

## MECHANISM FOR APPEALS

94. An appeals mechanism has been established for candidate countries when the GVAC denies (or defers) a request for validation of EMTCT of HIV and syphilis. If a candidate country does not agree with this decision, it may, working in collaboration with the NVC, NVS, RVS and the RVC, have the GVAC review the decision again. The health ministry initiates this appeals process.

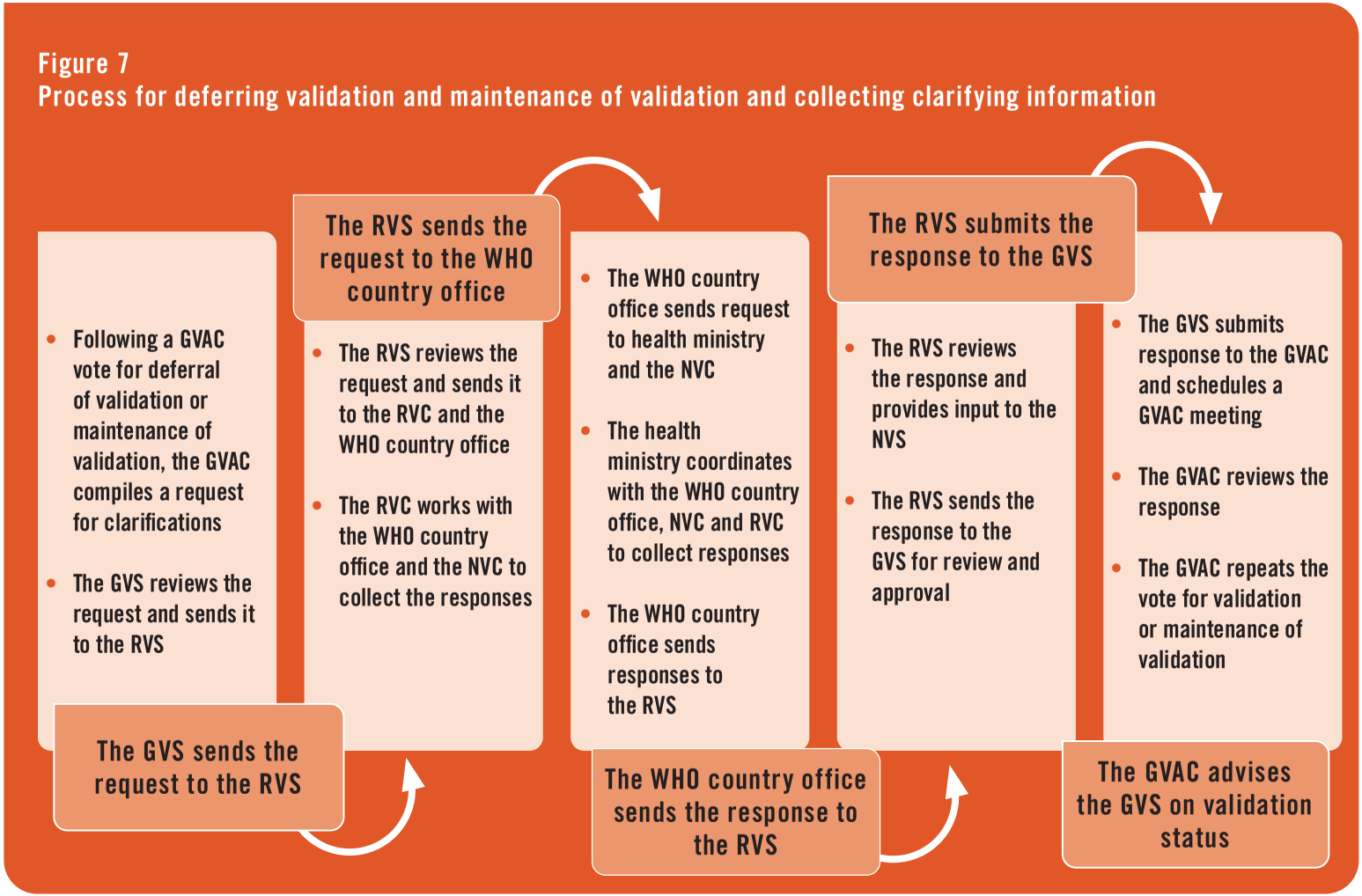
### GROUNDS FOR APPEALING A VALIDATION DECISION

- The only grounds for appealing are that the GVAC has made one or more significant and obvious errors in reviewing the national validation report or misinterpreted information presented in it.
- Applicants must demonstrate that this error was based on the national validation report that was reviewed by the RVC and RVS.
- No new information may be introduced in an appeal. However, the appeal may include a rebuttal or elaboration on information already in the report.

### SUBMISSION OF A VALIDATION APPEAL

93. The health ministry must submit the appeal to the NVS (which will submit it to the RVS) and will detail the clarifications needed, errors identified or recent changes to the programming structure or processes for achieving EMTCT of HIV and syphilis that the RVC did not include in their review of the national validation report that may have adversely affected the validation status. The chair of the NVC must support the appeal.

Figure 7
Process for deferring validation and maintenance of validation and collecting clarifying information



### TIMELINES

- The health ministry must submit a notice of appeal to the NVS within 30 working days from the date of receiving written notice that WHO has not recommended validation of or maintenance of the validation of EMTCT of HIV and syphilis (in accordance with the GVAC).
- The NVS submits the notice of appeal to the RVS.
- The NVC, RVC and health ministry develop and document an action plan to appeal within 30 working days from the date the RVS received the notice of appeal.
- If an action plan cannot be worked out in 30 days, then the RVS must bring the issue to the attention of the GVS and GVAC for final review and adjudication.
- Once it receives the appeal and additional information from the health ministry and the RVS, the GVS and GVAC review and decide on validation.

## SUSPENSION OF VALIDATION

94. Country validation of EMTCT of HIV and syphilis may be deferred or suspended following a majority (≥75%) GVAC vote not to maintain validation. This may occur if a country no longer meets the criteria for EMTCT of HIV and syphilis or if human rights violations are significant enough to warrant suspension. If the validation of EMTCT of HIV and syphilis is suspended, the country will be placed in a two-year probationary period in which the country must report yearly on indicators of EMTCT of HIV and syphilis that are no longer in compliance and any relevant human rights concerns.

Countries will be also asked to report on the activities undertaken to adhere to indicators on EMTCT of HIV and syphilis and/or to reverse and address human rights violations that warranted suspending validation.

If the country still does not meet the criteria to maintain the validation of EMTCT of HIV and syphilis at the end of the two-year probationary period, the GVAC may advise the WHO to revoke validation following a majority vote. The GVS will notify the RVS and NVS.

Communication regarding additional clarifying information needed from the national or regional committees related to this process will follow the information flow established for deferring validation (see Figure 7).

## AFTERWORD

This governance guidance document will continue to be refined and updated based on the experience of evaluating countries for EMTCT and PTE validation at national, regional and global levels. At the time of this first edition, process description related to specific aspects of PTE were not included pending experience from country recognition for PTE. Incorporation of governance for EMTCT of hepatitis B will be prioritized for the next edition following the adoption of global criteria and processes.

# ANNEX 1. SAMPLE TERMS OF REFERENCE FOR A NATIONAL VALIDATION COMMITTEE

## 1. Mission of the national validation committee

The mission of the national validation committee (NVC) on EMTCT of HIV and syphilis includes the following:

- to provide and support the development and review of national policies, strategies and guidelines for implementing services for EMTCT of HIV and syphilis in the country; and
- to evaluate the provision of services for achieving EMTCT of HIV and syphilis through the services delivery points of the national control programme for sexually transmitted infections and/or HIV, maternal and child health programmes and provincial and national health facilities in a quality-assured manner.

## 2. FUNCTIONS

The functions of the NVC are:

- to coordinate with and support institutions within and outside the health ministry to evaluate services for EMTCT and PTE for HIV and syphilis;
- to evaluate the capacity of individuals and institutions in the public and private sectors and in civil society organizations to provide services for prevention of mother-to-child transmission of HIV and syphilis in partnership with relevant programme areas in the national control programme for sexually transmitted infections and/or HIV and maternal and child health programmes;
- to evaluate and monitor the quality of services for EMTCT of HIV and syphilis;
- to advise on providing technical support, assistance and guidance to provinces, districts and other organizations and agencies in improving the quality and supply of and access to services for EMTCT of HIV and syphilis;
- to support the process of review of the services for EMTCT of HIV and syphilis in the country;
- to establish necessary working groups to collect and compile relevant data and documents to facilitate the validation of EMTCT of HIV and syphilis in programmes, data and monitoring, laboratory and human rights, gender equality and engagement of civil society;
- to advise on providing technical support, assistance and guidance to provinces, districts and other organizations and agencies in improving the quality, supply and access to services for EMTCT of HIV and syphilis; and
- to take responsibility for writing the national validation report and submitting it to the RVS.

## 3. COMPOSITION

The NVC may have up to 20 members, including one woman living with HIV.

Collectively, NVC members should have expertise in the following disciplines, in addition to one woman living with HIV and working with civil society being selected to serve on the NVC:

- epidemiology
- HIV and AIDS programme management
- Sexually transmitted infection programme management
- maternal and child health
- HIV and other sexually transmitted infections (viral hepatitis and immunization when applicable for EMTCT of hepatitis B)
- social sciences
- human rights, with a focus on at-risk and vulnerable groups
- advocacy, especially for at-risk and vulnerable groups
- laboratory science
- statistics, monitoring and evaluation
- public health
- private health sector.

Attention should be paid to gender balance and to selecting representatives from UNAIDS, UNFPA, UNICEF, civil society and key partners engaged in global efforts to achieve EMTCT of HIV and syphilis. Priority should be given to inclusion of at least one woman living with HIV.

## 4. ANTICIPATED RESPONSIBILITIES OF NVC MEMBERS

At a minimum, NVC members should be able and willing:

- to serve for at least one year or longer through the validation of the country (if possible);
- to participate in NVC orientation meetings at the start of and during the validation process;
- to participate in NVC meetings as necessary;
- to assist working groups with the necessary technical expertise as needed;
- to be willing to write and review the national validation report before finalization; and
- to work with the RVS, RVC and GVAC as necessary during validation reviews at these levels as needed.

# ANNEX 2. SAMPLE TERMS OF REFERENCE FOR A REGIONAL VALIDATION COMMITTEE

Terms of reference of the Regional Committee for Validation of Elimination of Mother-to-child Transmission of HIV and Syphilis (Pan American Health Organization (PAHO RVC))
[updated in December 2016 and edited in March 2020 by the GVS]

## BACKGROUND AND CONTEXT

In 2010, the PAHO Member Countries adopted the Strategy and Plan of Action for the Elimination of Mother-to-child Transmission of HIV and Congenital Syphilis (EMTCT) by the year 2015 (Resolution CD50.R15). In 2016, a second phase of the regional EMTCT strategy was incorporated into the Plan of Action for the Prevention and Control of HIV and Sexually Transmitted Infections 2016–2021 (Resolution CD55.R14).

The PAHO HIV, Hepatitis, Tuberculosis, and Sexually Transmitted Infections unit (CHA/HT), the PAHO Centre for Perinatology and Maternal Health (CLAP) and the United Nations Children's Fund (UNICEF) provide joint support for implementation of EMTCT strategy in collaboration with the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Population Fund (UNFPA), the United States Centers for Disease Control and Prevention (CDC) and other partners.

Through adoption of the resolutions CD50.R12 and CD55.R14, the PAHO Member States have committed to the following targets by the year 2015:

- reduction of mother-to-child transmission of HIV to <2%;
- reduction in the incidence of mother-to-child transmission of HIV to <0.3 cases per 1000 live births; and
- reduction in the incidence of congenital syphilis to <0.3 cases per 1000 live births (including stillbirths).

In addition, specific coverage levels of service delivery must be met to accomplish and maintain EMTCT of HIV and syphilis:

- antenatal coverage and births attended by skilled personnel of ≥95%;
- HIV and syphilis testing of pregnant women of ≥95%; and
- antiretroviral and syphilis therapy among seropositive women of ≥95%.

Countries can apply for validation of EMTCT of HIV and syphilis when they determine that they have:

- met the impact targets for at least two years (PAHO regional requirement); and
- achieved these targets in at least one of the lowest-performing subnational administrative unit for at least one year; and
- met the coverage targets for two years.

The term "validation" is used to attest that a country has successfully met the criteria for EMTCT at a specific point in time. Validation also implies that countries will need to maintain effective programme interventions and coverage and quality information systems for ongoing monitoring of the impact and coverage targets.

To facilitate harmonization of approaches and ensure consistency among regions and the credibility of the validation process, the World Health Organization (WHO) issued global guidance on criteria and processes for validation.

### GLOBAL VALIDATION SECRETARIAT (GVS) (WHO HEADQUARTERS)

Coordinates the Global Validation Advisory Committee (GVAC) and regional secretariats. Provides official notification of validation of EMTCT of HIV and/or syphilis and monitors maintenance of validation. Monitors impact and process indicators as epidemic evolves. Provides final sign-off of validation of EMTCT of HIV and/or syphilis for a country.

### GVAC

Reviews the regional validation report to ensure consistency and compliance with the minimum global criteria. Prepares a brief global validation report. Reviews any issues with maintenance of validation that the GVS has identified. Prepares an annual validation report.

### REGIONAL VALIDATION SECRETARIAT (RVC) (WHO REGIONAL OFFICE)

Establishes, convenes and coordinates the RVC and regional validation team, provides oversight to regional and national validation processes and activities, communicates with the NVC (NVC), GVAC and GVS, ensures coherence, compliance of national, regional, global validation criteria and process. Monitors maintenance of validation.

### RVC

Appoints regional validation team to carry out country reviews. Jointly with the health ministry, establishes an NVC. Reviews national validation reports and ensures compliance with regional and global criteria.

### HEALTH MINISTRY OR NVC

Initiates the validation process and prepares a national validation report.

### NATIONAL VALIDATION TEAM (NVT)

An optional body that collects and analyses national data for the national validation report. The NVC can also choose to do this function directly.

### REGIONAL VALIDATION TEAM (RVT)

An optional body that reviews country data, conducts in-country validation visits with the national validation team, and prepares the regional validation report for review by the GVAC.

These terms of reference detail the establishment and operation of the RVC for the Region of the Americas.

## PURPOSE AND OBJECTIVES OF THE RVC

The RVC will advise the RVS on the process for validation of achievement of the targets for achieving EMTCT of HIV and congenital syphilis in the Americas.

The main task of the RVC is to advise the RVS as to whether candidate countries' achievements in EMTCT of HIV and syphilis can be recommended for global validation.

The RVC will accomplish this by:

- evaluating candidate country EMTCT reports to determine eligibility for validation assessment;
- determining compliance with regional and global validation criteria through country assessments; and
- recommending countries for global validation or making suggestions for countries to address gaps or barriers to global validation discovered through the evaluative process.

The RVC is convened by PAHO, the RVS, and housed within PAHO. PAHO and UNICEF will provide joint support to the RVC.

In accordance with global guidance, the RVC will establish and supervise a regional validation team to assist with country validation. The main purpose of the regional validation teams is to share the workload associated with evaluating multiple countries and bring in additional technical expertise as needed. Their main role will be to assist with reviewing country EMTCT reports, participate in country assessments under supervision of the RVC and assist in developing validation reports. For composition of the regional validation teams, the RVC will draw from a roster of experts compiled and maintained by the RVS.

The RVC's activities are:

- to review EMTCT reports from candidate countries to preliminarily assess compliance with regional and global criteria for validation of EMTCT;
- to request additional information or clarification from NVCs to facilitate this determination;
- to coordinate regional validation teams to support country validation assessments;
- to coordinate and supervise country validation assessments;
- to coordinate the preparation of a country validation report that will inform national and global partners whether the country meets regional and global minimum criteria for validation; and
- to collaborate with the GVS and NVCs to ensure monitoring and maintenance of validation, including re-evaluation of impact and process indicators.

## DURATION AND MEMBERSHIP

The members of the RVC will be appointed by the PAHO Director for the duration of two years. RVC members will be replaced on a rolling schedule. For the first replenishment, 50% of the members will be replaced after two years and the other 50% after three years, to ensure continuity and preservation of institutional memory.

The RVC membership should bring together expertise in the following disciplines and areas:

- strategic information (surveillance and monitoring and evaluation)
- laboratory
- maternal and child health
- HIV prevention, treatment and care
- syphilis prevention, treatment and care
- viral hepatitis and immunization experts when applicable for EMTCT of hepatitis B
- sexual and reproductive health
- health systems.

The RVC will consist of a minimum of 13 and a maximum of 15 persons, composed as follows:

| Designation | Selection process |
|---|---|
| One representative of PAHO | Nominated by PAHO |
| One representative of UNICEF | Nominated by UNICEF |
| Two representatives of UNAIDS | Nominated by UNAIDS Regional Support Teams for Latin America and the Caribbean |
| One representative of UNFPA | Nominated by UNFPA |
| 8-10 independent experts | |

Through its networks with ministries of health, official public health agencies, academia, civil society organizations, foundations and other regional stakeholders, PAHO subregional HIV and sexually transmitted infection advisors will be asked to identify and submit nominations for experts for RVC membership. The nominees will be vetted by the PAHO regional team based on their CV and the complementarity of their areas of expertise with other nominees, followed by appointment.

Representatives of the United Nations (UNICEF, UNAIDS and UNFPA) will participate as non-voting members of the RVC.

Gender parity will be pursued in identifying RVC members.

Each RVC member will be asked to sign a confidentiality and conflict of interest statement. RVC members should not have any salary, bonuses or other compensatory elements tied to their RVC membership or actions.

## REPORTING AND EVALUATION

The RVC will report to the GVAC by way of the PAHO Director and RVS by submitting validation mission reports and recommendations to the RVS regarding validation of countries.

## FREQUENCY, DURATION AND COST OF ACTIVITIES

The frequency of validation assessments will depend on the progress made by countries and the number and timing of validation requests submitted by countries. A significant portion of the work of the RVC will be done via virtual means, including review of country reports, dialogue between the RVC members, with countries and with the RVS. Travel expenses for representatives from the United Nations agencies will be covered by their respective agencies, while PAHO/WHO, UNICEF and the other partners will mobilize resources to support additional costs, including travel of non-agency RVC members.

In addition to the validation exercises, the RVC will meet as needed (annually or less frequently) for periodic stock-taking and capacity building.

# ANNEX 3. TERMS OF REFERENCE FOR THE GLOBAL VALIDATION ADVISORY COMMITTEE

## THE GLOBAL VALIDATION ADVISORY COMMITTEE TERMS OF REFERENCE FOR VALIDATION OF ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION OF HIV AND SYPHILIS

### 1. MISSION OF THE GLOBAL VALIDATION ADVISORY COMMITTEE

The mission of the Global Validation Advisory Committee (GVAC) for elimination of mother-to-child transmission (EMTCT) of HIV and syphilis is to provide independent advice to the World Health Organization (WHO) Global Validation Secretariat (GVS) to support countries' efforts toward EMTCT of HIV and/or syphilis and to achieve global validation standards.

### 2. FUNCTIONS

The functions of the GVAC are:

- to critically review and evaluate national and regional validation reports to ensure compliance with the global criteria for validation of EMTCT and PTE;
- to provide clear recommendations to countries on their performance in the validation process of EMTCT and PTE;
- to provide clear guidance if validation is not achieved;
- to provide guidance to WHO for ongoing monitoring and maintenance of validation; and
- to review tools for EMTCT validation and recommend updates, to include *Global guidance on the criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis*, tools and governance documents on EMTCT.

The WHO secretariat will use the GVAC recommendations to prepare a letter of evaluation to be sent to the health ministry. WHO reserves the right to amend language as suggested by required signatories, including governing bodies. The letter:

- formally notifies a candidate country of their status of EMTCT and PTE of HIV and/or syphilis if validation is achieved; and
- ensures that a candidate health ministry receives clear explanations and/or suggestions for improvement, and in regions where countries request validation but RVCs have not been established, the GVAC may serve as both the RVC and GVAC.

### 3. COMPOSITION

The GVAC will have up 18–25 members, including two women living with HIV. The members must not be representatives of governments, organizations, institutions or entities but rather serve in an independent, personal and individual capacity and possess expertise in EMTCT of HIV and syphilis.

The WHO secretariat will select a chair and co-chair, who will serve for a minimum of 12 months.

A quorum is defined as two thirds of the current GVAC membership. The membership numbers will fluctuate depending on the technical needs of the membership.

Collectively, GVAC members should have expertise in the following disciplines, in addition to two women living with HIV and working with civil society being selected to serve on the GVAC:

- epidemiology
- HIV and AIDS programme management
- sexually transmitted infection programme management maternal and child health
- expertise in HIV and other sexually transmitted infections
- social sciences
- human rights, with a focus on at-risk and vulnerable groups
- advocacy, especially for at-risk and vulnerable groups
- laboratory science
- statistics, monitoring and evaluation
- public health
- private health sector.

Attention must be paid to gender balance and to the importance of selecting GVAC members from as wide a geographical basis as possible, especially low- and middle-income countries. The GVAC must include at least one representative from each WHO region. In regions with established RVCs, WHO must designate a representative from each such RVC to serve as an expert on the GVAC to ensure direct linkage between the global and regional levels.

1. The GVS will appoint GVAC members. Once an open position and specialty is identified, an open nomination period of two weeks will take place. This will enable other GVAC members and regional advisors to recommend new members. The GVS will ensure that the candidate does not have any conflicts of interest and is willing to sign the confidentiality agreement and then invites the candidate to join the GVAC. Members will serve for an initial term of up to three years, renewable twice for a period of up to three additional terms or nine years. If feasible, the first set of appointments will be staggered such that one third will serve for one, two or three years during their first term to avoid a full turnover.
2. GVAC members must respect the impartiality and independence required of the WHO secretariat. In performing their work, they may not seek or accept instructions from any government or from any authority external to WHO. They must be free of real, potential or apparent conflicts of interest. To this end, proposed members and active members will be subject to WHO's policy on conflicts of interest and will be required to complete a declaration of interest form. Their initial appointment and extension thereof will be subject to the evaluation of completed declaration of interest forms by the WHO secretariat, determining that their participation would not give rise to a real, potential

or apparent conflict of interest. GVAC members have an ongoing obligation throughout their tenure to inform WHO of any changes to the information they have disclosed on the declaration of interest form. In addition, and in accordance with WHO's policy on advisory committees and conflicts of interest, the names and short biographies of GVAC members will be made available on the WHO web site for public notice and comment before they are appointed.

3. The GVAC will be led by a chair and co-chair, identified by the WHO global secretariat. Through the chair and co-chair, the GVAC will work with the WHO secretariat in developing the meeting agendas and work plans.

4. GVAC members will not be remunerated for their participation in the GVAC. However, WHO will compensate for reasonable expenses such as travel expenses incurred by attendance at GVAC meetings and participation in regional and country activities for EMTCT of HIV and syphilis in accordance with the applicable rules and policies of WHO. GVAC members should not receive any financial or other incentives in relation to their GVAC functions.

5. In addition, before WHO confirms their appointment, GVAC members must sign a WHO confidentiality agreement and the standard agreement for WHO temporary advisors.

Representatives of UNAIDS, UNICEF, UNFPA, civil society and key partners engaged in global efforts to achieve EMTCT of HIV and syphilis will be invited to participate as observers in the GVAC meetings. Relevant staff from WHO headquarters and regional offices will attend as members of the secretariat. The WHO secretariat may also invite additional experts or technical resource people to meetings, as appropriate, to further contribute to specific agenda items.

## 4. ANTICIPATED RESPONSIBILITIES OF GVAC MEMBERS

At a minimum, GVAC members should be able and willing to:

- serve for at least one year;
- participate in an annual GVAC face-to-face meeting (as needed);
- participate in scheduled GVAC calls;
- review RVC and regional validation team country reports (through virtual meetings) to assess for compliance with global minimum standards;
- update existing and/or review new tools for validation;
- biannually, review data on maintenance of validation for countries successfully validated; and
- as needed, participate in country validation missions or regional validation meetings on behalf of the larger GVAC.

## 5. OPERATION

The GVAC will have a face-to-face meeting once a year. The WHO secretariat will provide any necessary technical and other support for the GVAC. WHO will convene additional scheduled meetings on a quarterly basis, including through teleconferences and videoconferences, including on an ad hoc basis.

The GVS may terminate membership in the GVAC for any reason, including but not limited to:

- failure to attend three consecutive GVAC calls or meetings;
- change in affiliation resulting in a conflict of interest; and
- a lack of professionalism involving, for example, a breach of confidentiality.

The GVS will write a report on all GVAC teleconferences and validation meeting recommendations to countries and submit it to the GVAC for comments. The GVAC will have two weeks to edit the reports. All recommendations from the GVAC are advisory to WHO, which retains full control over any subsequent decision or actions regarding any proposals, policy issues or other matters considered by the GVAC.

Information and documentation to which members may gain access in performing GVAC -related activities will be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. GVAC members must not purport to speak on behalf of or represent the GVAC or WHO to any third party. In this regard, non-WHO sources may approach GVAC members for their views, comments and statements on matters of public health concern and ask them to state the views of the GVAC or details related to GVAC discussions. GVAC members should refer all such enquiries to WHO.


**For more information, contact:**

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