GLOBAL GUIDANCE ON CRITERIA AND PROCESSES FOR VALIDATION: ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION OF HIV, SYPHILIS AND HEPATITIS B VIRUS

WEB ANNEX C
INITIAL VALIDATION REPORT ON THE ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION OF HIV, SYPHILIS AND HEPATITIS B VIRUS
This report template is designed for the regional validation structures to provide the Global Validation Advisory Committee (GVAC) with complete information for considering whether a country qualifies for initial validation of elimination of mother-to-child transmission (EMTCT) of HIV, syphilis and hepatitis B virus (HBV) according to criteria in the *Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus*. The template should also be used for initial application of Path to Elimination (for eligibility criteria, see Chapter 5 in the Global guidance).

**CHECKLIST FOR SUBMISSION**

The following documents must be submitted for global review of initial validation:

- initial validation report resulting from the regional validation and based on the national report, in compliance with all required components described in the report template; and
- supporting documents from the country and regional levels, as needed.

**TEMPLATE AND INSTRUCTIONS FOR SUBMISSION**

**1. INITIAL VALIDATION REPORT**

Instructions: The initial validation report should be completed by the national validation committee (NVC) and validated by the regional validation committee (RVC) or regional validation team (RVT). The sections/chapters in orange are to be added following the regional assessment by the RVC/RVT. The initial validation report provides a summary of the health system, report on validation indicators and key findings of the assessments of the foundational requirements for validation. A sample table of contents is provided below.

Length: 100 pages maximum

Sample table of contents and key areas to address in the report

i. Abbreviations (1–2 pages, optional)
ii. Preface/Acknowledgements (1 page, optional)
iii. Executive summary (1–2 pages)
   Table 1. Impact and process indicators for validation of elimination of mother-to-child transmission of HIV, syphilis and/or HBV (see Table 1A)
1. Introduction (1–2 pages)
   1.1 Background
   1.2 Objectives of validation assessment
2. Methodology
   2.1 Composition of the NVC and partners involved in the national validation assessment
2.2 National validation review methodology and timeline
2.3 Composition of the RVC and partners involved in the regional validation assessment
2.4 Regional validation review methodology and timeline

3. Country context and epidemiological profile (<8 pages)
   3.1 Geography
   3.2 Demography
   - Population size, by sex and age
   - Estimated number of pregnant women
   - Available data on populations relevant to HIV, syphilis and/or HBV transmission in the country, including key populations and migrant populations

3.3 Basic health and MCH indicators in the country
   3.3.1 Life expectancy
   3.3.2 Maternal, child and infant mortality rates
   3.3.3 Fertility rates
   3.3.4 Stillbirth trends and contributing factors

3.4 Epidemiological profile of HIV, syphilis and/or HBV in the country
   3.4.1 Disease burden, prevalence and incidence trends in the general population by age and sex
   3.4.2 Disease burden, prevalence and incidence trends in antenatal care (ANC) by age

3.5 Modes and drivers of HIV, syphilis and/or HBV transmission

4. Description of the health system in the country (<8 pages)
   4.1 Health infrastructure (<3 pages)
   4.2 Laboratory infrastructure (<3 pages)
   4.3 Laboratory service delivery
   - Available tests for each condition (gold standard, rapid diagnostic tests (RDTs) and the algorithms
   - Internal and external quality assurance
   - Where testing is conducted (MCH, HIV, family planning, public and non-public health facilities)

4.4 Access to health services and cost (<3 pages)
   - Insurance schemes available for citizens and non-citizens, including internally displaced and stateless persons, refugees, migrant workers, immigrants and other marginalized populations

5. Key findings for EMTCT of HIV, syphilis and/or HBV (<50 pages)
   - Report on required validation indicators at national level (see Table 1A)
     - Identify systems and data sources used.
     - Case definitions used for (1) HIV diagnosis in adults and infants, (2) syphilis diagnosis in adults, (3) congenital syphilis in infants and (4) HBV in adults and children (<3 pages)
     - Supporting data for validation (see Tables 1A, 1B, 2, 3, 4, 5, 6)
     - Consistency of data across geographical areas
       - How was the lowest-performing subnational unit(s) identified?
       - Describe the lowest-performing subnational unit and provide indicators according to Table 1B.
       - If indicators in the lowest-performing subnational unit do not meet validation criteria, what evidence is there that the programme is actively seeking to address issues or inequities in this subnational unit?
• Consistency and quality of data for key populations among pregnant women living with HIV (WLHIV)
  - Supporting data for key and/or vulnerable populations among pregnant WLHIV, if available (use copy of Table 1A)
  - Commentary on data availability and quality on key and vulnerable populations relevant to the HIV, syphilis and HBV EMTCT
• Summary findings on foundational requirements for validation
  • Programme
    - Fully describe national EMTCT of HIV policies and programmes.
      - Are women living with HIV offered universal lifelong ART, and what are the user costs for treatment?
      - National breastfeeding policy, in general and for women living with HIV. Choices women are given and if they are counselled on the risks and benefits of breastfeeding.
      - National caesarean section policy for WLHIV. What choices are WLHIV given?
      - Describe treatment adherence and retention. Should include any data on women living with HIV who are lost to follow-up during the breastfeeding period and the number of infants that do not receive a final HIV test post-breastfeeding.
    - Fully describe national EMTCT of syphilis policies and programmes.
    - Fully describe national EMTCT of HBV policies and programmes (to include policies on HBV vaccine availability and access).
    - What proportion of ANC and delivery services are public versus non-public, and are services similar in each system?
  • Data quality
    - Completeness and representativeness of data used in EMTCT indicators.
    - How are coverage and impact indicators determined? Programme data must be used to model the reliability of the annual HIV, congenital syphilis rate and HBV impact indicators.
    - Description of data inputs used for any model-based estimates of EMTCT of HIV, syphilis and HBV impact indicators, including how these inputs were measured to ensure that they are population based.
  • Laboratory
    - Describe the laboratory landscape in the country.
    - Describe and attach the relevant testing algorithms for mothers and infants screened for HIV, syphilis and HBV.
    - Insert Table 2 with external quality assurance (EQA) results. Note the number of laboratories (public and private) in the country and the number which have been enrolled in an EQA programme.
    - Describe any corrective actions taken to improve laboratory quality.
  • Human rights, gender equality and community engagement (HR GE CE)
    - Description of methods for HR GE CE data collection and analysis for the validation report, including engagement of communities.
    - Describe how WLHIV and WLHBV are involved in national planning and evaluation of EMTCT services.
    - Describe the key barriers for pregnant women seeking EMTCT services and how the country is addressing these barriers.
    - Summary of findings in areas assessed for HR GE CE (see Table 6)
- Ending criminalization of HIV, syphilis and HBV
- Ensuring voluntary testing and treatment
- Ensuring prior and informed consent
- Eliminating coercive practices, including involuntary sterilization, contraception or abortion
- Ensuring confidentiality of health information
- Ensuring equality and non-discrimination
- Ensuring accessibility and quality of women-centred health care services
- Addressing gender-based violence (GBV)
- Engaging and being accountable to communities
- Ensuring access to justice
- Describe how the national programme is proactively seeking equity in EMTCT services.

- Assessment of overall key strengths for sustaining EMTCT
- Potential risks to sustaining EMTCT, including:
  - Potential and actual impact from natural disasters, pandemics/disease outbreaks (including COVID-19), civil conflicts or refugee/migrant influxes, or government policy or budget changes that may have affected the context of provision of services or achievement of targets.
- Describe any country responses undertaken to alleviate the effects of the potential or actual risks to MTCT service provision and EMTCT indicators.

6. Regional commentary and recommendations
   6.1 RVC/RVT key observations, deliberations and outcomes of the regional review
   6.2 RVC/RVT decision on whether to support validation and recommendations

7. Conclusion

8. References
TABLE TEMPLATES FOR INCLUSION IN THE REPORT

Table 1A. Required EMTCT validation data table

Instruction: Edit the table to show the years being reviewed (for example, Year 1 to 2022). Add columns if there are more years of data. Add rows if there are additional data sources to report on a particular indicator. Include comments related to issues which may have affected indicators or to explain any differences in the reporting.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Target</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3 (if applicable)</th>
<th>Year 4 (if applicable)</th>
<th>Data sources</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
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<tr>
<td>HIV mother-to-child transmission (MTCT) rate (%)</td>
<td>&lt;2% (or &lt;5% in breastfeeding populations)</td>
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<tr>
<td>Annual rate of new paediatric HIV infections per 100 000 live births</td>
<td>≤50</td>
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<tr>
<td>Annual rate of congenital syphilis cases (including syphilis-associated stillbirths) per 100 000 live births</td>
<td>≤50</td>
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<tr>
<td>Prevalence of HBsAg in children ≤5 years old</td>
<td>≤0.1%</td>
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<td>HBV MTCT rate (%)</td>
<td>≤2%</td>
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<tr>
<td>All ANCI coverage</td>
<td>&gt;95%</td>
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<td>Syphilis</td>
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<td>Process indicators</td>
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<tr>
<td>HIV testing coverage of pregnant women</td>
<td>≥95%</td>
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<tr>
<td>ART coverage of HIV-positive pregnant women</td>
<td>≥95%</td>
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<td>Syphilis</td>
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<tr>
<td>Syphilis testing coverage of pregnant women among those attending at least 1 ANC visit</td>
<td>≥95%</td>
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<tr>
<td>Adequate treatment coverage of syphilis-positive pregnant women</td>
<td>≥95%</td>
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<td>HBV</td>
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<tr>
<td>HBV testing coverage of pregnant women*</td>
<td>≥90%</td>
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<tr>
<td>Antiviral coverage for eligible HBsAg-positive women*</td>
<td>≥90%</td>
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<tr>
<td>Coverage with 3 doses of hepatitis B vaccine (HepB3) in infants</td>
<td>≥90%</td>
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<tr>
<td>Coverage with timely hepatitis B birth dose (HepB-BD)</td>
<td>≤50</td>
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</table>

*For countries that provide selective targeted hepatitis B birth dose vaccination to infants born to HBsAg-positive women.
Table 1B. Required EMTCT validation data table for lowest-performing subnational unit

Instruction: Edit the table to show the years being reviewed (for example, Year 1 to 2022). Include comments related to issues which may have affected indicators or to explain any differences in the reporting.

If data is available for subpopulations which are least served, copy the table to provide the additional data.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Target</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3 (if applicable)</th>
<th>Year 4 (if applicable)</th>
<th>Data sources</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Impact indicators</strong></td>
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<tr>
<td>HIV</td>
<td>HIV mother-to-child transmission (MTCT) rate (%)</td>
<td>&lt;2% (or &lt;5% in breastfeeding populations)</td>
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<tr>
<td>Syphilis</td>
<td>Annual rate of congenital syphilis cases (including syphilis-associated stillbirths) per 100 000 live births</td>
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<tr>
<td>HBV</td>
<td>Prevalence of HBsAg in children ≤5 years old</td>
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<tr>
<td></td>
<td>HBV MTCT rate (%)*</td>
<td>≤2%</td>
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<td><strong>Process indicators</strong></td>
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<td>HIV</td>
<td>HIV testing coverage of pregnant women</td>
<td>≥95%</td>
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<td></td>
<td>ART coverage of HIV-positive pregnant women</td>
<td>≥95%</td>
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<td></td>
<td>Adequate treatment coverage of syphilis-positive pregnant women</td>
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<tr>
<td>HBV</td>
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<td>≤50</td>
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</tbody>
</table>

*For countries that provide selective targeted hepatitis B birth dose vaccination to infants born to HBsAg-positive women.
### Table 2. Laboratory EQA results matrix

Instruction: Fill with EQA results according to years of review. Edit the table to show the year (for example, Year 1 to 2022).

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Supplier of proficiency test (PT)</th>
<th>Type of test</th>
<th>Periodicity of PT challenge (per year)</th>
<th>Annual average results per reporting year (%)</th>
<th>Overall result</th>
<th>Are PT results reviewed</th>
<th>Is corrective action taken and documented</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td></td>
<td></td>
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<tr>
<td>Syphilis</td>
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<tr>
<td>HBV</td>
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</tbody>
</table>
Table 3. **Overall summary of HIV-exposed infants who were diagnosed with HIV**

Instructions: Fill the table with information on infant diagnosis of HIV-exposed infants (HEI). Please note that in countries with small numbers of cases, Web Annex I should be used in addition to complete case descriptions of each infant diagnosed with HIV to describe the circumstances of the care and treatment of the mother–baby pair.

<table>
<thead>
<tr>
<th>Overall infant diagnosis of HEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total # of HEI</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>HEI at &lt;8 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td># HEI at &lt;8 weeks</td>
</tr>
<tr>
<td>---</td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HEI at final status</th>
</tr>
</thead>
<tbody>
<tr>
<td># HEI at &lt;8 weeks</td>
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<tr>
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</tbody>
</table>
**Table 4. Overall summary of HIV-exposed infants who are diagnosed negative**

Instructions: Fill the table with information on diagnosis of HIV-exposed infants who are negative.

<table>
<thead>
<tr>
<th># with 1 PCR (+) and subsequent negative testing</th>
<th># with 1 PCR (–)</th>
<th># with &gt;2 PCR (–) and antibody (Ab) (–) at 18 months</th>
<th>Overall # (%) with Ab (–) at 18 months (of all those considered uninfected)</th>
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</table>
**Table 5. Syphilis data table**

Instructions: Fill out the table with additional data summarizing maternal and congenital syphilis.

<table>
<thead>
<tr>
<th>Year</th>
<th>Year</th>
<th>Year</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence of syphilis in pregnant women (# of syphilis cases in pregnant women/# of pregnant women tested)</td>
<td></td>
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<tr>
<td># of congenital syphilis (CS) cases</td>
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<tr>
<td># of CS stillbirths</td>
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<tr>
<td># of CS live births</td>
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<tr>
<td># of CS cases in untreated mothers (less than 30 days prior to delivery)</td>
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</tbody>
</table>
### Table 6. Review of issues around human rights, gender equality and community engagement

Instructions: Fill out the summary table, guided by Web Annexes G and H. Based on synthesis of the data collected, reflect on whether the country meets requirements for validation and any key areas for country attention and investment.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Summary of findings from assessment</th>
<th>Does the country meet validation criteria?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ending criminalization of HIV, syphilis and HBV</td>
<td></td>
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<tr>
<td>Ensuring voluntary testing and treatment</td>
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<tr>
<td>Ensuring prior and informed consent</td>
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<tr>
<td>Eliminating coercive practices, including involuntary sterilization, contraception or abortion</td>
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<tr>
<td>Ensuring confidentiality of health information</td>
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<tr>
<td>Ensuring equality and non-discrimination</td>
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<tr>
<td>Ensuring accessibility and quality of women-centred health care services</td>
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<tr>
<td>Addressing gender-based violence</td>
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<tr>
<td>Engaging and being accountable to communities</td>
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<tr>
<td>Ensuring access to justice</td>
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</tbody>
</table>
2. SUPPORTING DOCUMENTS

(TO BE COMPILED BY THE REGIONAL VALIDATION SECRETARIAT)

Instructions: With the support of the regional validation secretariat (RVS), the NVC and RVC/RVT should provide a list of supporting documents reviewed or referenced in the report. These documents should be provided as electronic copies, if available, along with the report.

List of suggested documents:

- list of NVC and/or national validation team members and areas of expertise;
- list of RVC and/or RVT members and areas of expertise;
- list of NGO representatives and community partners supporting the national validation review;
- RVC or RVT consensus meeting notes for the record;
- documents from the regional validation mission;
- summary of cases of MTCT of HIV and syphilis for the years under review (see Web Annex I);
- list of documents reviewed for the national and regional validations, if available, which may include but are not limited to:
  - national guidelines for HIV, STIs and/or HBV service delivery at ANC clinics
  - HIV testing algorithm(s)
  - early infant diagnosis (EID) testing algorithm
  - syphilis testing algorithm(s)
  - detailed surveillance, monitoring and evaluation tools and information flow for reporting
  - flowchart for management of maternal HIV infection
  - flowchart for management of maternal and congenital syphilis
  - national laboratory trainings
  - national audits
  - complaints procedures and redress flowchart for people living with HIV
  - references of relevant policies reviewed.
- list of persons interviewed for the national and regional validations including: (1) position title and affiliation, (2) duties related to EMTCT programming or implementation and (3) the target population or civil society group that they represented.
For more information, contact:

World Health Organization
Department of HIV/AIDS
20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int

www.who.int/hiv