

**GUIDANCE**



GLOBAL GUIDANCE ON  
CRITERIA AND PROCESSES FOR VALIDATION:

**ELIMINATION OF  
MOTHER-TO-CHILD  
TRANSMISSION OF  
HIV, SYPHILIS AND  
HEPATITIS B VIRUS**

2021

**MONITORING AND EVALUATION**



**World Health  
Organization**



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## **Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus**

This publication is the update of the document published in 2017 entitled “Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis, second edition”.

ISBN 978-92-4-003936-0 (electronic version)

ISBN 978-92-4-003937-7 (print version)

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# FOREWORD

The global community has committed to eliminating mother-to-child transmission (EMTCT), also known as vertical transmission, of HIV and syphilis as a public health priority. In 2014 the World Health Organization (WHO) released the first edition of the *Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis*. In 2015 the Global Validation Advisory Committee for EMTCT was established and that same year the first country, Cuba, was validated. The second edition of the guidance, published in 2017, captured the learning from validation efforts, making it more relevant for high burden countries, expanding the capacity of maternal and child health services to address vertical transmission of communicable diseases. This third version includes guidance for validation of elimination of vertical transmission of hepatitis B virus (HBV), within the Triple Elimination Initiative (EMTCT of HIV, syphilis and HBV).

We support the renewed focus to end the epidemics of HIV, viral hepatitis and sexually transmitted infections (STIs) by making sustained investments in disease responses and leveraging health system resources more strategically. The five-year Start Free, Stay Free, AIDS Free framework launched in 2016 by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the US President's Emergency Plan for AIDS Relief (PEPFAR) accelerated efforts to prevent and treat HIV among children and adolescents and young women. The new global health sector strategies on HIV, viral hepatitis and STIs (2022–2030) further advance these efforts, leveraging universal health care, primary health care and health systems strengthening to ensure an integrated approach.

We welcome the revitalized global interest in addressing maternal, newborn and child health issues as well as the strong political will shown by countries in support of the United Nations Secretary General's Global Strategy for Women's, Children's and Adolescent's Health and their determination to dedicate significant resources and attention to achieving the Sustainable Development Goals (SDGs) for health. These goals provide a powerful unifying vision for how to achieve unprecedented gains in human well-being.

We are grateful to our United Nations partners – UNAIDS, the United Nations Children's Fund (UNICEF) and the United Nations Population Fund (UNFPA) – as well as our other partners, including networks of women living with HIV, for their support in preparing this guidance document and their consistent efforts to achieve global EMTCT. While achieving validation of EMTCT is a tremendous accomplishment, maintaining this status is equally important and will require sustained, broad programme efforts to prevent new infections in infants, children and adults.

In all countries success depends on the combined efforts of advocates, policy-makers, health care providers and community representatives. WHO and partners will continue to support countries in strengthening the capacity of health systems to provide comprehensive services that respect and protect the human rights of women living with HIV or HBV and to ensure the involvement of women in service planning and delivery to see that services are non-coercive and the human rights of women, children and families affected by HIV, syphilis and hepatitis are protected.

This third version of the EMTCT global validation guidance document provides standardized processes and consensus-developed criteria to validate EMTCT of HIV, syphilis and HBV and to recognize high burden countries that have made significant progress on the Path to Elimination. The guidance strongly emphasizes country-led accountability, rigorous analysis, intensive programme assessment and multilevel collaboration, including the involvement of communities of women living with HIV or HBV. A harmonized approach to triple elimination is encouraged, but, depending on readiness, countries may choose to pursue validation of single, dual or triple EMTCT.

We are convinced that setting the bar high will result in the best results for all and, in particular, for women and children at risk for HIV, syphilis and HBV. WHO is pleased with the progress of this elimination initiative and anticipates ongoing success by countries and regions in achieving the elimination targets.

**Dr. Meg Doherty,**

Director  
Global HIV, Hepatitis and STIs Programmes  
World Health Organization



# ACKNOWLEDGEMENTS

This guidance document is the result of collaboration between the WHO Global HIV, Hepatitis and STI Programmes, led by their Director, Meg Doherty, the Global Validation Advisory Committee for elimination of mother-to-child transmission (GVAC) members and observers, WHO counterpart programmes at the regional and country levels, and contributing member states.

Many professionals from a range of backgrounds and specialties have contributed to the development of this guidance. WHO is sincerely grateful for their time and support. The third version was developed through three virtual consultation meetings with more than 50 experts, including staff and advisors from WHO headquarters and all six WHO regions, members and observers of the Global Validation Advisory Committee for elimination of mother-to-child transmission (EMTCT) of HIV, syphilis and hepatitis B virus (HBV). Collaborators also reviewed and provided detailed written contributions throughout the drafting process to inform this update to the validation criteria and processes.

Contributors to the guidance revision included both past and current members of the World Health Organization (WHO) EMTCT Global Validation Advisory Committee (GVAC):

**Angela Mushavi** (chair), **Annette Sohn** (co-chair), **Shabbir Argaw**, **Benjamin Cowie**, **Merceline Dahl Regis** (former chair), **Sandra Dudareva**, **Sarah Hawkes**, **Monir Islam**, **Mary Kamb**, **Bakita Kasadha**, **Eszter Kismodi**, **Lorraine Misquith**, **Michele Montandon**, **Lillian Mworeko**, **Lori Newman**, **Natalya Nizova**, **Rosanna Peeling**, **Genesis Samonte**, **Nathan Shaffer**, **Melanie Taylor**, **Rania Tohme**, **Fatima Tsiouris**, **Deborah von Zinkernagel**, **Su Wang**, **Valerie Wilson**, **Clement Zeh**.

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GVAC observers **Sophie Brion** (ICW Global) and **Aditi Sharma** (GNP+) were the technical writers for the section on human rights, gender equality and community engagement, representing organizations of affected communities and people with lived experience.

Experiences from the countries and territories validated for EMTCT – in chronological order, Cuba, Thailand, Belarus, Republic of Moldova (syphilis only), Armenia (HIV only), Anguilla, Montserrat, Cayman Islands, Bermuda, Antigua and Barbuda, St Christopher and Nevis, Malaysia, Maldives, Sri Lanka and Dominica – have been instrumental in updating this third version of the global guidance. We also acknowledge the contribution of the Botswana experience and all who supported the strengthening of the process for certification on the Path to Elimination.

WHO particularly thanks the national programme managers, country-level WHO and other UN staff, health care providers, the community of women living with HIV and hepatitis B virus (HBV), and women affected by syphilis, who have enabled countries to advance towards a generation free of HIV, syphilis and HBV.



Past and current advisors and EMTCT focal points from the six WHO regions contributed to the guidance revision based on the experiences from national and regional EMTCT validation committees, secretariats and teams. African Region: **Francoise Bigirimana, Innocent Nuwagira**. Region of the Americas: **Sandra Jones, Leandro Sereno, Massimo Ghidinelli**. South-East Asia Region: **Mukta Sharma, B.B. Rewari**. European Region: **Nicole Seguy, Elena Vovc, Antons Mozalevskis**. Eastern Mediterranean Region: **Joumana George Hermez, Bridget Akora Mugisa**. Western Pacific Region: **Naoko Ishikawa, Anne Brink, Po-Lin Chan**.

At headquarter level, past and present colleagues from the WHO Global HIV, Hepatitis and STIs Programmes, the WHO Departments of Sexual and Reproductive Health and Research (SRHR), Immunization, Vaccines and Biologicals (IVB) and Maternal, Newborn, Child and Adolescent Health and Ageing (MCA) contributed to revision of this guidance.

The following WHO consultants were a core part of the guidance revision team: **Maura Laverty, Caitlin Quinn and Nicholas Walsh**.

The United States President's Emergency Plan for AIDS Relief (PEPFAR) through the United States Centers for Disease Control and Prevention (CDC) and the US Agency for International Development (USAID) contributed to funding this guidance revision.



# ESSENTIAL WHO EMTCT RESOURCES

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

## **Triple elimination initiative of EMTCT of HIV, syphilis and HBV**

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

## **EMTCT validation processes and tools**

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

## **Regional EMTCT websites**

WHO Regional Office for Africa

<http://www.afro.who.int/health-topics/hivaids/emtct>

Pan American Health Organization

[www.paho.org/emtct](http://www.paho.org/emtct)

WHO Regional Office for the Western Pacific

<https://www.who.int/westernpacific/activities/eliminating-mother-to-child-transmission-of-hiv-hepatitis-syphilis>

## **Essential complementary documents and guidance on validation of EMTCT of HIV, syphilis and HBV**

*Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis*

<https://www.who.int/publications/i/item/governance-guidance-for-validation-of-emtct-syphilis-hiv>

*Interim guidance for country validation of viral hepatitis elimination*

<https://www.who.int/publications/i/item/9789240028395>

# ABBREVIATIONS AND ACRONYMS

<b>ABOs</b>	adverse birth outcomes	<b>MIPA</b>	meaningful involvement of people living with HIV/AIDS
<b>ANC</b>	antenatal care	<b>MTCT</b>	mother-to-child transmission
<b>ART</b>	antiretroviral therapy	<b>NASBA</b>	nucleic acid sequence-based amplification
<b>ARV</b>	antiretroviral	<b>NAT</b>	nucleic acid test
<b>CDC</b>	United States Centers for Disease Control and Prevention	<b>NVC</b>	national validation committee
<b>CHB</b>	chronic hepatitis B	<b>NVS</b>	national validation secretariat
<b>CS</b>	congenital syphilis	<b>NVTF</b>	national validation task force
<b>CSF</b>	cerebrospinal fluid	<b>PAHO</b>	Pan American Health Organization
<b>EID</b>	early infant diagnosis	<b>PCR</b>	polymerase chain reaction
<b>EMTCT</b>	elimination of mother-to-child transmission	<b>PMTCT</b>	prevention of mother-to-child transmission
<b>EQA</b>	external quality assurance	<b>PTE</b>	Path to Elimination
<b>FPC</b>	finite population correction	<b>PVST</b>	post-vaccination serological testing (of HBsAg in infants)
<b>GAM</b>	UNAIDS Global AIDS Monitoring	<b>RDT</b>	rapid diagnostic test
<b>GHSS</b>	global health sector strategy	<b>RPR</b>	rapid plasma reagin
<b>GIPA</b>	greater involvement of people living with HIV/AIDS	<b>SRH</b>	sexual and reproductive health
<b>GMEF</b>	Global Multi-disease Elimination Framework	<b>STIs</b>	sexually transmitted infections
<b>HBeAg</b>	hepatitis B e antigen	<b>TRUST</b>	toluidine red unheated serum test
<b>HBIG</b>	hepatitis B immune globulin	<b>UHC</b>	Universal Health Coverage
<b>HBsAg</b>	hepatitis B surface antigen	<b>UN</b>	United Nations
<b>HBV</b>	hepatitis B virus	<b>UNAIDS</b>	Joint United Nations Programme on HIV/AIDS
<b>HepB3</b>	three doses of hepatitis B vaccine (infant vaccination)	<b>UNFPA</b>	United Nations Population Fund
<b>HepB-BD</b>	hepatitis B birth dose vaccine	<b>UNGA</b>	United Nations General Assembly
<b>HIV</b>	human immunodeficiency virus	<b>UNICEF</b>	United Nations Children's Fund
<b>HTS</b>	HIV testing services	<b>VDRL</b>	Venereal Disease Research Laboratory
<b>M&amp;E</b>	monitoring and evaluation	<b>WHO</b>	World Health Organization
<b>MCH</b>	maternal and child health		

# GLOSSARY

The following glossary definitions are sourced from current relevant WHO guidelines (1-5).

**Adequate treatment of syphilis:** The treatment of seropositive women with at least one dose of intramuscular benzathine penicillin G at least 30 days prior to delivery is the minimum time necessary to prevent transmission of syphilis to the infant. Ideally, maternal treatment should be given in the first trimester, or as early as possible if antenatal care (ANC) is started later.

**Early infant diagnosis:** The testing of HIV-exposed infants before two months of age, to establish timely diagnosis and access to life-saving HIV treatment.

**Elimination as a public health problem:** Reduction of disease incidence, prevalence, morbidity or mortality as a result of deliberate efforts to reduce below a level at which the public health burden is considered negligible. The target level for a particular disease is generally defined globally by WHO. When reached, continued action is required to maintain the reduced level. In this document the term “elimination as a public health threat”, as used in the global health sector strategies on HIV, sexually transmitted infections and viral hepatitis (2016–2021), is considered equivalent to “elimination as a public health problem”.

**Exposed infants:** Infants born to mothers with HIV, syphilis or HBV.

**External quality assurance (EQA):** Inter-laboratory comparison to determine if the testing services can provide correct test results and diagnosis. Sample panels are usually provided by an external reference laboratory.

**Hepatitis B e antigen (HBeAg):** Viral protein found in the high replicative phase of HBV. HBeAg is usually a marker of high levels of replication with wild-type virus but is not essential for viral replication.

**Hepatitis B surface antigen (HBsAg):** HBV envelope protein often produced in excess [of normal] and detectable in the blood in acute and chronic HBV infection.

**HIV testing services (HTS):** A term that embraces not only HIV testing itself but also the full range of services that should be provided together with HIV testing. This includes counselling (brief pre-test information and post-test counselling); linkage to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support quality assurance.

**HIV status:** This is the final interpretation of the client’s disease state and is based on a collection of testing results generated from one or more assays. HIV status may be reported as HIV-positive, HIV-negative or HIV-inconclusive.

**Infant diagnosis:** The testing of infants and young children to determine their HIV status following possible exposure to HIV during pregnancy, delivery and postpartum. Infant diagnosis should be performed using molecular (nucleic acid) technologies at younger than 18 months; serological assays can be used for children older than 18 months of age.

**Informed consent:** People receiving testing services must give informed consent to be tested and counselled. (Verbal consent is sufficient; written consent is not required.) They should be informed of the process for testing and counselling and of their right to decline testing.

**Integrated service delivery:** Health services that are managed and delivered in a way that ensures that people receive a continuum of health promotion, infection prevention, diagnosis, treatment, disease management, rehabilitation and palliative care services at the different levels and sites of care within the health system and according to their needs throughout the life-course.

**Integration:** The co-location and sharing of services and resources across different health service delivery areas. This may include the provision of HIV, syphilis and HBV testing, prevention, treatment and care services alongside other health services, including general medical services as well as those focused on tuberculosis (TB), sexually transmitted infections (STIs) or hepatitis B/C, antenatal care (ANC), vaccination, contraception and other family planning services, and screening and care for other conditions, including non-communicable diseases.

**Key populations:** Groups that have a high risk and disproportionate burden of HIV in all epidemic settings. They frequently face legal and social challenges that increase their vulnerability to HIV, including barriers to accessing HIV prevention, diagnosis, treatment and other health and social services. Key populations include men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people.

**Maintenance of validation:** The confirmation that a country has sustained the systems and responses for long-term prevention of new paediatric infections and maintained the health of mothers by continuing to meet all criteria for validation.

**Meaningful engagement of women living with HIV:** Based on the “greater involvement of people living with HIV/AIDS” (GIPA) and “meaningful involvement of people living with HIV/AIDS” (MIPA) principles that promote people’s right to participate in decision-making processes that affect their lives. It states, *“As active participants in the health system, the perspectives of women in communities are a key influence on how services and interventions are delivered to respond to their priorities, concerns and rights.”* Governments first committed to this principle in 1994 and since then in subsequent UN Political Declarations on HIV/AIDS.

**Non-treponemal testing (syphilis):** Serological tests for syphilis that are indirect markers measuring host immune response to infections, including rapid plasma reagin (RPR), Venereal Diseases Research Laboratory (VDRL) and the toluidine red unheated serum test (TRUST). These tests are able in most cases to detect current syphilis infection, but, should be used in the context of a diagnostic testing strategy as they are not 100% sensitive or 100% specific. Non-treponemal tests are also used to monitor response to treatment.

**Nucleic acid testing (NAT):** A molecular technology, for example, polymerase chain reaction (PCR) or nucleic acid sequence-based amplification (NASBA), that can detect very small quantities of viral nucleic acid (DNA or RNA), either qualitatively or quantitatively.

**Path to Elimination (PTE):** A set of criteria for recognition of substantial progress in high-burden countries toward EMTCT of HIV, syphilis and HBV.

**Policy:** An institutional statement to guide the action of an institution or a sector in a particular domain.

**Quality assurance:** Part of quality management focused on providing confidence among stakeholders that quality requirements will be met.

**Quality control:** Verifies that the product meets quality requirements. It is a mechanism to identify product defects and to formally reject a defective product.

**Quality management system:** A system to direct and control an organization with regard to quality. Systematic and process-oriented efforts are essential to meet quality objectives.

**Rapid diagnostic test (RDT):** Immunoassays that detect antibodies or antigens and can give a result in less than 30 minutes. Most RDTs can be performed with capillary whole blood collected by finger-stick sampling and some, by oral fluid sampling.

**Testing algorithm:** When specific products are populated into a testing strategy. A specific product is defined with a product name, product code(s), a manufacturing site and regulatory version. The testing algorithm is likely to change depending on which specific products are verified for use together and are procured.

**Testing strategy:** A sequence of tests conducted on assays to achieve a specific objective, such as screening for infection or diagnosing infection.

**Treponemal testing (syphilis):** Serological tests for syphilis that measure antibodies to infection including *Treponema pallidum* haemagglutination assay (TPHA), *Treponema pallidum* particle agglutination assay (TPPA) and fluorescent treponemal antibody absorbed (FTA-ABS). Treponemal tests identify any lifetime infection. This test is not able to differentiate between a person who is currently infected or one who has been cured.

**Validation:** An independent confirmation of elimination as a public health problem/threat that attests and documents that a country has successfully met the criteria for elimination of mother-to-child transmission of HIV, syphilis and HBV.



# EXECUTIVE SUMMARY

The global community has committed to the elimination of mother-to-child transmission (MTCT), also referred to as vertical transmission, of HIV, syphilis and hepatitis B virus (HBV) as a public health priority. The global commitment to EMTCT was established due to the continued high global burden of mother-to-child (MTCT), or vertical transmission, of these infections. The purpose of the elimination goal is to ensure the availability of quality reproductive and maternal and child health (MCH) services to reduce and control the transmission of HIV, syphilis and HBV between mothers and their offspring and to provide the best available treatment to the mother, such that incidence is reduced to a very low level and ceases to be a public health concern.

Achieving and maintaining elimination requires strong political and public health commitment to resilient health systems that (i) ensure continued and unimpaired access to services that deliver quality primary prevention and treatment for women and girls and their newborns (or young children), through the life-course; (ii) deliver services respecting and protecting human rights and ensuring gender equality and community engagement; and (iii) have functional surveillance systems with the ability to comprehensively identify and monitor women living with or at risk of infection and infant outcomes. Strengthening the health system to address vertical transmission serves to improve a broad range of MCH services and outcomes. This directly contributes to Sustainable Development Goals 3, 5 and 10, which aspire to ensure health and well-being for all, achieve gender equality, empower women and girls and reduce inequalities in access to services and commodities (6).

The similarity of the critical interventions necessary to prevent transmission adds to the feasibility and benefit of an integrated approach to EMTCT of all three infections (7). Building on an integrated MCH platform, WHO has moved to operationalize universal health coverage (UHC) in the context of integrated communicable disease prevention. The UHC model facilitates bringing together the EMTCT efforts for HIV, syphilis and HBV as part of *triple elimination*. WHO regions have advanced strategies for triple elimination and have supported Member States. The Pan American Health Organization (PAHO) has developed the “EMTCT Plus” strategy, which includes EMTCT of the three conditions and of congenital Chagas infection (8). The WHO Western Pacific Regional Office has developed the *Regional Framework for Triple Elimination of Mother-to-Child Transmission of HIV, Hepatitis B and Syphilis in Asia and the Pacific, 2018–2030* (9).

Efforts to establish criteria for validation of EMTCT began in 2007, based on the foundation of quality MCH services that supported the Millennium Development Goals and the launch of the WHO-led initiative for the elimination of congenital syphilis (CS). This was followed by WHO consultations on the EMTCT of HIV, the *Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive*, WHO recommendations for treatment for all persons living with HIV and the adoption by the Joint United Nations Programme on HIV/AIDS (UNAIDS) of a strategy to end the AIDS epidemic as a public health threat by 2030. Most recently, the WHO 2016–2021 three global health sector strategies (GHSS) on HIV, sexually transmitted infections (STIs) and viral hepatitis call for Member States and WHO to work together towards the goals of zero new HIV infections in infants and young children by 2030, elimination of CS and viral hepatitis as public health threats by 2030 and  $\leq 0.1\%$  prevalence of hepatitis B surface antigen (HBsAg) among children  $\leq 5$  years of age by 2030 (10–12).

In 2014 WHO led a global consultation that resulted in the first edition of *Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis*, also known as the “Orange Book”. This guidance document supported the standardization and formal approach to EMTCT validation, including criteria, indicators and targets to be achieved. These formed the basis for foundational requirements for validation in the four areas of (i) data, (ii) laboratory, (iii) programme and (iv) human rights, gender equality and community engagement.

A second edition was published in 2017. It established revised validation criteria and guidance on how to assess countries with small numbers of HIV- or syphilis-positive pregnant women, as well as criteria for the recognition of progress in countries with a high burden of HIV and/or syphilis, known as the Path to Elimination (PTE). The second edition also included expanded descriptions of case definitions, data reporting for exposed infants and young children, the selection of low-performing subnational administrative units for review and evaluation of special populations as well as clearer determination of targets for breastfeeding and non-breastfeeding populations.

As of November 2021, the 15 countries or territories validated for EMTCT of HIV and syphilis, in chronological order are: Cuba, Thailand, Belarus, Armenia (HIV only), Republic of Moldova (syphilis only), Anguilla, Montserrat, Cayman Islands, Bermuda, Antigua and Barbuda, St Christopher and Nevis, Malaysia, Maldives, Sri Lanka and Dominica. In addition, Botswana is the first country which has applied for Path to Elimination and been reviewed at the global level for certification.

This third version of *Global guidance on criteria and processes for validation of elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus* brings together the package of interventions and metrics to support the integrated management and monitoring of mother-to-child transmission, also known as vertical transmission, of these major communicable diseases across a wide range of epidemiological and programmatic contexts. Table 1 summarizes the impact and process/programmatic targets for EMTCT of HIV, syphilis and HBV.





**Table 1. Summary of impact and process/programmatic targets for EMTCT of HIV, syphilis and HBV**

Elimination targets	HIV EMTCT	Syphilis EMTCT	HBV EMTCT
<b>2030 WHO GHSS (8, 10, 11) and UNGA political declaration (13) aspirational targets</b>	Zero new infections among infants and young children and achievement of the 95-95-95 targets	≤50 cases of CS per 100 000 live births in 80% of countries	95% reduction in incidence of chronic HBV infections
<b>EMTCT impact targets</b>	A population case rate of new paediatric HIV infections due to MTCT of ≤50 cases per 100 000 live births  MTCT rate of HIV of <2% in non-breastfeeding populations OR <5% in breastfeeding populations	A case rate of CS of ≤50 per 100 000 live births	≤0.1% prevalence* HBsAg in children ≤5 years old <sup>a,b</sup>  Additional target ≤2% MTCT rate (for countries using targeted timely HepB-BD)
<b>EMTCT process/ programmatic targets</b>	<b>ANC coverage</b> (at least one visit (ANC-1)) of ≥95% <b>Coverage of HIV testing</b> of pregnant women of ≥95% <b>ART coverage</b> of pregnant women living with HIV of ≥95%	<b>ANC coverage</b> (at least one visit (ANC-1)) of ≥95% <b>Coverage of syphilis testing</b> of pregnant women of ≥95% among those who attended at least one ANC visit <b>Adequate syphilis treatment</b> (see Box 3.6) of syphilis-seropositive pregnant women of ≥95%	<b>Countries with universal timely HepB-BD</b> ≥90% HepB3 vaccine coverage ≥90% HepB-BD coverage <sup>c</sup>  <b>Countries with targeted timely HepB-BD or without universal timely HepB-BD</b> ≥90% HepB3 vaccine coverage ≥90% HepB-BD coverage ≥90% coverage of maternal HBsAg testing ≥90% coverage with antivirals for eligible HBsAg-positive pregnant women <sup>d</sup>

HBV=hepatitis B virus; GHSS=global health sector strategy; CS=congenital syphilis; EMTCT=elimination of mother-to-child transmission; MTCT=mother-to-child transmission; ANC=antenatal care; ART=antiretroviral therapy; HepB3=three doses of hepatitis B vaccine (infant vaccination); HepB-BD=hepatitis B birth dose vaccine; HBsAg=hepatitis B surface antigen; UNGA=United Nations General Assembly

a Childhood prevalence is a proxy for HBV incidence.

b The ≤0.1% HBsAg prevalence can be measured among either 5 year olds, 1 year olds or those aged 1–5 years, according to existing country surveillance and data collection activities. For those regions and countries with a long history of high hepatitis B vaccination coverage (e.g. WHO Region of the Americas), and that already conduct school-based serosurveys, there could be flexibility to conduct serosurveys in older children >5 years.

c Timely birth dose (HepB-BD) is defined as within 24 hours of birth.

d In accordance with national policies or WHO 2020 guidelines on use of antiviral prophylaxis on PMTCT of HBV

Changes, clarifications and new guidance in this third version address the following topics areas:

1. inclusion of validation criteria and processes for EMTCT of HBV (section 3.1.3), including criteria for the recognition of progress in countries with a high burden of HBV (PTE) (section 5);
2. revision of laboratory quality standards, including external quality assurance (EQA) for validation (section 4.2);
3. expansion of guidance on selection of low-performing subnational administrative units and inclusion of subpopulations with the lowest coverage or access to services (section 4.3.1);
4. inclusion of further guidance on assessing countries with small numbers of HIV-, HBV- or syphilis-positive pregnant women (section 6.3);
5. provision of step-by-step guidance on meaningful engagement of women to ensure that human rights, gender equality and community engagement are well integrated into validation assessments from planning through implementation (section 4.4);
6. revision of guidance on maintenance of validation assessment and reporting, including:
  - a. revision of time intervals for assessing maintenance of validation (section 8)
  - b. revision of details on maintenance of validation for countries with small numbers of pregnant women with HIV, syphilis or HBV, including specific time intervals for small countries and territories (section 6.3);
7. inclusion of assessment and reporting of EMTCT validation components provided by the entire health sector, comprising the public and non-public (for example, private, faith-based) sectors (section 6.4).
8. addition of details on the decentralization of Global Validation Advisory Committee functions to the regional structures, where appropriate (section 8.1.2);

In addition, tools and checklists for end users of the guidance in the areas of assessment of (i) data and surveillance systems, (ii) laboratory services, (iii) programme and (iv) human rights, gender equality and community engagement have been updated and are available as online supplements to the guidance.

The third version was developed by WHO and the Global Validation Advisory Committee. It is intended for use by national, regional and global validation committees as they prepare or review national and regional submissions for validation of EMTCT of HIV, syphilis and HBV. A harmonized approach to triple elimination (EMTCT of HIV, syphilis and HBV) is encouraged, but, depending on readiness, countries may choose to pursue validation of single, dual or triple EMTCT of any of the three infections (as determined by the WHO region).

This document summarizes the validation process, but further details on the standardized structure and processes used to validate EMTCT can be found in the *Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis (14)*. That guidance provides an overview of the validation structures and roles and responsibilities at national, regional and global levels. The document is being revised and will be available at the link provided above.

The validation processes are aligned with the Global Multi-disease Elimination Framework (GMEF), which is currently under development by WHO and which seeks to harmonize and standardize elimination concepts, terminology and validation processes. The GMEF establishes a framework for planning for future elimination strategies, and it promotes greater standardization, alignment and coordination across existing disease elimination processes. WHO believes that this third version of the EMTCT global guidance will further standardize and catalyse regional and country progress towards achieving the validation of EMTCT of HIV, syphilis and HBV as public health priorities.

# 1. INTRODUCTION

## 1.1. Mother-to-child transmission in the HIV, syphilis and HBV epidemics

Mother-to-child transmission (MTCT), or “vertical transmission”, is a significant contributor to the HIV pandemic, accounting for 9% of new infections globally in 2017 (15). The Joint United Nations Programme on HIV/AIDS (UNAIDS) reported that, globally, in 2020 an estimated 150 000 children newly acquired HIV, and an estimated 1.8 million children were living with HIV (16, 17). Although this is still a large number of new infections, at the peak of the HIV epidemic in 2000 there were close to 470 000 children acquiring HIV through MTCT each year (18). HIV can be transmitted from a woman living with HIV to her baby during pregnancy, labour or delivery, or after delivery through breastfeeding. Globally, an estimated 1.3 million women living with HIV become pregnant every year (19-21). Without treatment, approximately 15–30% of infants born to women living with HIV will acquire HIV during gestation and delivery, with a further 5–15% acquiring HIV through breastfeeding (22). Without treatment, HIV infection in infants and young children results in early mortality for many or creates a lifelong chronic condition that greatly increases morbidity, shortens life expectancy, imposes a great burden on the child and the family and contributes to substantial human, social and economic costs.

### Box 1.1. Terminology

Women living with HIV and their advocates have promoted use of the phrase “vertical transmission” as an alternative to “mother-to-child transmission” in an effort to avoid language that places mothers at the center of HIV transmission. To reduce stigma felt by women living with HIV, ‘vertical transmission’ is considered neutral and is consistent with other disease elimination language. There are ongoing consultations about mainstreaming the phrase ‘vertical transmission’ in HIV programmes, while recognizing previous discussions on the topic and views from a broad network of civil society members and technical partners. In this document the two terms are used interchangeably.

The strict definition of the medical term “vertical transmission” does not include transmission through breastfeeding (23), but, for the purposes of this document, we use the term to include transmission both during pregnancy and during the breastfeeding period. In addition, women in all their diversity may access and utilize services for the prevention of vertical transmission. Noting that trans and gender diverse persons can in some cases become pregnant, and involve risk for vertical transmission, this guidance also applies to this group.

Interventions that contribute to the prevention of mother-to-child transmission (PMTCT) of HIV, and, thereby, reduce maternal and child morbidity and mortality include:

- primary prevention of incident HIV infections;
- prevention of unintended pregnancies and provision of other sexual and reproductive health (SRH) services;

- universal and equitable access to HTS for pregnant and breastfeeding women;
- initiation of lifelong triple antiretroviral therapy (ART) for pregnant women living with HIV, with support for adherence;
- retention in care and viral suppression for pregnant and postpartum women and girls living with HIV;
- safe delivery practices;
- optimal infant-feeding practices;
- access to postnatal antiretroviral (ARV) prophylaxis for HIV-exposed infants; and
- access to HTS for early infant diagnosis (EID) and determination of final outcome, and early treatment for infants and young children diagnosed with HIV.

The World Health Organization estimates that 19.3 million women were living with HIV globally in 2020, and 660 000 women were newly infected. In 2020, 1.7 million children were living with HIV (10).

With the global shift to highly effective and simplified interventions based on lifelong maternal ART and infant prophylaxis, risk of infection in the population of infants born to women living with HIV has fallen from approximately 30% to <5% (or <2% if no breastfeeding). It is now feasible to virtually eliminate new HIV infections in infants and young children, while assuring the health of the mother (19, 21).

Syphilis is caused by the *Treponema pallidum* bacterium, renowned for its invasiveness. It can be transmitted via sexual exposure or vertically from mother to child during pregnancy (in utero infection). If the infection remains untreated, adverse pregnancy outcomes are frequent. Over half of the pregnancies among women with active syphilis result in stillbirth, early neonatal death, a preterm or low-birth-weight infant or serious neonatal infection (24). Screening for maternal syphilis early in pregnancy, using recommended point-of-care tests with single or dual HIV/syphilis rapid tests in antenatal care (ANC) (25), and prompt treatment of seropositive women (at least four weeks prior to delivery with intramuscular benzathine penicillin G, a long-acting penicillin) cures syphilis in both mother and fetus and prevents most complications associated with MTCT of syphilis and can prevent congenital syphilis (CS) when there is high ANC coverage (5).

In 2019 (using 2016 data), WHO estimated that over 900 000 pregnant women were infected with syphilis. The total number of CS cases was estimated at 661 000 [538 000–784 000], including 355 000 (290 000–419 000) adverse birth outcomes (ABOs) and 306 000 (249 000–363 000) non-clinical CS cases (infants without clinical signs born to untreated mothers). The ABOs included 143 000 early fetal deaths and stillbirths, 61 000 neonatal deaths, 41 000 preterm or low-birth weight births and 109 000 infants with clinical CS. Of these ABOs, 203 000 (57%) occurred in pregnant women who had attended ANC but were not screened for syphilis; 74 000 (21%) in mothers not enrolled in ANC, 55 000 (16%) in mothers screened but not treated and 23 000 (6%) in mothers enrolled, screened and treated (26).

The viral hepatitis epidemic takes a heavy toll on lives, communities and health systems. Globally, it is responsible for an estimated 1.1 million deaths per year from acute infection and hepatitis-related liver cancer. In 2019, 820 000 deaths were attributed to hepatitis B infection-related causes. The African and South East Asia Regions account for 83% of new hepatitis B infections (10).

Globally, the main routes of HBV transmission are mother-to-child and early childhood transmission, which can be prevented with effective infant and timely hepatitis B birth dose vaccination. Childhood infections also account for most of the chronic infections, which can result in the complications of liver cancer and cirrhosis. While infections can occur in adults through exposure to blood (through unsafe injections or sharing of needles or syringes) and through sexual transmission,

this leads to chronic disease much less often. WHO recommends universal immunization of infants with at least three doses of the hepatitis B vaccine and timely hepatitis B birth dose (HepB-BD) vaccination (as soon as possible after birth, preferably within 24 hours) (27).

## 1.2. Triple elimination of mother-to-child transmission and its validation

In public health elimination is generally defined as reduction to zero of the incidence of a disease or infection in a defined geographical area (28). However, because HIV, syphilis and HBV remain public health issues and prevention of mother-to-child transmission (PMTCT) measures are highly but not 100% effective, it is not feasible in most settings to reduce MTCT to “zero” new infections, as proposed in the vision of the global health sector strategy for HIV (10, 11). The goal of EMTCT programmes is to ensure that MTCT of HIV, syphilis and HBV is controlled and incidence is reduced to a very low level, such that these infections cease to be a public health concern. The same principle has been applied to elimination programmes for several other diseases, including leprosy (29), onchocerciasis (30), lymphatic filariasis (31), dracunculiasis (32) and maternal and neonatal tetanus (33). It is also currently being considered for the WHO Global Multi-Disease Elimination initiative, which is under development.

Triple elimination targets can be achieved only when access to quality services for SRH and maternal and child health (MCH) is assured and all women, children and their families use these services. Achievement of elimination requires strong political and public health commitment, including the adoption of enabling legal and policy frameworks that maintain primary prevention, care and treatment programmes and services. It also requires a strong surveillance system to capture incident cases and to monitor performance indicators over time.

Successful prevention of MTCT of HIV depends on detecting maternal infection early and initiating and sustaining lifelong treatment for all women and girls of childbearing age living with HIV, as well as prevention and care programmes for male partners. Similarly, prevention of MTCT of syphilis requires early detection of and cure for women and their partners diagnosed with syphilis and, when eligible, treatment for women with HBV. All infants and young children exposed to HIV or HBV should be provided with prevention and care services, including appropriate prophylaxis, routine immunization, follow-up and treatment where indicated.

Strengthening the health system to address vertical transmission of HIV, syphilis and HBV serves to improve a broad range of MCH services and outcomes. This achievement directly contributes to Sustainable Development Goals 3, 5 and 10, which aspire to ensure health and well-being for all, achieve gender equality and empower women and girls, as well as to reduce inequalities in access to health services and commodities (6). Additionally, the similarity of the critical interventions necessary to prevent transmission of HIV, syphilis, and HBV in pregnancy adds to the feasibility and benefit of an integrated approach to EMTCT of all three infections (7).

Building on an integrated MCH platform, WHO headquarters and several WHO regions have moved to “triple elimination” by incorporating PMTCT of HBV into the EMTCT framework. The Pan American Health Organization (PAHO) is promoting a strategy of “EMTCT Plus”, which includes the EMTCT of HBV and Chagas disease (in countries where it is endemic), in addition to the dual EMTCT of HIV and syphilis (8). The WHO Western Pacific Regional Office supports Member States to achieve EMTCT of HIV, syphilis and HBV through a coordinated approach outlined in the *Regional Framework for Triple Elimination of Mother-to-Child Transmission of HIV, Hepatitis B and Syphilis in Asia and the Pacific, 2018–2030* (9).

“Validation” is a term used to attest that a country has successfully met the criteria for EMTCT of HIV and/or syphilis and/or HBV. A unique consideration for validation of EMTCT is that elimination must be achieved while protecting and respecting human rights. It must also include the meaningful involvement of women, particularly those living with HIV or HBV, as well as affected communities in all interventions, including planning and designing programmes, implementation and monitoring and evaluation (M&E).

These standards include human rights in relation to equitable access to SRH services and antenatal care (ANC); pregnant women’s autonomy in decision-making; informed consent for HIV, syphilis and HBV testing and treatment; respect for privacy and confidentiality; adequately addressing violence, abuse and coercive practices; decriminalization of HIV, syphilis and HBV transmission; and ensuring meaningful participation of people living with HIV and/or HBV in the design and delivery of programmes. As syphilis is curable, it may not be practical to expect the participation of communities of women living with syphilis.

Gender equality considerations are particularly pertinent in the context of vertical transmission, as gender norms and practices can significantly affect women’s sexual and reproductive health and the realization of their rights, as well as health outcomes for their children. Promoting and ensuring gender equality can significantly improve opportunities for people to access necessary information and services, to make autonomous decisions about their sexuality and reproduction and to protect themselves against HIV and other sexually transmitted infections (STIs).

The processes and criteria to validate EMTCT of HIV, syphilis and HBV described in this guidance were developed to apply across a wide range of epidemiological and programmatic contexts. They have been further elaborated in the *Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis* (14), first published in July 2020, to support standardization of the governance process and in the 2021 *Interim guidance for country validation of viral hepatitis elimination* (3). They also seek to ensure that representatives of civil society, including women living with HIV and HBV, are fully involved in the assessment and validation efforts (3).

### 1.3. Standard criteria and processes

A harmonized and integrated approach to EMTCT of HIV, syphilis and HBV is encouraged. However, depending on the progress of national EMTCT efforts and regional preferences, countries may choose to validate the EMTCT of one infection, two infections, or, ideally, HIV, syphilis and HBV.

WHO and the Global Validation Advisory Committee revised this document to clarify and update existing guidance and advice, update assessment checklists and tools and integrate EMTCT of HBV (Box 1.2). The document is intended for use by national, regional and global validation committees and secretariats as they prepare or review national or regional submissions for validation of EMTCT of HIV, syphilis and/or HBV. It is intended to be used in conjunction with the *Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis* (14) and the *Interim guidance for country validation of viral hepatitis elimination* (3). In updating the document, WHO and the Global Validation Advisory Committee considered the input of national programmes, national validation structures, regional validation structures, subject matter experts and civil society representatives. WHO collated the revisions recommended by these groups.

The first edition of the global EMTCT guidance, released in 2014, outlined the minimum global processes and criteria that countries should address to achieve validation of EMTCT of HIV and syphilis. The second version included changes, clarifications and new guidance in criteria and processes.

## Box 1.2. What's new in the third version

This third version includes changes, clarifications and new guidance on criteria and processes for validation, including the following:

1. inclusion of validation criteria and processes for EMTCT of HBV (section 3.1.3), including criteria for the recognition of progress in countries with a high burden of HBV (PTE) (section 5);
2. revision of laboratory quality standards, including external quality assurance (EQA) for validation (section 4.2);
3. expansion of guidance on selection of low-performing subnational administrative units and inclusion of subpopulations with the lowest coverage or access to services (section 4.3.1);
4. inclusion of further guidance on assessing countries with small numbers of HIV-, HBV- or syphilis-positive pregnant women (section 6.3);
5. provision of step-by-step guidance on meaningful engagement of women to ensure that human rights, gender equality and community engagement are well integrated into validation assessments from planning through implementation (section 4.4);
6. revision of guidance on maintenance of validation assessment and reporting, including:
  - a. revision of time intervals for assessing maintenance of validation (section 8)
  - b. revision of details on maintenance of validation for countries with small numbers of pregnant women with HIV, syphilis or HBV, including specific time intervals for small countries and territories (section 6.3);
7. inclusion of assessment and reporting of EMTCT validation components provided by the whole health sector, comprising the public and non-public (for example, private, faith-based) sectors (section 6.4).
8. addition of details on the decentralization of Global Validation Advisory Committee functions to the regional structures, where appropriate (section 8.1.2);

### 1.3.1. Revisions in criteria

In the second edition (2017), which still focused on HIV and syphilis and did not address HBV, WHO included criteria for certification of three levels of achievement – bronze, silver and gold – on the PTE for countries with a high burden of maternal HIV or syphilis that had demonstrated significant and sustained progress towards elimination.

In many of these countries, the high background prevalence of HIV-positive or syphilis-positive pregnant women makes it very difficult to reach the full validation targets for elimination despite sustained efforts over many years. These countries were encouraged to apply for validation in this new category, added specifically to recognize the substantial accomplishments of high-burden countries in markedly reducing their MTCT rates and the numbers of infants and children acquiring HIV and syphilis by vertical transmission each year.



Also revised in the second edition were the (i) criteria for evaluation of human rights, gender equality and community engagement, (ii) surveillance case definition of CS, which was expanded, (iii) maintenance of validation requirements and (iv) guidance on special circumstances and special populations.

This third version now moves to triple elimination by including HBV. The key changes include clarifications and new guidance on inclusion of validation criteria for EMTCT of HBV, details on maintenance of validation for countries with small numbers of HIV-, syphilis- and HBV-positive pregnant women and revision of laboratory quality standards, including external quality assurance (EQA) for maintenance of validation.

In this guidance WHO also proposes criteria for validation of three levels of achievement – bronze, silver and gold – on the PTE of HBV, as milestones for countries with a high burden of maternal HBV. As with validation of EMTCT of HIV and syphilis, key considerations consistent with international, regional and national human rights standards include equitable access to immunization services, decriminalization of HBV transmission and ensuring meaningful participation of people living with HBV in the design and delivery of programmes.

### 1.3.2. Revisions in processes

The second edition included changes, clarifications and new guidance in processes: (i) how to assess countries with small numbers of HIV- or syphilis-positive pregnant women, (ii) selection of low-performing subnational administrative units, (iii) defining and evaluating special populations, including transient, marginalized and vulnerable populations, (iv) selecting breastfeeding versus non-breastfeeding HIV MTCT targets, (v) assessment and reporting in the non-public (for example, private, faith-based) sector and (vi) data reporting on infants and young children who have been exposed to HIV and syphilis.

In addition, tools and checklists for use by validation teams in the four areas of (i) data, (ii) laboratory, (iii) programme, and (iv) human rights, gender equality and community engagement have been periodically revised and made available as online supplements to the second edition.

This third version includes changes, clarifications and further guidance on how to assess countries with small numbers of HIV-, HBV- or syphilis-positive pregnant women as well as guidance for countries on assessing and reporting on maintenance of validation.

This third version also provides step-by-step processes for meaningful engagement of women to ensure that human rights, gender equality and community engagement are well-integrated into validation assessments from planning to implementation. Meaningful engagement and participation of women living with HIV and HBV, in particular in the formulation of health laws, policies, programmes and M&E systems that affect them, results in better, more effective programmes. It also helps to ensure that women living with HIV or HBV and women infected with syphilis get the treatment they need to keep themselves well and their children free from infection.

Since the validation of the first country, Cuba, by the then newly established Global Validation Advisory Committee in 2015, 15 countries and territories have been validated for EMTCT of HIV and/or syphilis as of November 2021. Many countries are preparing to submit applications for validation or for certification on the PTE, with Botswana being the first country to successfully apply for PTE. WHO hopes that this third version will further standardize the EMTCT global guidance and catalyse regional and country progress towards achieving the validation of EMTCT of HIV, syphilis and HBV as public health concerns.



## 2. RATIONALE FOR STANDARDIZED CRITERIA AND PROCESSES FOR EMTCT OF HIV, SYPHILIS AND HBV

### 2.1. Qualifying requirements for EMTCT of HIV, syphilis and HBV

Before initiating the validation process, countries should be confident that they can meet the global minimum criteria listed below. They are advised to complete the *Checklist for country preliminary assessment of EMTCT and Path to Elimination criteria (34)* (Web Annex A), which is currently being updated to include EMTCT of HBV. Any country that feels it has met the qualifying global requirements, as well as any additional regional requirements, is encouraged to apply for validation.

- [1] National-level evidence of achievement of the EMTCT validation process indicator targets for HIV and syphilis for two consecutive calendar years and achievement and maintenance of validation impact indicator targets for at least one year, including the most recent year, within the period being assessed. However, in the case of countries applying for triple elimination, since impact indicators for EMTCT of HBV are measured only every five years (see section 3.1.3), the HBV EMTCT data demonstrating achievement should overlap the period in which the HIV and syphilis data are being assessed. Countries should ensure that indicators are clearly defined in their M&E frameworks and surveillance tools and that there are standard instructions on how to capture these data. Data to be used for validation should have been verified and reported through global reporting mechanisms, such as the UNAIDS Global AIDS Monitoring (GAM) system (35) or the Global Reporting System for Hepatitis (GRSH) (36). Indicators that are not captured in the GAM should be reported directly to the regional validation secretariat through the WHO country office.
- [2] Evidence that EMTCT of HIV, syphilis and/or HBV has been adequately addressed in the lowest-performing subnational administrative units and has been attended to in subpopulations with the lowest coverage or least access to services. The lowest-performing subnational administrative units are those known to perform poorly on relevant health indicators (for example, those with the highest disease burden, lowest levels of service coverage or an estimated MTCT rate of HIV and/or CS and an HBV rate that may not meet the global EMTCT validation targets). This helps to ensure that the validation process addresses equity in health service coverage. Where specific populations are important contributors to MTCT, for example, key and marginalized populations, assessment of EMTCT efforts for these groups should be part of the process and documented in the national and regional validation reports.

Countries are encouraged to work with the regional validation structures to determine an appropriate process for selecting the lowest performing subnational administrative unit. This is described further in section 4.3.

- [3] Existence of an adequate national monitoring and surveillance system that can capture process data from the whole health sector, comprising both the public and non-public health sectors, and can detect a majority of the cases of MTCT of HIV, syphilis and HBV. Data from this system can be used for modelling infant HIV, syphilis and HBV case numbers (see sections 3.1 and 4.1 and Annex 2). Monitoring and surveillance must be supported by a strong laboratory system.
- [4] Validation criteria must have been met in a manner consistent with basic human rights considerations and with the engagement of civil society, including women living with HIV and HBV, from the beginning of the assessment (see section 4.4).

## 2.2. Standardized criteria used in EMTCT of HIV, syphilis and HBV

The ability to achieve EMTCT of HIV, syphilis and HBV in a particular country will depend on a number of factors: political and public health commitment; the prevalence of the infections; the extent of antenatal and other SRH and MCH service coverage; available financial, human and other resources; availability of appropriate diagnosis and treatment; access to infant HBV immunizations; and whether women who belong to marginalized, vulnerable or key populations with high transmission risk can, and do, access health care. Successful national-level EMTCT of HIV, syphilis and HBV is possible only where there are sustained improvements and innovation in national and subnational public health systems and services, including updated policies and interventions consistent with WHO guidelines, adequate infrastructure, well-trained and sufficient staff, quality-assured testing services, funding to procure commodities and high-quality monitoring and surveillance systems (37, 38).

Standardized criteria for validation of EMTCT of HIV, syphilis and HBV are needed for the following reasons:

- To provide national EMTCT programmes and participating stakeholders with a clear and consistent set of measures for evaluating and monitoring programme achievements;
- To measure global progress toward EMTCT goals;
- To ensure:
  - achievement of EMTCT of HIV, syphilis and HBV in accordance with agreed upon minimum standards;
  - adequate coverage and quality of HIV, syphilis and HBV interventions (including immunizations) within MCH services, including postpartum follow-up of mother–infant pairs and exposed infants and young children through to the final diagnosis;
  - reliable national routine data collection and programme monitoring systems;
  - quality testing services, including quality-assured laboratory services;
  - the promotion of quality HBV programming integrated with HIV and syphilis EMTCT efforts;
  - gender equality and the protection of human rights of women living with HIV or HBV;
  - meaningful involvement of communities of people living with HIV and HBV, particularly women, in programme design, monitoring and implementation.

The criteria selected for measuring EMTCT of HIV, syphilis and HBV take into account the following aspects of HIV, syphilis and HBV epidemiology and available prevention interventions, treatment and care:

- HIV, syphilis and HBV infection can very often be asymptomatic in adults and infants or young children, meaning that detection is frequently delayed, and it depends on the initiative of the individual and the capacity of the health system to promote and facilitate access to and utilization of testing services for early detection.
- To date, there is no cure for HIV or chronic HBV infection. However, antiretroviral therapy (ART) and resulting viral suppression can prolong and improve the quality of life and greatly reduce the risk of transmission, including vertical transmission.
- Syphilis infection in pregnant women and their infants and young children can be easily cured with timely intramuscular injection of benzathine penicillin G. Congenital syphilis and its related ABOs can be prevented if maternal treatment with benzathine penicillin G is given as early as possible in pregnancy.

The following strategies are important components of successful elimination programmes:

- sustained interruption of vertical transmission through quality ANC and prevention services that provide timely identification and treatment of pregnant women with HIV, syphilis or HBV, their sexual partners and their exposed infants and young children;
- reduction in the number of HIV, syphilis and HBV infections among pregnant and breastfeeding women through:
  - primary prevention of new infections in women and girls of reproductive age and their sexual partners;
  - promotion of a healthy reproductive life, including prevention of unintended pregnancies, support for safer conception among women living with HIV and access to other SRH interventions;
  - control of HIV, syphilis and HBV in general and in key populations, and a decrease in prevalence of these infections;
  - access to testing and treatment for pregnant women with HIV, syphilis or HBV for their health and to prevent vertical transmission;
- infant HBV vaccination: the most important intervention for reducing vertical transmission of HBV; high coverage of universal and timely HBV birth dose vaccination and completion of the infant HBV vaccine series are critical to achieving elimination goals;
- promotion and protection of the human rights and gender equality of women living with HIV and HBV;
- greater engagement of women living with HIV and HBV in related decision-making, programming and service delivery.

### 3. INDICATORS AND TARGETS FOR VALIDATION OF EMTCT OF HIV, SYPHILIS AND HBV

Validation indicators and targets are used to monitor achievement of EMTCT over a defined period of time. The processes in place for validation assess the quality and ability of the national monitoring and surveillance systems to detect the large majority of MTCT cases, in both public and non-public health facilities. Also, there should be assessment of the capacity of national programmes and health systems to sustain and maintain the EMTCT target and indicators levels following validation and to promote transparent reporting of transmission events and use these data for programmatic improvement (for example, to assess factors contributing to transmissions).

Countries may apply for single, dual or triple elimination of HIV, syphilis or HBV validation. Countries applying for single or dual validation of EMTCT or for reaching a level on the PTE will be required to report indicator data on all three infections, even if triple validation is not sought. This is to ensure that activities promote triple elimination (Table 3.1).

**Table 3.1. Country options for applications for single, dual or triple validation of EMTCT of HIV, syphilis and HBV**

	HIV	Syphilis	HBV
Single validation	●		
		●	
			●*
Dual validation	●	●	
	●		●
		●	●
Triple validation	●	●	●

\*Single validation for HBV is done at the regional level (3). Upon special request from the regional validation secretariat or committee, single validation for HBV may be reviewed at the global level and will include reporting on HIV and syphilis.

## Box 3.1. Summary of required impact and process targets for global validation of EMTCT of HIV, syphilis and HBV

### EMTCT IMPACT TARGETS

(Must be the most recent verified data and must be achieved for at least one year)

- MTCT rate of HIV of <2% in non-breastfeeding populations OR <5% in breastfeeding populations (see section 6.2)
- a population case rate of new paediatric HIV infections due to MTCT of  $\leq 50$  cases per 100 000 live births
- a case rate of CS of  $\leq 50$  per 100 000 live births
- hepatitis B surface antigen (HBsAg) prevalence of  $\leq 0.1\%$  in the  $\leq 5$ -year-old birth cohort (and older children)<sup>a</sup>
- In countries that provide targeted timely HepB-BD, an additional impact target of HBV MTCT rate of  $\leq 2\%$  should be utilized.

### EMTCT PROCESS TARGETS

(Must be the most recent verified data and must be achieved for two consecutive years)

Maternal ANC and testing coverage

- $\geq 95\%$  ANC coverage (at least one visit) (ANC-1)
- $\geq 95\%$  coverage of HIV testing of pregnant women
- $\geq 95\%$  coverage of syphilis testing of pregnant women in ANC
- $\geq 90\%$  coverage of HBsAg antenatal testing among pregnant women.

### MATERNAL TREATMENT

- $\geq 95\%$  ART coverage of pregnant women living with HIV
- $\geq 95\%$  adequate treatment of syphilis-seropositive pregnant women (see Box 3.6)
- $\geq 90\%$  coverage with antivirals for eligible HBsAg-positive pregnant women with high viral loads (plus coverage of HBV-exposed babies with hepatitis B immune globulin (HBIG), where available).

### INFANT HBV VACCINATION

- $\geq 90\%$  coverage with three doses of HBV infant vaccinations (HepB3)<sup>b</sup>
- $\geq 90\%$  HepB timely<sup>c</sup> birth dose coverage (with universal programme) or infants at-risk<sup>d</sup> (with targeted timely HepB-BD).

<sup>a</sup> Childhood prevalence is a proxy for HBV incidence. The  $\leq 0.1\%$  HBsAg prevalence can be measured among either 5-year-olds, 1-year-olds or those ages 1–5 years, according to existing country surveillance and data collection practices. For regions and countries with a long history of high hepatitis B vaccination coverage (for example, the WHO Region of the Americas) and those that already conduct school-based serosurveys, there could be flexibility to conduct serosurveys in older children, >5 years of age.

<sup>b</sup> Generally for vaccination, a five-year period of sustainability is required to be able to measure impact via serosurveys (39).

<sup>c</sup> Timely birth dose (HepB-BD) is defined as within 24 hours of birth.

<sup>d</sup> At-risk infants are neonates of HbsAg-positive mothers.

## 3.1. Impact indicators and targets for validation of EMTCT

### 3.1.1 Impact indicators and targets for validation of EMTCT of HIV

Prior to submission of the application for validation, countries are required to have achieved and maintained for at least one year both of the following impact targets for validating EMTCT of HIV:

- an HIV MTCT rate of <5% (breastfeeding populations) OR <2% (non-breastfeeding populations) and
- a population case rate of new paediatric HIV infections due to MTCT of  $\leq 50$  per 100 000 live births (Boxes 3.2 and 3.3).

According to WHO guidance, HIV testing of infants and young children, which is the basis of infant diagnosis, is conducted with nucleic acid testing at birth, at 4–6 weeks (or as soon after as possible before two months of age) and at nine months, and final status serological testing is conducted at 18 months (or three months after the end of breastfeeding, whichever is later) (19, 21).

The case rate calculation (Box 3.2) will allow a country to estimate how close it is to the case rate of  $\leq 50$  per 100 000 live births by using prevalence data from the antenatal clinic programme and a population-level MTCT rate.

### **Box 3.2. Calculation of population case rate and MTCT rate of new HIV infections due to vertical transmission per 100 000 live births**

The population case rate due to vertical transmission per 100 000 live births is calculated as:

$$\frac{\text{(Annual new vertical HIV infections)}}{\text{annual live births}} * 100\ 000$$

The MTCT rate is calculated as:

$$\frac{\text{Annual number of new HIV infections due to vertical transmission}}{\text{annual births to women living with HIV}}$$

High HIV burden countries (countries applying for PTE; see Chapter 5) with access to modelled population-level estimates of the final MTCT rate can also calculate the case rate as follows:

$$\text{Case rate per 100 000 live births} = \% \text{ HIV prevalence in pregnant women} * \text{MTCT rate} * 100\ 000$$

This is useful when the number of births or the number of new vertical HIV infections is not readily available.

The MTCT rate measures vertical transmission (that is, the percentage of vertical infections among births to women living with HIV) and specifically measures the impact of treatment programmes for preventing vertical infections. The MTCT rate is closely related to the case rate but does not capture all of the interventions required to reach EMTCT (Box 3.3).

With effective interventions and a high level of maternal treatment coverage, the MTCT rate of HIV can be reduced to levels below 5% in breastfeeding settings and below 2% in non-breastfeeding settings. Therefore, in countries where mothers living with HIV breastfeed, a target MTCT rate of <5% at the population level at the end of breastfeeding should be achieved for validation of EMTCT of HIV. In contrast, in countries with policies discouraging women living with HIV from breastfeeding, a target MTCT rate of <2% at six weeks postpartum or later must be achieved for validation. (See section 6.2 on selecting targets for breastfeeding and non-breastfeeding populations.) In keeping with revised WHO guidelines on infant feeding in the context of HIV, the period of breastfeeding, as determined by national policy, may be up to 24 months or longer, which can be done safely only if the HIV-positive breastfeeding woman is on suppressive triple ART (40).

### Box 3.3. Rationale for use of a case rate of new paediatric HIV infections due to vertical transmission

The use of a case rate as a standard metric has three advantages:

1. Presenting the case rate as per 100 000 births allows for a measure that is comparable across different country population sizes.
2. It considers maternal seroprevalence and reflects both reduction in the number of pregnant women living with HIV (through primary prevention of HIV and reducing unintended pregnancies among women with HIV) and the effectiveness of the programme in identifying and treating pregnant women living with HIV and, thus, preventing MTCT.
3. It is a standardized measure that can be applied across all countries regardless of their starting point. For example, the reason that we do not use a percentage reduction in new child infections as a target for validation, such as the 90% reduction target used under the Global Plan (41), is that, for a very high-burden country, this can still amount to a large number of infant HIV infections, constituting a sizeable public health challenge. By contrast, a 90% reduction in a very low-burden country may be nearly impossible to achieve, but the remaining cases represent a small public health concern.
4. We calculate this case rate at the population level rather than at the programme level to ensure the outcomes of women who are not receiving services are included.

Both the annual vertical transmission case rate and the MTCT rate must be measured at the population level to reflect all pregnant women in the country and must not be limited to those women accessing the health system. The case rate and MTCT rate will likely be higher than the rates derived from health information systems ("programme rates") if access to services is limited due to high levels of stigma, geographical or financial barriers or gaps in coverage.

#### Acceptable methods of measuring impact indicators

To qualify for validation of elimination, countries need to ideally have monitoring and surveillance systems that can accurately monitor and identify all new child infections in the full population. There are two key requirements for this:

- These systems need to identify mothers who might have acquired HIV while pregnant or breastfeeding, recognizing the challenges of monitoring postpartum seroconversion among women and related new paediatric infections until at least three months after the cessation of breastfeeding. Women who seroconvert while breastfeeding have a 26% probability of transmission to their breastfeeding child (42). In countries with high ART coverage among pregnant women living with HIV, transmission due to seroconversion during pregnancy or breastfeeding periods can often account for almost half of new vertical infections. Countries that are not able to monitor postpartum transmission through breastfeeding do not meet the criteria of having adequate monitoring systems for EMTCT.
- The indicators and targets are specifically set as population-level indicators. Thus, they should be measured among the entire population of pregnant women living with HIV and not just those who attend health facilities in the public or non-public sectors, and they should include migrants and members of key populations at increased risk to HIV.



HIV transmission and case rates derived from studies (including household surveys) should be carefully reviewed to ensure that the following limitations do not apply:

- They miss women outside of the PMTCT programme.
- They miss vertical infections due to a woman seroconverting during pregnancy or breastfeeding.
- They miss children who died between birth and the study reference period.
- They miss mother–infant pairs who are lost to follow-up.
- They determine the rate before the end of breastfeeding.

Using modelled estimates of population level HIV case rates and MTCT rates can address most of these limitations (Box 3.4). Modelled estimates of HIV vertical transmission are available in most countries. However, modelled estimates may have limited reliability in countries with low overall HIV prevalence but an epidemic concentrated among key populations. This pattern is often due to stigma and discrimination against members of key populations and, thus, low uptake of services. In addition, modelled estimates are not available in most countries with populations under 250 000 people (UNAIDS does not have the capacity to support the production of estimates in these countries.)

### Box 3.4. Using and understanding Spectrum HIV estimates

Mathematical models, such as the Spectrum AIDS Impact Model, can be used to estimate the population-level transmission rate and case rate. Spectrum estimates are produced by over 170 countries (including all high HIV burden countries) with support from UNAIDS. Countries teams, usually led by the Ministry of Health or National AIDS Coordination office, as well as development partners and UNAIDS, produce the Spectrum estimates every year to estimate the impact of HIV on populations. More information on the use of Spectrum for estimating vertical transmission can be found in the annual Global AIDS Reports at <https://www.UNAIDS.org>, and the model itself, at <https://avenirhealth.org>.

Spectrum uses demographic data from 1970 through to the current year, including age-specific fertility, mortality and international migration patterns, derived from the United Nations Population Division's World Population Prospects 2019 to produce estimates of child HIV infection. Countries can update the assumptions if they have recent census or survey data that have not yet been included in World Population Prospects data.

Fertility data combined with data on HIV prevalence among pregnant women (either from antenatal programme data or from sentinel surveillance) are used to estimate the number of births to women living with HIV. Country teams enter into the model the number of pregnant women on different ART regimens, the timing of starting the specific regimen and retention on those regimens.

Breastfeeding duration determines the exposure of children during the postnatal period. The breastfeeding duration is based on household survey data for the country, or the region, for women living with HIV. The probability of transmission to the infant is applied based on the treatment regimen the mother received and when she started ART (before the pregnancy, during the pregnancy or late in the pregnancy).

The model estimates the number of children acquiring HIV during pregnancy, delivery or breastfeeding. The modelled estimates are captured at the population level and, thus, include new child infections that occurred among women not in the PMTCT programme or not attending health facilities. The Spectrum model also incorporates seroconversions among mothers during pregnancy and breastfeeding and, thus, include the resulting vertical transmissions.

The model depends heavily on the programme data entered for the number of pregnant women on ART and retained on treatment. If the programme data double-count women or include women who were not retained on ART, the estimated number of women with a suppressed viral load and risk of vertical transmission will be incorrectly estimated.

More information specifically on the child models can be found in the AIDSFree toolkit (43) at <https://www.who.int/tools/aids-free-toolkit>.

The Spectrum PMTCT stacked bar analysis can provide proportional estimates of the causes of new child HIV infections in a given country or region. It uses programmatic and modelled data to estimate new child HIV infections and attributes those infections to one of six groups: mothers who newly acquired HIV, mothers who received no antiretroviral prophylaxis or treatment, mothers who previously started ART but stopped, mothers who started ART just before delivery, mothers who started ART during pregnancy and mothers who started ART before pregnancy. It can be used to identify missed opportunities at the national and, where possible, subnational levels. The stacked bar analysis can be found at <https://aidsinfo.unaids.org>.

### 3.1.2. Impact indicator and target for validation of EMTCT of syphilis

Countries are required to have achieved and maintained for at least one year the following impact target for validating EMTCT of syphilis:

- a case rate of CS of  $\leq 50$  per 100 000 live births.

Indicators of EMTCT of syphilis use a surveillance case definition for CS rather than a clinical case definition. A surveillance case definition, which is presumptive, provides a uniform set of criteria to define a condition for public health surveillance purposes. Use of a surveillance case definition permits public health programmes to classify and count cases consistently across jurisdictions and countries. A surveillance case definition may not always be consistent with a clinical case definition, and in the case of CS it is not intended to be used by health care providers for making a clinical diagnosis or for determining treatment. Unlike with HIV, infant testing is not required for meeting the surveillance definition for CS. However, adequacy of maternal treatment is an important factor.

Depending on the clinical context, either of the two following options for the surveillance case definition of CS may be used (38):

- [1] a live birth or fetal death at  $>20$  weeks of gestation or  $>500$  g (including stillbirth) born to a woman with positive syphilis serology and without adequate syphilis treatment (4)

OR

- [2] a live birth, stillbirth or child  $<2$  years of age born to a woman with positive syphilis serology or with unknown serostatus and with laboratory and/or radiographic and/or clinical evidence of syphilis infection (regardless of the timing or adequacy of maternal treatment).

## Box 3.5. Rationale for use of the surveillance case definition for CS

CS is underreported for many reasons:

- Laboratory and radiographic testing may not be available in some countries or clinical settings.
- Congenital infections that result in spontaneous abortion or stillbirth may not be recognized or reported. Stillbirths are often not delivered in health facilities, and care providers may not realize that stillbirths are the most common adverse pregnancy outcome caused by maternal syphilis.
- To make a diagnosis, health care providers must rely on a combination of suggestive history, maternal and infant tests and clinical findings. However, these findings may be non-specific, subtle and easily overlooked; providers require training and a high level of skill to recognize them.

A series of consultations convened by WHO, as discussed in *The global elimination of congenital syphilis: rationale and strategy for action (44)*, reached consensus on a simplified global surveillance case definition for CS that is intended to promote standardization and improve the sensitivity of case reporting. While in some settings the surveillance case definition may overestimate cases, for monitoring the control and elimination of CS, the surveillance case rate is the single impact measure that is collected to address the adverse health outcomes of syphilis infection in pregnancy.

The surveillance case rate for CS is an important measure for programmes to monitor in order to identify failures of programmes to detect and treat pregnant women with syphilis early enough to prevent adverse outcomes in the fetus and infant. Even if the exposed infant is not diagnosed clinically as having CS, if either of the two surveillance definitions is met, the case should be counted.

However, an infant born to a woman with a documented history of adequate treatment for syphilis prior to and during the current pregnancy and who has no physical or laboratory evidence of reinfection (for example, increasing maternal non-treponemal titre) can be excluded from the country counts of CS cases.

### Rationale for use of live births as the denominator for CS case rate calculation

Stillbirth is the most common adverse birth outcome resulting from MTCT of syphilis. Although an estimate of the number of pregnancies would account for both stillborn infants as well as live-born infants with CS, methodologies for estimating the number of pregnancies vary widely by country and change over time. In 2015, based on expert consensus, it was decided that the denominator of live births would be used in the calculation of CS to align the infant case rate of CS with that of MTCT of HIV (38).

Laboratory and radiographic evidence consistent with a diagnosis of CS includes any of the following:

- a. demonstration by dark-field microscopy or fluorescent antibody detection of *Treponema pallidum* in the umbilical cord, placenta, nasal discharge or skin lesion material or autopsy material of a neonate or stillborn infant;
- b. analysis of cerebrospinal fluid (CSF) is reactive for the Venereal Disease Research Laboratory (VDRL) test, or elevated CSF cell count or protein;
- c. long bone radiographs suggestive of CS (for example, osteochondritis, diaphyseal osteomyelitis, periostitis);
- d. infant with a reactive non-treponemal serology titre four-fold or more than that of the mother;
- e. infant with a reactive non-treponemal serology titre less than four-fold or more than that of the mother but that remains reactive  $\geq 6$  months after delivery;
- f. infant with a reactive non-treponemal serology test of any titre AND any of the clinical signs listed below who is born to a mother with positive or unknown serology, independent of treatment (5);
- g. in settings where a non-treponemal titre is not available, an infant born to a mother with positive or unknown serology, independent of treatment, and whose 6-month examination demonstrates any of the clinical signs of CS listed below;
- h. for stillborn infants, maternal syphilis serostatus should be determined. Any case with a reactive maternal test should be considered a CS case (that is, a syphilitic stillbirth).

### Clinical signs associated with CS

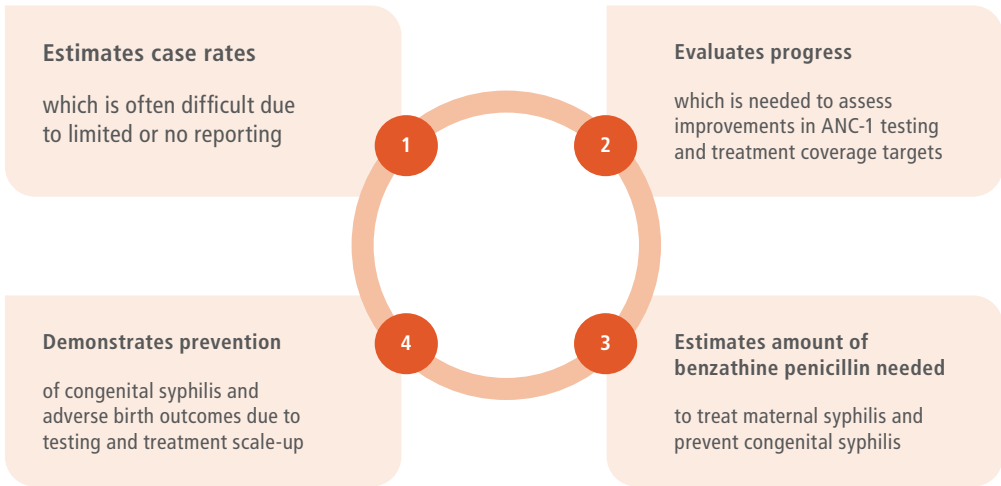
Early clinical signs that may be present in an infant with CS include non-immune hydrops, hepatosplenomegaly, rhinitis (snuffles), skin rash, pseudoparalysis of an extremity or failure to thrive or to achieve developmental milestones. An older infant or child may develop additional signs or symptoms, such as frontal bossing, notched and pegged teeth (Hutchinson teeth), clouding of the cornea, blindness, bone pain, decreased hearing or deafness, joint swelling, sabre shins and scarring of the skin around the mouth, genitals and anus. Note that these clinical signs are not applicable to the surveillance case definition (5).

### Estimating congenital syphilis case rate for validation

In 2018 WHO published the Congenital Syphilis Estimation Tool (Web Annex B) to support countries in assessing their progress toward obtaining validation of EMTCT of syphilis. It contributes to the estimation of impact indicators for CS particularly in countries without adequate syphilis data.

The tool estimates case rates, project progress, treatment doses needed and prevention of ABOs due to treatment scale-up (Fig. 3.1). Using pre-loaded estimates from the Global AIDS Monitoring system and user-selected treatment and testing parameters, the tool can inform practical steps towards reaching targets for validation of EMTCT of syphilis.

## Fig. 3.1. Key strengths of the WHO Congenital Syphilis Estimation Tool



### Box 3.6. Management of maternal syphilis

The *WHO guideline on syphilis screening and treatment for pregnant women* (45) provides updated recommendations for syphilis screening and treatment for pregnant women as well as details of the test types and recommendations for presumptive treatment without confirmatory tests.

Adequate maternal treatment is defined as at least one injection of 2.4 million units of intramuscular benzathine penicillin G at least 30 days prior to delivery.

#### WHO recommendations for treatment of maternal syphilis

In pregnant women with early syphilis, the WHO STI guideline recommends benzathine penicillin G 2.4 million units once intramuscularly. In pregnant women with late syphilis (more than two years' duration) or unknown stage of syphilis, the WHO STI guideline recommends benzathine penicillin G 2.4 million units intramuscularly once weekly for three consecutive weeks (4).

A woman with a history of past syphilis diagnosis and for whom previous syphilis treatment can be confirmed should be evaluated for risk of reinfection but does not automatically require re-treatment. However, women living in high-prevalence settings (>1%) or whose own or partner's behaviours places them at risk, or whose partners were not treated for syphilis, may warrant evaluation for reinfection later in pregnancy and in subsequent pregnancies.

Those without physical signs (for example, ulcer, unexplained rash) or laboratory evidence of syphilis (increasing non-treponemal titre) need not be classified as having current syphilis.

### 3.1.3. Impact indicators and targets for validation of EMCT of HBV

The goal of programmes for the EMCT of HBV is to ensure that MTCT of hepatitis B is prevented or reduced to a very low level.

To achieve validation of EMCT of HBV, it is necessary to demonstrate the attainment of a set of impact and programmatic targets (Boxes 3.7-3.9).

#### Box 3.7. Impact targets for validation of EMCT of HBV

Countries that provide **universal timely HepB-BD** to all neonates should have achieved the following impact target for validation of EMCT of HBV:

- $\leq 0.1\%$  HBsAg prevalence among the  $\leq 5$ -year-old birth cohort.<sup>a</sup>

Countries that provide **targeted timely HepB-BD**<sup>b</sup> should have achieved additional impact targets for validation of EMCT of HBV:<sup>c</sup>

- $\leq 0.1\%$  HBsAg prevalence among the  $\leq 5$ -year-old birth cohort<sup>a</sup>

AND

- HBV MTCT rate of  $\leq 2\%$ .

<sup>a</sup> The  $\leq 0.1\%$  HBsAg prevalence can be measured among either 5-year-olds, 1-year-olds or those ages 1–5 years, according to existing country surveillance and data collection activities. For regions and countries with a long history of high HBV vaccination coverage (for example, the WHO Region of the Americas) and that already conduct school-based serosurveys, there could be the flexibility to conduct serosurveys in older children,  $>5$  years.

<sup>b</sup> WHO does not recommend a targeted birth-dose strategy. See Box 3.9.

<sup>c</sup> Countries that provide targeted HepB-BD, or countries with a low HBsAg prevalence where vertical transmission continues to occur due to specific populations of pregnant women with a high HBsAg prevalence (for example, indigenous populations or other higher-risk vulnerable populations) are required to show both  $\leq 0.1\%$  HBsAg prevalence among  $\leq 5$ -year-old children and an MTCT rate of  $\leq 2\%$ .

## Box 3.8. Rationale for HBV impact targets

### Universal HepB-BD: HBsAg prevalence $\leq 0.1\%$ in $\leq 5$ -year-olds (and older children in certain circumstances)

In the absence of preventive interventions, MTCT of HBV at the time of, or shortly after, birth accounts for most of the global burden of chronic hepatitis B infection (CHB) because about 90% of these perinatal infections lead to chronic infection. The prevalence of HBsAg in children  $\leq 5$  years old captures new infections from both these vertical transmissions as well as early horizontal transmission routes and is, therefore, a proxy for the true incidence of CHB infection. There is flexibility for countries to include age grouping of those 1–5 years of age or 1-year-old children<sup>1</sup> to measure this indicator using representative serosurveys. It is also recognized that conducting surveys in  $\leq 5$ -year-old children may be challenging in certain countries. Since many countries already conduct school-based hepatitis B serosurveys (for example, in the WHO Western Pacific Region) or among vaccinated cohorts across a wider age range (for example, in the WHO European Region), there could be flexibility to use these existing serosurveys in children  $> 5$  years of age (as well as  $\leq 5$  years), especially if there is a long history and programmatic evidence of high infant vaccination coverage maintained over several years (for example, in the WHO Region of the Americas). This will also capture the impact on both vertical and horizontal transmission.

The GHSS of viral hepatitis proposes the elimination of viral hepatitis as a public health problem by 2030 (1, 10), defined as a 90% reduction in the incidence of new cases (95% for HBV) and a 65% reduction in deaths compared with the 2015 baseline. The GHSS 2030 targets of 95% reduction in new chronic HBV infections is equivalent to  $\leq 0.1\%$  prevalence of HBsAg in  $\leq 5$ -year-olds based on modelled outputs (global and from China) (46).

Attainment of this impact target is feasible: In 2020, for example, based on modelled data from the Center for Disease Analysis, 52 of 119 countries evaluated (47, 48) were estimated to be already at  $\leq 0.1\%$  HBsAg prevalence (one country in the WHO African Region, 13 in the Region of the Americas, 10 in the Eastern Mediterranean Region, 23 in the European Region, five in the Western Pacific Region (48-50) and are, therefore, candidates for validation of EMTCT of HBV. Based on serosurvey data, there are eight countries/territories in the Western Pacific Region and one country in the South-East Asia Region that have an HBsAg prevalence  $\leq 0.1\%$  (49).

<sup>1</sup> Testing for HBsAg in infants  $< 9$  months of age is not accurate and may result in false negatives due to transmitted maternal antibodies. Hence, WHO recommends post-vaccination serological testing (PVST) in those at least nine months of age. For the purpose of these guidelines, we have rounded the age to 1 year.

### Box 3.9. Rationale for HBV impact targets when provision of HepB-BD is targeted

#### Targeted HepB-BD: HBsAg prevalence $\leq 0.1\%$ in $\leq 5$ -year-olds and MTCT rate of $\leq 2\%$

The HBV MTCT rate of  $\leq 2\%$  is an additional target for countries that provide targeted timely Hep B-BD or for countries with a low HBsAg prevalence but where there is still continuing higher prevalence in specific subpopulations of pregnant women with high HBsAg (for example, among indigenous populations or migrant populations from high HBsAg-prevalence countries). Targeted HepB-BD is defined as providing hepatitis B birth dose only to infants born to mothers who tested positive for HBsAg.

The HBV MTCT rate measures the proportion of HBsAg-positive infants (numerator) among those infants exposed (denominator), that is, infants of HBsAg-positive mothers. Calculation of this transmission rate requires both high levels of coverage ( $>95\%$ ) of antenatal HBsAg testing to identify positive mothers and of PVST of exposed infants at 9–12 months of age to identify infants who have acquired HBV. It is recognized that some countries providing targeted timely HepB-BD that do not currently have the required data collection systems and linkages between programmes in place to capture this target will require WHO support.

The HBV MTCT target threshold of  $\leq 2\%$  was modelled on the MTCT rates from two countries, China and Thailand, who have high vaccination coverage and provide HBIG, making this an achievable target (51). Although the MTCT target of  $\leq 2\%$  was not specified in the GHSS targets for 2030 (10), it was included in the 2015 *WHO Regional Action Plan for Viral Hepatitis in the Western Pacific* (52).

## 3.2. Process indicators for validation of EMCT of HIV, syphilis and HBV

This section summarizes process indicators, also referred to as programmatic indicators, for all three conditions. HIV and syphilis process indicators for EMCT are similar and presented together in section 3.2.1. For EMCT of HBV, targets for immunization and maternal testing and treatment indicators are pertinent only in selected situations. They are detailed in section 3.2.2.

### 3.2.1. HIV and syphilis process indicators

Countries should have achieved the following process indicator targets for at least two years for validation of EMCT of HIV and/or syphilis:

- Population-level ANC-1 coverage (at least one visit) of  $\geq 95\%$
- Coverage of HIV testing among pregnant women of  $\geq 95\%$  (population-based data)
- Coverage of syphilis testing among pregnant women in ANC of  $\geq 95\%$ .



### **Box 3.10. Rationale for maternal HIV and syphilis testing coverage**

Near-universal testing for HIV and syphilis in early pregnancy is necessary to identify women living with HIV who will benefit from services to prevent MTCT. Testing remains an entry point for providing prevention, treatment and care services to women for their own health as well as for their families and to prevent MTCT. ANC attendance and testing coverage also measure the strength of MCH services. WHO recommends that all pregnant women be tested for HIV and syphilis.

### **Box 3.11. Rationale for use of the denominator of pregnant women attending ANC to calculate service coverage of syphilis testing**

While historically the HIV community has used the estimated number of live births as the denominator for calculating the proportion of pregnant women tested for HIV, the calculation of the service coverage indicators for maternal syphilis uses the number of pregnant women attending ANC-1 as the denominator, since there was no historical precedent and it was decided by expert opinion that use of ANC-1 would be a better measure of the health care delivery system performance.

#### **Indicator for HIV treatment**

- ART coverage of pregnant women living with HIV of  $\geq 95\%$ .

### **Box 3.12. Rationale for HIV treatment coverage**

The risk of MTCT of HIV can be significantly reduced through the provision of maternal ART, ideally prior to conception or as early as possible during pregnancy. All women living with HIV, including pregnant and breastfeeding women, should receive lifelong ART with treatment monitoring according to current WHO HIV treatment guidelines (1, 19).

#### **Indicator for syphilis treatment**

- Adequate treatment coverage of syphilis-seropositive pregnant women of  $\geq 95\%$ .

### Box 3.13. Rationale for syphilis treatment coverage

When treating seropositive pregnant women with at least one dose of intramuscular benzathine penicillin G, 30 days prior to delivery is the minimum time needed to prevent transmission of syphilis to the infant. Ideally, maternal treatment should be given in the first trimester, or as early as possible if the first ANC is delayed. Pregnant women with syphilis should receive treatment according to WHO syphilis treatment guidelines (4, 5).

**Note:** Countries should follow WHO-recommended processes and algorithms for HIV (2) and syphilis testing (4) among pregnant women. Newer technologies such as dual HIV/syphilis rapid diagnostic tests (RDTs) can be considered in ANC settings to improve testing coverage and reduce missed opportunities for timely treatment (25).

### 3.2.2. HBV process indicators

The timely delivery (within 24 hours of birth) of the hepatitis B vaccine birth dose should be a performance measure for all immunization programmes, and reporting and monitoring systems should be strengthened to improve the quality of data on the birth dose. To monitor accurately the delivery of doses given within 24 hours of birth, these doses should be recorded as “timely birth dose” of hepatitis B vaccine to differentiate them from birth doses given later (“late birth dose”) (27).

#### Indicators for universal timely HepB-BD provision

Countries that provide timely HepB-BD to all neonates, in addition to HepB3 vaccinations, should have achieved and maintained both of the following programmatic targets for at least two years.

- $\geq 90\%$  coverage of HepB3 vaccination
- coverage of timely HepB-BD.

**Note:** A target of  $\geq 80\%$  coverage of timely HepB-BD and HepB3 in all provinces or subnational areas can support evidence of equity of EMTCT of HBV in countries with universal timely HepB-BD, but it is not required for validation of elimination.

#### Indicators for targeted timely HepB-BD provision

Countries that provide only targeted timely HepB-BD to neonates of HBsAg-positive mothers should have achieved and maintained all four of the following programmatic targets for at least two years.

- $\geq 90\%$  coverage of HepB3 vaccination
- $\geq 90\%$  coverage of infants at risk (neonates of HbsAg-positive mothers) with targeted timely HepB-BD
- $\geq 90\%$  coverage of HBsAg antenatal testing among pregnant women
- $\geq 90\%$  coverage with antivirals for eligible HBsAg-positive pregnant women with high viral loads<sup>1</sup> (in addition to reporting coverage of HBV-exposed babies with HBIg, if available).

<sup>1</sup> High viral load is defined as an HBV DNA level  $>200\,000$  IU/mL or, where PCR testing is not available, HBeAg positivity.

## Box 3.14. Rationale for programmatic targets for EMTCT of HBV

The GHSS on viral hepatitis sets programme coverage targets not only for the most important preventive interventions ( $\geq 90\%$  of infants with three or more doses of vaccination and  $\geq 90\%$  of neonates who receive HepB-BD vaccination within 24 hours of birth), but also for diagnosis of 90% of people with HBV and ART for 90% of people with HBV who are eligible for treatment especially for countries using targeted timely HepB-BD. Global models have estimated that achievement of these programme coverage targets in vaccination, testing and treatment in the applicable birth cohort would likely result in a country achieving the impact targets.

### Universal timely HepB-BD

Achievement of  $\geq 90\%$  HBV third-dose infant vaccination coverage and  $\geq 90\%$  timely HepB-BD vaccination coverage are aligned with the GHSS global programmatic targets (10) based on modelling of the coverage required to reach the impact targets. These targets are also consistent with the Global Vaccine Action Plan ending in 2020 and the new Immunization Action Plan (53, 54). These vaccine coverage indicators are annually estimated by WHO and the United Nations Children's Fund (UNICEF), based on assessment of the Joint Reporting Form (55), as a core hepatitis indicator (56). By 2019, 51 of 95 countries (where data were available) were estimated to have  $\geq 90\%$  timely HepB-BD coverage, and 117 of 186 countries (where data were available) were estimated to have coverage of the HepB3 vaccine dose of  $\geq 90\%$ , with 75 of these countries at  $\geq 95\%$  (57). The WHO regions of the Americas and the Western Pacific have set regional timely HepB-BD and HepB3 coverage targets at  $\geq 95\%$ .

An important implementation consideration is achievement of  $\geq 80\%$  coverage of HepB3 vaccination in all provinces or subnational areas, which is consistent with the Global Vaccine Action Plan coverage goal for 2020 and equitable immunization coverage in the Immunization Agenda 2030 (53, 54). Because of heterogeneity in coverage and population distribution, a country can achieve 90% nationally but fail to reach remote populations. By ensuring 80% coverage at subnational levels, the immunization programme aims to achieve equity throughout the country.

### Targeted timely HepB-BD

If the national policy is targeted timely HepB-BD, countries are additionally required to meet coverage targets for newborn vaccination (HepB-BD and HepB3), maternal HBsAg testing and antivirals for those eligible.

For the offspring of HBsAg-positive mothers, the same  $\geq 90\%$  coverage of HepB3 and HepB-BD applies as for universal timely HepB-BD.

The  $\geq 90\%$  coverage of HBsAg testing of pregnant women is an essential programmatic target only in countries that offer targeted timely HepB-BD to infants of mothers with high risk. The high coverage serves to ensure the identification of mothers with high risk and exposed infants for interventions and is broadly consistent with the  $>95\%$  testing coverage required for EMTCT of HIV and syphilis, which lack vaccination as an intervention to prevent MTCT.

The  $\geq 90\%$  coverage of use of antivirals in eligible HBsAg-positive pregnant women with a high HBV DNA level ( $>200\,000$  IU/mL) or hepatitis B e antigen (HBeAg) positivity is an additional indicator based on the 2020 WHO PMTCT recommendations for the use of antivirals in HBsAg-positive pregnant women (58).

The treatment coverage indicator for HBV is lower than the coverage levels set for ART and syphilis treatment for HIV and syphilis elimination, respectively, because for HBV administration of vaccines (HepB-BD and infant vaccination) is the most effective intervention for PMTCT of HBV.

### 3.2.3. Other indicators and targets for EMTCT validation

In addition to careful documentation of the required indicators, countries should review the foundational requirements to support validation of EMTCT of HIV syphilis and HBV in Chapter 4. Tools and checklists to assist in conducting these assessments can be found in the online EMTCT validation tools (34).

It is important to have a robust MCH information system that can monitor other indicators – for example, HIV incidence among women of reproductive age and syphilis seropositivity among pregnant women – to gauge the effectiveness of primary prevention programmes. Other programme indicators to monitor include maternal viral load testing to monitor viral suppression, early initiation of ANC, family planning and contraceptive use and teenage pregnancy rates. In addition, programmes should monitor follow-up care and treatment of infants born to HIV-, syphilis- or HBV-seropositive women (see Annex 1) (37, 38).

Regions may identify and apply additional indicators that provide important information for the regional programme review and validation process. These additional regional indicators are not required for global validation purposes but could help provide a regional context.

# 4. FOUNDATIONAL REQUIREMENTS OF EMTCT VALIDATION

A standardized approach to providing evidence that demonstrates whether a country has achieved EMTCT of HIV, syphilis and HBV across a wide range of epidemiological and programmatic contexts goes beyond achievement of numerical targets. To achieve and maintain elimination, foundational requirements must ensure that quality diagnostics and primary prevention and treatment services are available to and accessed by pregnant and postpartum women and that there is a strong health information system that can effectively capture and monitor cases. In addition, validation requires respect and protection of human rights, gender equality and community engagement to ensure continued and unimpaired access to services for EMTCT of HIV, syphilis and HBV.

The foundational requirements are assessed by in-country exercises that are completed using the online EMTCT validation tools on data quality, laboratory services, programme and human rights, gender equality and community engagement assessments (34). Depending on the context, regional validation exercises can be completed in-person or virtually by the regional review team with national-level cooperation (see section 7.2 for the steps of the validation process). Findings from the country assessment exercises are compiled in a validation report (Web Annex C).

## 4.1. Data quality assessment

### Box 4.1. Key requirements for data quality assessment

1. Review service delivery and outcome data from the public and non-public sectors
2. Review the functionality of information systems
3. Review indicator definitions and measurement
4. Examine population-level estimates (see section 3.1.1 for further information)
5. Complete the data quality assessment and verification tool (Web Annex D).

A country should have a functional system for monitoring and surveillance that can accurately assess intervention coverage (maternal and infant testing, treatment of all those eligible, determination of infant outcomes for infants exposed to HIV and syphilis and infant HBV vaccination) and can detect the majority of cases of MTCT of HIV, syphilis, and HBV in a timely manner. It should be able to capture service delivery and outcome data from both the public and non-public health sectors and minimize sources of error. As part of meeting this standard, systems should:

- apply standardized case definitions
- have in place and implement standards for data privacy and confidentiality

- make data available for national and subnational administrative units and disaggregation for relevant subpopulations (for example, adolescents, migrants, internally displaced, immigrants, non-citizen residents and indigenous/aboriginal populations).

Similar to what is required for most other disease elimination or eradication initiatives, the monitoring and surveillance system must be in place for the country to be eligible for validation of elimination or being on the PTE of HIV, syphilis and HBV.

Data quality for each of the required global EMTCT validation impact and process indicators should be assessed by the country for completeness, accuracy, consistency and timeliness using the Data Quality Assessment and Verification tool. For example, underreporting of paediatric HIV and HBV infections and CS is a recognized problem and should be reviewed to determine if the country has a system that adequately assesses intervention coverage and can detect the great majority of cases of MTCT of HIV, syphilis and HBV in a timely manner.

Data quality standards for validation should build on existing protocols and tools used in countries and regions for EMTCT within the MCH platform and those used to strengthen health reporting systems and improve overall data quality. WHO guidance is available for impact measurement of EMTCT of HIV (59) and syphilis (38). Operational tools and a checklist to ensure a minimum standard for information systems and data quality for the impact and process indicators have been developed to assist in documenting data quality (34).

Population-level estimates of HIV (UNAIDS Spectrum estimates, where available), of CS (WHO Congenital Syphilis Estimation Tool) (Web Annex B) (60) and of HBV among pregnant women and exposed infants (from periodic surveys) should be used, where applicable, to complement country-level programme data on process and impact indicators. Population data are available through nationally representative surveys, models or other mechanisms and should be used to adjust programme data to reflect women who are not captured in health programme data, including women who do not attend ANC or otherwise do not have access to HIV, syphilis and HBV testing, where applicable (see sections 3.1.1 and 3.1.3 and Annexes 1 and 2).

## 4.2. Laboratory quality assessment

### Box 4.2. Key requirements for laboratory quality assessment

1. Summarize the quality management system
2. Review testing algorithms and strategies and assess the quality of tests and testing
3. Report on internal quality assurance and control
4. Participate in and report on EQA programme
5. Complete the laboratory quality validation assessment and verification tool (Web Annex E)

Meeting laboratory standards is critical to the validation process and review, and it draws from existing WHO guidance for laboratory audits, the laboratory quality improvement and accreditation guidance of PAHO and the International Organization for Standardization (ISO) 15189 standards.

Laboratories that contribute data to the surveillance and clinical monitoring systems should:

- [1] have a quality management system in place with sufficiently supportive leadership and governance;
- [2] ensure the quality of test kits and procedures: that tests are procured, stored and used according to international standards, such as WHO pre-qualification or other regulatory equivalent;
- [3] ensure the quality of testing: personnel performing the tests who have been trained in accordance with nationally recommended algorithms; and
- [4] have a laboratory quality assurance mechanism that is routinely and consistently applied and verified through participation in both external and internal quality assurance programmes for HIV, syphilis and HBV testing.

Laboratory quality assurance, including EQA, is a mandatory requirement for validation of EMTCT of these infections. An example of an overall internal laboratory quality assurance programme for testing is the Stepwise Laboratory Quality Improvement Process Towards Accreditation (61). An example of an EQA programme for syphilis testing is the WHO/US Centers for Disease Control and Prevention (CDC) Syphilis Serology Proficiency Programme (62). CDC also provides international assistance in EQA for HIV testing (63). Countries should consistently achieve scores >80 percentile in the EQA.

When point-of-care tests are used, the quality and diagnostic performance of the test kits should be verified in accordance with international standards set by stringent regulators such as the WHO prequalification programme. National reference laboratories should oversee and monitor procurement and storage of the tests and perform routine lot testing to verify satisfactory test kit performance. Laboratory quality management systems should include proficiency testing of clinical, laboratory and other staff to ensure the quality of testing and monitor compliance with approved algorithms.

Overall, laboratory assessment has four components.

- [1] **Laboratory quality management.** This is an assessment of the general organization and functioning of the national HIV, syphilis and HBV laboratory programme. In line with existing WHO laboratory guidance, the assessment covers leadership and governance, including the policy framework, structure and coordination, management and supervision of the laboratory network for EMTCT. It also assesses service delivery, including organization of services, roles and responsibilities, and quality control of HIV, syphilis and HBV testing among pregnant women. Other aspects assessed are supply chain management, including the availability of HIV, syphilis and HBV testing materials during pregnancy, labour and delivery and postpartum.
- [2] **Quality of tests.** This is an assessment of tests to evaluate whether they have acceptable operational characteristics as specified by international and national organizations such as WHO, UNICEF, the Global Fund to Fight AIDS, Tuberculosis and Malaria and relevant government health and regulatory agencies. HBV tests should be verified in accordance with international standards by stringent regulatory authorities or WHO's prequalification programme. This assessment includes areas such as the existence of national HIV, syphilis and HBV testing algorithms in accordance with WHO-recommended or international practices that are appropriate, as well as the choice of sufficiently performing tests that are suitable for the country's maternal and child health service settings.

- [3] **Quality of testing.** This is an assessment of staff competence in general through professional licensure as technologists or appropriate training of other health care workers as well as of staff proficiency in performing the tests used.
- [4] **Laboratory data management.** This is an assessment of the laboratory's information management. It focuses specifically on a functional laboratory information system for recording HIV, syphilis and HBV test results and processes for the timely return of results.

## 4.3. Programme assessment

### Box 4.3. Key requirements for EMTCT programme assessment

1. Review relevant national policies, plans, guidelines and protocols
2. Assess evidence that services exist in both public and non-public sectors
3. Complete the programme validation assessment and verification tool (Web Annex F), including review of low-performing administrative units and coverage of relevant subpopulations.

The elements that should be reviewed for programme assessment include national policy, plans, guidelines and protocols, which should be in line with current WHO recommendations. These guide implementation of interventions aimed at elimination of vertical transmission. Programme components pertinent to the elimination strategy include comprehensive maternal, newborn and child health services (including ANC, maternity care, postnatal care and newborn, child and adolescent health services). Services specific to EMTCT include maternal and infant HIV, syphilis and HBV testing and treatment; comprehensive care for exposed infants; and follow-up for pregnant and postpartum women with HIV, syphilis and/or HBV, their infants, young children and partners. These elements should be reviewed to verify the relevance and scope of national guidance.

To verify whether services are sufficient in scope, accessibility and quality to sustain the EMTCT targets, these elements should be reviewed during country and regional assessments using the programme assessment tool (34). Programme assessment for HBV is ideally integrated with HIV and syphilis testing, treatment and care for pregnant and postpartum women and with birth-dose vaccination of their newborns against HBV. WHO's Expanded Programme on Immunization regularly assesses national immunization programme quality, including those for HBV birth dose and infant vaccination. Priority should be placed on leveraging these existing efforts, as well as assessments of the national immunization programme, which could inform HBV immunization-related activities, avoid duplication of efforts and further develop interprogrammatic relations at the national level.

To achieve validation of EMTCT, countries must provide evidence that high-quality services for PMTCT of HIV, syphilis and HBV occur in both the public and non-public health sectors.



### 4.3.1. Assessment of low-performing units and of subpopulations with lowest coverage and access to services

Countries must also provide evidence that, even in the lowest-performing subnational administrative units and among subpopulations with the lowest coverage and the least access to services, there is a concerted effort to deliver high-quality services for PMTCT of HIV, syphilis and/or HBV to women. Lowest-performing subnational administrative units may be identified using subnational data and defined in a number of ways. Examples include regions or areas in the country (identified by national or regional validation teams or working groups):

- that perform poorly on relevant health indicators
- with the highest disease burden
- with marginalized or vulnerable populations of women and girls (see Chapter 5)
- where some or all of the impact and/or process indicators have not been met.

Countries are encouraged to work with the regional validation committee or regional validation secretariat to determine an appropriate process to identify the lowest-performing subnational administrative units. To be eligible for validation, a country does not have to meet elimination targets in the lowest performing subnational units, but there must be evidence that performance in subnational units has been reviewed and that substantial efforts are being made to address and improve service delivery in these units. These efforts should include outreach to impoverished, remote or marginalized communities and evidence that PMTCT services are being offered, accessed and have achieved success that can be maintained.

## 4.4. Human rights, gender equality and community engagement assessment

### Box 4.4. Key requirements for human rights, gender equality and community engagement assessment

1. Desk review of laws, policies and reports
2. Interviews with key stakeholders
3. Organize independent consultation with women using relevant services
4. Organize multistakeholder consultation and facilitated dialogue to review the findings
5. Complete validation assessment and verification tool (Web Annex G) for human rights, gender equality and community engagement.

A foundational requirement for validation of a country for eliminating vertical transmission of HIV, syphilis and HBV is that the programme and interventions must have been implemented in a manner that is consistent with international, regional and national standards on:

- human rights

- gender equality
- community engagement.

The concepts of no one left behind and health equity are central to the WHO global health sector strategies and the broader WHO mission (10-12). Prevention of vertical transmission of HBV, new to this guidance, also values the principles of human rights, gender equality and community engagement as fundamental to countries' ability to effectively address viral hepatitis (64, 65).

#### 4.4.1. Human rights

Governments have an obligation to respect, protect and fulfil human rights, including sexual and reproductive health and rights in the provision of health care, including programmes and interventions to prevent vertical transmission of HIV, syphilis and HBV. Among the basic human rights (66) that must be respected in this context are the rights to:

- equality and non-discrimination
- confidentiality
- information
- informed consent
- have a family and to decide freely the number, spacing and timing of children
- make decisions concerning reproduction free of discrimination, coercion and violence
- bodily integrity
- autonomy
- health
- justice
- freedom from violence.<sup>1</sup>

Despite advances in prevention science, including efforts to prevent vertical transmission of HIV, syphilis and HBV, women, particularly women living with HIV, continue to face a range of obstacles to achieving their right to the highest attainable standard of health and to fully realizing their sexual and reproductive health and rights, including in health care settings. Stigma from health care workers based on HIV or HBV status, gender or belonging to a key population (who are often criminalized) is at the root of many of these obstacles and manifests itself in the form of discrimination and other human rights violations.

Violations of human rights in health care settings can have a damaging impact on an individual woman's health and are counterproductive to public health goals and efforts to prevent vertically transmitted infections. There is global consensus that a human rights-based approach is essential to the success of efforts to end vertical transmission of HIV, syphilis and HBV and to ensure that all women can enjoy their right to the highest standard of health, including their sexual and reproductive health and rights (67).

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<sup>1</sup> This list is not exhaustive; it is possible that the validation processes may identify other human rights that ought to be addressed.

### 4.4.2. Gender equality

Gender inequality and harmful gender norms and practices in a country can obstruct women's exercise of their rights, including their sexual and reproductive health and rights. In the context of preventing vertical transmission of HIV, syphilis and HBV, promoting gender equality is critical, as it influences the opportunities that women and girls have to access relevant information and services, to make autonomous decisions about their sexuality and reproduction and to protect themselves from STIs (68).

The human rights, gender equality and community engagement assessment and verification tool employs three key markers to determine how well countries are promoting gender equality. These are efforts to prevent and respond to gender-based violence, to ensure the meaningful engagement of women in decision-making and to promote the right to equality and non-discrimination for all women.

### 4.4.3. Community engagement

Meaningful engagement, especially of the women and communities most affected, is a right and essential to achieving public health goals (69). In this context, "communities" refers to all groups of women with shared interests using these services, including women living with HIV or HBV, those affected by syphilis and those from key and other populations who are marginalized because of intersecting inequalities. These inequalities may include, but are not limited to, socio-economic status, migration status, sexuality, gender identity, disability, race or ethnicity. Networks of people living with HIV have successfully campaigned for governments and United Nations (UN) agencies to commit to the principle of meaningful involvement to realize their right to participate in decision-making processes that affect their lives.

In the context of programmes to prevent vertical transmission of HIV, syphilis and HBV, it is essential that all women are involved in all aspects of EMTCT – from developing policies, designing and delivering services to monitoring programmes and policies and advocating improvements. Assuring this involvement includes involving women in the decision-making spaces and processes of validating countries in their efforts to end vertical transmission of HIV, syphilis and HBV.

### 4.4.4. Using the human rights, gender equality and community engagement tool

The human rights, gender equality and community engagement assessment tool (Web Annex G) is designed to gather data that will help validation committees to determine whether the country's interventions and programmes to end vertical transmission of HIV, syphilis and HBV have been implemented in a way that meets the human rights, community engagement and gender equality requirements.

The assessment must include an examination of existing laws, policies and services and of their implementation. For each issue, specific questions address both policy and practice, and together they aim to answer three overarching questions:

- Do the programmes and interventions respect, promote and fulfil human rights?
- Do the programmes and interventions promote gender equality?
- Do the programmes and interventions meaningfully engage women with HIV, syphilis or HBV?

The validation assessment should be carried out by people with expertise in the relevant areas and must include representatives of networks of women living with HIV and other human rights and gender experts (Box 4.5).

### **Box 4.5. Who should be engaged in the assessment?**

- Legal and policy experts in human rights, particularly sexual and reproductive health and rights, gender equality and health
- Women with experience using the relevant health services
- Members of communities of women living with HIV and HBV and of other communities of women, depending on the country's context.

The questions in the tool are qualitative in nature, and the data collection and assessment process necessarily involve consultations with a range of stakeholders, in particular with communities of women who use the relevant health services. Women who use the programmes know how current laws and policies affect their lives and how these may be put into practice in health care settings, and they can both identify challenges as well as propose potential solutions to improve the programme and help the country achieve validation.

The networks and organizations that represent communities of women living with or affected by HIV, syphilis and HBV must also have the opportunity to monitor policy and practice relating to preventing vertical transmission and to report on any gaps in implementation or concerns regarding the promotion and protection of human rights, gender equality and community engagement. In countries that seek only syphilis or HBV validation but do not have networks or organizations that represent either of these two affected populations, opportunities should be provided for an organized group of women that represents at least one affected community to monitor and participate as previously described.

The evidence and information needed for the validation assessment should be gathered and analysed in a consultative manner, involving all key stakeholders. This serves as an opportunity for dialogue between communities and governments on how to improve health care services and ensure that women enjoy their right to the highest attainable standard of health.

The process of gathering and analysing the information is spelled out in detail in the tool (Web Annex G) and in the accompanying analysis guide (Web Annex H). In summary, it includes:

- desk review of laws, policies and reports
- interviews with identified key stakeholders
- independent consultation with women who use the relevant services
- multi-stakeholder consultation and facilitated dialogue to review the findings.

Throughout the data gathering and analysis processes, the confidentiality and safety of participants, and particularly women's safety, must be the first consideration and priority.

**Table 4.1. Key steps for human rights, gender equality and community engagement in the validation assessment**

Phase	Roles and responsibilities	Responsible entity
1	Ensure that validation structures include representatives of networks of women living with HIV and HBV.	<b>National validation structures</b>
	Review and understand the human rights, community engagement and gender equality criteria and tool.	
	Select an independent focal point/consultant with human rights, community engagement and gender expertise to support the process.	
	Identify and engage with networks of women living with HIV or HBV and other relevant community organizations and provide any technical/financial support needed for their engagement from the beginning of the validation process.	
2	Review and understand the human rights, community engagement and gender equality criteria, methodology and tool.	<b>Independent consultant or focal point</b>
	Conduct a literature/desk review to respond to questions in all sections.	
	Develop and implement a plan to consult/interview relevant stakeholders, including government officials and officers, service providers, civil society organizations, human rights and gender experts and communities of women.	
	Coordinate with networks of women living with HIV, HBV and other women's organizations to support them in organizing and facilitating an independent consultation with women who use services in order to prepare independent feedback for the tool.	
	Triangulate and analyse data to draft a report that includes the different perspectives as part of the assessment.	
3	Organize a multi-stakeholder forum to review key findings of the assessment.	<b>National validation structures</b>
	Support facilitation of a dialogue to review findings and build consensus on gaps and possible solutions in readiness for validation.	
	Follow up on recommended actions from the multistakeholder forum.	
	Provide feedback to all stakeholders consulted, including networks and organizations of women	

## 5. PATH TO ELIMINATION: RECOGNIZING PROGRESS TOWARDS EMTCT IN COUNTRIES WITH A HIGH BURDEN OF HIV, SYPHILIS AND HBV

Most countries in sub-Saharan Africa have reported a maternal HIV seroprevalence of  $>2\%$  and a maternal syphilis seroprevalence of  $>1\%$ . Many countries in East and Southern Africa have maternal HIV prevalence of  $>15\%$ , with some as high as  $25\%$ . Even if the MTCT rate of  $<5\%$  is reached, high HIV burden countries have been unable to achieve EMTCT validation due to their elevated HIV prevalence among pregnant women, which results in a case rate of new infections in children that remains above the threshold of 50 per 100 000 live births. Similarly, countries with a high syphilis burden (maternal syphilis  $>1\%$ ) are unable to reach elimination thresholds, even if they achieve  $95\%$  maternal treatment, as each untreated pregnancy results in a surveillance case of CS. Countries in these situations that are making progress toward elimination can obtain certification of their progress through the Path to Elimination (PTE) and its three levels of achievement – bronze, silver and gold (Box 5.1).

### Box 5.1. Country prevalence requirements for eligibility to apply for PTE

- Maternal HIV prevalence  $>2\%$
- Maternal syphilis prevalence  $>1\%$
- HBsAg prevalence  $>1\%$  among  $\leq 5$ -year-olds and/or general population prevalence  $>5\%$ .

There is also considerable global heterogeneity in the epidemiology of HBV and the implementation and coverage of key prevention interventions, especially HBV vaccination. Since the HBV vaccine first became available almost 30 years ago, uptake of both birth-dose and infant HBV vaccination has varied because of resource constraints and varying political will and/or community awareness. Many high-burden countries (HBsAg prevalence  $>1\%$  among  $\leq 5$ -year-olds and/or general population prevalence  $>5\%$ ) have made considerable progress in the scale-up of infant HBV vaccination, with or without birth-dose vaccination. However, there are also many countries with high HBV burden that face major challenges in achieving and validating the 2030 goal of  $\leq 0.1\%$  HBsAg prevalence in  $\leq 5$ -year-olds.

Table 5.1 shows the impact and process indicators for achieving each of the three tiers (or levels) on the PTE. These indicators mirror those for full EMTCT validation. As countries advance from bronze to gold, targets for achievement of each tier reflect higher service coverage (process indicators) and progressively lower case rates (impact indicators).

A country seeking certification on the PTE for HIV and syphilis follows the same procedure as a country requesting validation of EMTCT. See Chapter 7 and the *Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis (14)* for details on the validation process.

**Table 5.1. Prevalence requirements, indicators and targets for certification on the PTE of MTCT of HIV, syphilis, and/or HBV**

Tier	Infection	Impact indicators for at least one year	Process/programme indicators for at least two years
Bronze tier	HIV	<ul style="list-style-type: none"> <li>MTCT of HIV rate of &lt;2% in non-breastfeeding populations OR &lt;5% in breastfeeding populations</li> <li>A case rate of new paediatric HIV infections due to MTCT of ≤750 cases per 100 000 live births</li> </ul>	<ul style="list-style-type: none"> <li>≥90% ANC coverage (at least one visit) (ANC-1)</li> <li>≥90% HIV testing coverage in pregnant women</li> <li>≥90% ART coverage in pregnant women living with HIV</li> </ul>
	Syphilis	<ul style="list-style-type: none"> <li>A case rate of CS of ≤750 per 100 000 live births</li> </ul>	<ul style="list-style-type: none"> <li>≥90% ANC coverage (at least one visit) (ANC-1)</li> <li>≥90% syphilis testing coverage in pregnant women attending ANC</li> <li>≥90% treatment coverage in syphilis-seropositive pregnant women</li> </ul>
	HBV <sup>b</sup>	<ul style="list-style-type: none"> <li>Not required</li> </ul>	<ul style="list-style-type: none"> <li>≥90% coverage of HepB3 infant vaccination</li> <li>Implementation of universal timely HepB-BD policy</li> </ul>
Silver tier	HIV	<ul style="list-style-type: none"> <li>MTCT of HIV rate of &lt;2% in non-breastfeeding populations OR &lt;5% in breastfeeding populations</li> <li>A case rate of new paediatric HIV infections due to MTCT of ≤500 cases per 100 000 live births</li> </ul>	<ul style="list-style-type: none"> <li>≥90% ANC coverage (at least one visit) (ANC-1)</li> <li>≥90% HIV testing coverage in pregnant women</li> <li>≥90% ART coverage in pregnant women living with HIV</li> </ul>
	Syphilis	<ul style="list-style-type: none"> <li>A case rate of CS of ≤500 per 100 000 live births</li> </ul>	<ul style="list-style-type: none"> <li>≥90% ANC coverage (at least one visit) (ANC-1)</li> <li>≥90% syphilis testing coverage in pregnant women attending ANC</li> <li>≥90% treatment coverage of syphilis-seropositive pregnant women</li> </ul>
	HBV <sup>b</sup>	<ul style="list-style-type: none"> <li>Not required</li> </ul>	<ul style="list-style-type: none"> <li>≥90% coverage of HepB3 infant vaccination</li> <li>≥50% coverage of universal timely HepB-BD</li> <li>Availability of antenatal HBsAg testing in the public sector</li> </ul>

Table continued on next page

Tier	Infection	Impact indicators for at least one year	Process/programme indicators for at least two years
Gold tier	HIV	<ul style="list-style-type: none"> <li>• MTCT of HIV rate of &lt;2% in non-breastfeeding populations OR &lt;5% in breastfeeding populations</li> <li>• A case rate of new paediatric HIV infections due to MTCT of ≤250 cases per 100 000 live births</li> </ul>	<ul style="list-style-type: none"> <li>• ≥95% ANC coverage (at least one visit) (ANC-1)</li> <li>• ≥95% HIV testing coverage in pregnant women</li> <li>• ≥95% ART coverage in pregnant women living with HIV</li> </ul>
	Syphilis	<ul style="list-style-type: none"> <li>• A case rate of CS of ≤250 per 100 000 live births</li> </ul>	<ul style="list-style-type: none"> <li>• ≥95% ANC coverage (at least one visit) (ANC-1)</li> <li>• ≥95% HIV testing coverage in pregnant women attending ANC</li> <li>• ≥95% treatment coverage for syphilis-seropositive pregnant women</li> </ul>
	HBV <sup>a</sup>	<ul style="list-style-type: none"> <li>• Not required</li> </ul>	<ul style="list-style-type: none"> <li>• ≥90% coverage of HepB3 infant vaccination</li> <li>• ≥90% coverage of universal timely HepB-BD</li> <li>• &gt;30% coverage of antenatal HBsAg testing</li> </ul>

Countries are required to achieve high coverage at the district level, as follows: ≥90% coverage in all districts for HepB3 in all tiers and ≥80% coverage in all districts for HepB-BD in gold tier and ≥50% for targeted timely HepB-BD in all districts for the silver tier.

## 5.1. Rationale for selecting criteria for the PTE

### 5.1.1. HIV and syphilis

Many high-burden countries have made substantial progress in preventing new infections of HIV, syphilis and HBV in children. In some countries new cases of HIV in children have been reduced by more than 80% over the past few years, and several high-burden countries have achieved HIV MTCT rates of <5% (70). However, due to the successful scale-up of ART for women living with HIV, resulting in improved health and fertility in women living with HIV, and also due to continued new maternal infections, prevalence rates among pregnant women are likely to remain stable in the near term. Similarly, high prevalence rates of syphilis among pregnant women preclude achievement of EMTCT CS case rate targets in some countries despite high maternal service coverage of syphilis testing and treatment.

WHO, in collaboration with the Africa Regional Validation Secretariat and with the input of the Global Validation Advisory Committee, coordinated development of a set of criteria for recognition of the impressive achievements of high-burden countries as they progress along the PTE. This approach and the defining criteria were developed over a series of consultations with multiple countries in the WHO African Region, which took place in late 2016 and early 2017. Countries selected a three-tier system that recognizes stages of progress on the PTE. Each tier requires progressively increasing levels of service coverage for pregnant women and progressively lower HIV and syphilis case rates of new infections in children per 100 000 live births. Moving to a higher tier brings a country closer to elimination (Table 5.1). Table 5.2 shows scenarios that, when achieved, qualify as PTE in countries with high ANC prevalence but which have strong programmes to reduce MTCT rates. These same principles apply to the PTE milestones for HBV.



**Table 5.2. Scenarios of prevalence, indicators and targets for certification on the PTE of MTCT of HIV**

	HIV prevalence in ANC	HIV MTCT rate	Expected HIV infant case rate/100 000	Applicable tier
<b>Certification of PTE:</b> for countries with strong programmes but high ANC prevalence, which makes it virtually impossible to achieve the case rate criterion for validation	5.0%	<5.0	<250	Gold
	7.0%	<5.0	<350	Silver
	9.0%	<5.0	<450	Silver
	11.0%	<5.0	<550	Bronze
	15.0%	<5.0	<750	Bronze
<b>Validation of EMTCT:</b> for countries with indicator thresholds consistent with other public health control programmes and low enough to affirm elimination of new paediatric infections resulting from MTCT as a "public health problem"	1.0%	<5.0	50	Not applicable
	2.0%	2.5	50	
	5.0%	1.0	50	

### 5.1.2. HBV

The PTE for HBV seeks to recognize high burden countries that have implemented key HBV vaccination interventions but may not yet be able to achieve the elimination impact goal of  $\leq 0.1\%$  HBsAg prevalence in  $\leq 5$ -year-olds. This may be because of a current high HBsAg prevalence. Countries with an estimated HBsAg prevalence in 5-year-olds of  $\geq 1\%$  and/or general population prevalence exceeding 5% can be considered eligible for PTE (Table 5.1).

As noted, there is considerable heterogeneity in the epidemiology of HBV across different countries and in the implementation and coverage of key interventions for PMTCT, especially timely HepB-BD and infant vaccination interventions. Many high-burden countries have made considerable progress in scaling up infant hepatitis B vaccination for PMTCT of HBV, with or without HepB-BD vaccination. Hepatitis B vaccination is highly efficient in preventing MTCT of HBV and will result in countries being able to achieve elimination in future years. Of note, there is the opportunity for low-income countries to access funding for introduction of timely HepB-BD through the investment strategy of Gavi, the Vaccine Alliance (71).

The WHO African Region, for example, is characterized by high endemicity of HBV infection, suboptimal coverage of routine infant vaccination, low coverage of timely HepB-BD and limited availability of diagnostics and treatment. In addition, as recently as 2019, about 60% of pregnant

women delivered in a health care facility, compounding challenges in delivering the timely HepB-BD (72). A number of Pacific Island countries of the WHO Western Pacific Region also have a high HBV prevalence, a general lack of health infrastructure, and supply chain issues, including difficulties with cold chain management for effective vaccine delivery.

If a country uses a targeted timely HepB-BD strategy and qualifies for the PTE, there are national and district-level requirements for high coverage that must be met:

- $\geq 80\%$  coverage in all districts for HepB3 in all tiers
- $\geq 80\%$  coverage in all districts for timely HepB-BD in the gold tier
- $\geq 50\%$  for targeted timely HepB-BD in all districts for the silver tier.

An overview of the approach for HBV can be found in *Interim guidance for country validation of viral hepatitis elimination* (3). A country seeking certification as being on the PTE for HBV will have the opportunity to be recognized for their HBV EMTCT efforts to date and participate in a consultative process to further develop the national strategy to achieve elimination in the coming years. While validation of elimination is documented at the global level, recognition of PTE for HBV is completed only at the regional level, unless the region specifically requires that this be raised to the global level for higher-level advocacy to accelerate national response.

## Box 5.2. Rationale for the PTE for HBV

A key principle is that each tier of the PTE represents a milestone in progress towards elimination, where validation of elimination is the ultimate goal. The indicators for PTE reflect the critical role of timely HepB-BD and infant vaccination in eliminating MTCT of HBV.

- The **bronze** level recognizes that a country has implemented a universal timely HepB-BD policy as a first critical step towards EMTCT.
- The **silver** level of timely HepB-BD coverage of  $\geq 50\%$  recognizes the attainment of the 2020 milestone target for BD coverage in the GHSS (10).
- The **gold** level of timely HepB-BD coverage of  $\geq 90\%$  recognizes the attainment of the 2030 service coverage target for timely HepB-BD coverage in the GHSS (10); it further introduces the importance of HBsAg testing in pregnant women within the triple elimination framework.

The cost of measurement of the impact indicator HBsAg prevalence in  $\leq 5$ -year-olds through a national survey could be an impediment to monitoring progress towards elimination. Therefore, the PTE criteria require only achieving programmatic coverage targets. Other programmatic indicators are not included in the PTE process to maintain the simplicity of using routinely measured indicators that can be captured in most countries.

# 6. GUIDANCE ON SPECIAL POPULATIONS AND SPECIAL CIRCUMSTANCES

## 6.1. Special populations

Most countries face challenges with delivery of health care services to members of key and vulnerable populations (including migrants, the internally displaced, immigrants, non-citizen residents, indigenous/aboriginal/First Nation people, members of other mobile populations and adolescent girls and young women). Women and their partners belonging to these groups may be at higher risk for HIV, syphilis and HBV and may have relatively poorer access to health care. Vulnerable populations such as these may be disproportionately represented among pregnant women with late or no ANC. Follow-up in health facilities or the community, including contact tracing, may be challenging, as some women may leave the country during the pregnancy or just after birth.

The national validation report should identify these vulnerable populations; describe the relevance of these populations to the epidemiology of HIV, syphilis and HBV in the country; describe policies related to EMTCT services for members of these populations who are pregnant or breastfeeding; and describe how the country programme addresses health care access for them. In addition to migrants, countries should report on their undocumented and non-citizen immigrants/residents in terms of access to health care services. In principle, WHO recognizes that countries have a duty to promote and protect the health of all populations living within their borders, including legal and illegal migrants, displaced persons and other vulnerable populations. Rates of service coverage may be lower in these populations; there should be concerted and demonstrated efforts to address gaps and improve outreach. Similar to the principle of providing equitable services in lower-performing subnational units, the country should give evidence of equitable EMTCT services provided to mobile, marginalized and vulnerable populations.

## 6.2. Selecting targets for EMTCT of HIV in breastfeeding and non-breastfeeding populations

The target HIV MTCT rates for any country applying for validation should be based on that country's national policy for breastfeeding versus non-breastfeeding among mothers living with HIV in order to account for the longer period of exposure to HIV transmission in breastfed infants and young children (Box 6.1). The national validation report should include information on the national breastfeeding policies and protocols, including dates and extent of implementation. The report on ANC, peri- and postpartum programme evaluation should include what choices women are given and if they are counselled on the risks and benefits of breastfeeding with and without ART, and how their autonomy and freedom of choice are ensured.

### Box 6.1. Targets depending on country breastfeeding policies

- Non-breastfeeding policy countries: MTCT rate <2%
- Breastfeeding policy countries: MTCT rate <5%.

The national validation report should provide testing data for infants and HIV-exposed children at 6–8 weeks of age and at the end of 18 months (or three months after the end of breastfeeding, if longer than 18 months). This schedule should ensure that all possible cases of infants and young children who acquire HIV are captured and recorded. Countries that are designated as non-breastfeeding must still consider each mother's choice of infant and young child feeding practice and apply the appropriate clinical follow-up.

The additional and most recent verified data to be provided are as follows:

- 1) For non-breastfed infants and young children, data from direct programme reporting or modelled/estimated data to validate the 6-week and final status (that is, available 18-month antibody data).
- 2) For breastfed infants and young children, a combination of programme data and modelled or estimated data can be used, which should include EID testing (for example, polymerase chain reaction (PCR) testing at birth or at six weeks) and final antibody testing at 18 months (or three months after the end of breastfeeding).


## 6.3. Countries with small numbers of HIV-, syphilis- and HBV-positive pregnant women

For countries defined as having small populations, such as certain Small Island Developing States,<sup>1</sup> and/or countries with small numbers of pregnant women with HIV, syphilis and HBV per year, validation structures may elect to use alternative strategies to assess the HIV, syphilis and HBV impact and process indicators. When there are cases of MTCT of HIV, syphilis and HBV, de-identified data should be available to assess the circumstances surrounding the case(s).

### Validation in countries with small populations or small numbers of pregnant women with HIV or syphilis

Countries with small numbers of HIV- and syphilis-positive pregnant women may pool data for the four most recent consecutive years to provide more stable estimates of the impact and process indicators. Table 6.1 describes the effect of pooling of data on MTCT rates and population case rates in countries with small populations. However, even with pooling of data, these countries/territories may not meet the impact targets for elimination, despite having strong EMTCT programmes. A process has been developed to flexibly assess whether these countries can be validated for EMTCT of HIV and syphilis, as in the situations below. Regional validation structures should evaluate and verify this information during the country mission.

<sup>1</sup> There is no formal definition of Small Island Development States, but there is a list which includes countries that participate in the main political group, Alliance of Small Island States: <https://www.aosis.org/>.

- 1. Cases determined not to be a failure of the programme or services.** If cases are determined at the regional and global reviews not to result from failure of the programme or services, they may be removed from the numerator, with subsequent recalculation of screening and treatment coverage and case rates. Criteria for assessing these cases are as follows.
    - At the discretion of the regional validation committee and, ultimately, the Global Validation Advisory Committee, individual case reports can be reviewed to assess if there are gaps in utilization of ANC services, including maternal testing or treatment, determination of infant outcomes and social issues affecting access or uptake. When infant infection has occurred, it should be determined whether the programme and services had provided all appropriate measures to prevent infant infection.
    - If it is documented that, despite application of all appropriate PMTCT measures, a transmission still occurred, the regional validation committee and the Global Validation Advisory Committee may decide not to count the case against a country during evaluation of achievement of EMTCT.
    - In situations of recorded infant transmission, two members of the Global Validation Advisory Committee will be asked to perform an independent review of the case(s) and present each case review to the Global Validation Advisory Committee for discussion and final decision.
  - 2. Countries with a small number of cases.** Validation reports should include a section describing how many infants and young children were exposed and followed-up, providing their final outcome status and case studies, while maintaining data anonymity. Web Annex I provides a sample case study form. These data should be provided to and confirmed by national and regional validation teams or working groups.
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**Table 6.1. Scenarios for HIV MTCT rate and infant case rate of HIV and CS in countries with small populations of pregnant women**

HIV MTCT rate for small countries				Population case rate of new infant and young child HIV infections due to MTCT, or infant and young child case rate for syphilis for small countries			
Number of pregnant women with HIV in one year	Number of infant cases in one year	Annual MTCT rate (%)	4-year pooled MTCT rate (%) <sup>*</sup>	Number of pregnant women in one year	Number of infant cases (HIV or syphilis) in one year	1-year infant case rate/100 000 LB	4-year pooled infant case rate <sup>*</sup>
10	1	10%	2.5	500	1	200	50
10	2	20%	5	600	1	167	42
20	1	5%	1.3	700	1	143	36
20	2	10%	2.5	1000	2	200	50
30	1	3%	0.8	1500	2	133	33
30	2	7%	1.7	2000	2	100	25
40	2	5%	1.3	2500	3	120	30
40	3	8%	1.9	3000	3	100	25
50	2	4%	1.0	3500	3	86	21
50	3	6%	1.5	4000	4	100	25

LB=live births; MTCT=mother-to-child transmission

<sup>\*</sup>Pooled MTCT rate calculations and pooled infant case rate calculations assume no additional infant cases are identified other than those presented for the 1-year period. These 4-year pooled estimates are calculated by multiplying the value in the first column (for example, number of pregnant women with HIV/year or number of live births/year) of each table by four and recalculating the MTCT rate and infant case rate.

### Validation in countries with small populations or small numbers of pregnant women with HBV

Countries with a small population size may have a birth cohort insufficient to be able to measure prevalence accurately through a serosurvey. In such instances an appropriate finite population correction factor is utilized for assessment of the main impact target (see section 3.1.3), and an additional impact target for the MTCT rate of  $\leq 2\%$ <sup>1</sup> can be utilized.<sup>2</sup>

<sup>1</sup> Achieving this rate will require high coverage levels of antenatal HBsAg testing coverage (that is,  $>80\%$ ) to be valid.

<sup>2</sup> Countries with targeted birth dose strategies are required to show both  $\leq 0.1\%$  HBsAg prevalence among  $\leq 5$ -year-old children and an MTCT rate of  $\leq 2\%$ .

## 6.4. Assessing ANC EMTCT service coverage in non-public settings

In addition to public sector health services, PMTCT services may be provided by private, nongovernmental organizations, faith-based organizations, non-health sector institutions, such as health services in correctional facilities and some other non-public entities. Ideally, national programme monitoring systems should include data from the non-public sectors. Thus, public and non-public data should not be separately reported for achievement of validation criteria. However, there should be evidence in the report that non-public data are included.

In some countries, it is also common for pregnant women to seek ANC and/or delivery care in both the public and non-public sectors. While it is often harder to capture data outside of the public sector, or to properly account for women who utilize services in both the public and non-public sectors (mixed usage), it is expected that data on the performance of these service indicators be provided to validation teams for assessment, if available. Evaluation of EMTCT services in the non-public sector should be part of the programme assessment. This includes services such as ANC, HIV, syphilis and HBV testing, prevention and treatment. Evaluation should assess access, delivery and payment and how it compares with the public sector.



# 7. THE VALIDATION PROCESS

Achieving EMTCT of HIV, syphilis and HBV requires a public health approach based on strengthening the health system to provide the maximum health benefit within the available resources while realizing rights to health, participation and gender equality. The validation approach sets the standards for quality and accessible interventions and services, with a focus on integration, person-centred care and community engagement within each country's context.

Before initiating the EMTCT validation process (or certification on the PTE), countries should be reasonably confident that they have met the global minimum criteria (see Chapters 3 and 4) as well as any specific regional requirements. Countries may also embark on pre-assessments, utilizing the *Checklist for country preliminary assessment of EMTCT of HIV, syphilis and HBV and Path to Elimination criteria* (Web Annex A) (34) to better assess their status, what specific issues need attention and whether to move forward with the certification or validation process.

This chapter summarizes the various structures and processes governing EMTCT validation. As a supplement to this publication, the *Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis* (14) provides further detail on the standardized structures and processes used in the country review and validation process for EMTCT of HIV and syphilis. The governance document comprehensively covers operations, detailed steps in the validation process, roles and responsibilities at each level of validation, suggested membership on validation committees, terms of reference for each committee, required components of the national and regional validation reports and other pertinent information to assist in the validation process.

For additional detail on processes and operations for validation of EMTCT of HBV, the *Interim guidance for country validation of viral hepatitis elimination* (3) serves as the primary reference for EMTCT of HBV as part of validation of triple elimination.

## 7.1. Validation structures

Validation of EMTCT of HIV, syphilis and HBV occurs at national, regional and global levels. Each level is composed of secretariats, committees and teams, which function together with relevant partners to complete key activities for validation of EMTCT (Fig. 7.1).

- **Validation secretariats** have the overall responsibility for providing technical support for validation of country achievement of EMTCT of HIV, syphilis and/or HBV and PTE criteria, and they serve as the focal points for communication between the validation structures and key partners.
- **Validation committees or task forces** are composed of independent experts engaged in efforts to achieve EMTCT, including civil society and communities of women living with HIV. Committees review, evaluate and endorse the evidence that a country has met or maintained the minimum global criteria for validation of EMTCT.
- **Validation teams/working groups**, which may be assembled at the national or regional levels, undertake a mission to collect data or verify the information contained in the country report. These teams use the set of standardized EMTCT assessment tools for data, laboratory, programme and human rights, gender equality and community engagement.



### 7.1.1. Key partners in validation of EMTCT

Guiding principles for the process of validation of EMTCT of HIV, syphilis and HBV or progress on the PTE involve aligning the process with relevant national and global strategies and engaging relevant stakeholders in a multisectoral approach. Relevant United Nations partners, such as UNAIDS, UNICEF and UNFPA, and other international and national implementing partners that are involved in the efforts to achieve EMTCT of HIV, syphilis and HBV may also participate in the national, regional and global validation structures. Importantly, the country's health ministry initiates the validation work at the country level and leads the National Validation Committee.

**Civil society and communities of women living with HIV and HBV** play a key role within validation structures at each of the national, regional and global levels, and they must be meaningfully involved in the work to validate countries for EMTCT of HIV, syphilis and HBV (see sections 4.4 and 7.2).

### 7.1.2. Operations and activities of validation

The work of the national and regional validation structures is to develop validation reports, which are then submitted for the next step in the validation process. The reporting templates and tools for EMTCT validation used by the validation structures can be found at: <https://www.who.int/initiatives/triple-elimination-initiative-of-mother-to-child-transmission-of-hiv-syphilis-and-hepatitis-b/validation/process-and-tools>.

## 7.2 Steps in the validation process

The steps in the validation process for EMTCT, or certification on the PTE, at the national, regional and global levels are summarized below and illustrated in Fig. 7.1. Details are available in the *Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis: an overview of structures and responsibilities at national, regional and global levels* (14). For HBV EMTCT validation, steps are outlined in the *Interim guidance for country validation of viral hepatitis elimination* (3).

From the beginning of the validation process, there must be meaningful engagement of communities of women living with HIV and HBV (73). Community engagement is a process of developing relationships that enable stakeholders to work together to address health-related issues and promote positive health impacts and outcomes (74). The validation process represents an important opportunity for dialogue with and feedback from communities, and the information required to evaluate a country's readiness for validation cannot be gathered without this involvement. The engagement of women in validation efforts should be multidimensional and be initiated as early as possible in the process of preparing for validation.

### 7.2.1. Steps at the national level

**[1] Request for validation.** The Ministry of Health initiates a letter of request for validation of EMTCT, which is typically sent to the WHO country office representative for forwarding to the regional level.

- [2] **Establishment of the national validation committee or national validation task force.** The Ministry of Health establishes a national validation committee or task force and, optionally, a validation team or working group.
- [3] **Completion of the preliminary assessment.** The national validation committee, task force, team or working group completes the *Checklist for country preliminary assessment of EMTCT of HIV, syphilis and HBV and Path to Elimination criteria (34)*, a tool designed to assist countries in the stage of planning for application for validation (Web Annex A). This can be considered a preliminary, draft self-assessment, which can then be reviewed (and further completed/updated) during an EMTCT orientation/training and external technical assistance mission (if needed).
- [4] **Data collection and completion of the national report.** The national validation committee or task force uses the checklist as the basis for further collection of information to develop the national validation report. Using a standard template, they describe the basic structure and functions of the national programme, including the four foundational components of validation (data, laboratory, programme and human rights, gender equality and community engagement).

### 7.2.2. Steps at the regional level

- [5] **Establishment of regional validation structures.** The WHO regional director or regional validation secretariat establishes and convenes a regional validation committee or task force. Any of these groups can convene and manage a regional validation team or working group, consisting of experts addressing the different components of validation assessment, to perform selected functions of the regional validation secretariat, as per the governance document (14).
- [6] **Completion of validation assessment.** Members of the regional validation team/working group carry out verification of the country validation assessment in four areas:
  - a. data
  - b. programme
  - c. laboratory
  - d. human rights, gender equality and community engagement.
- [7] **Regional review and submission.** The regional validation team, working group or committee will then:
  - a. present a draft regional validation report and key findings to the regional validation committee;
  - b. complete and submit the regional validation report.

### 7.2.3. Steps at the global level

- [8] **Validation report review.** The regional validation secretariat submits the regional validation report to the global validation secretariat at WHO. The global validation secretariat initiates the global review process, which includes a preliminary review before the report is sent to the Global Validation Advisory Committee for validation review. This committee reviews the regional validation report and advises WHO whether the candidate country has reached elimination targets and should be validated or certified for PTE.

**[9] Official validation.** If a country is successfully validated, the Director-General of WHO signs a certificate recognizing the candidate country's achievement of validation of EMTCT. The certificate and recommendations for follow-up actions related to the validation review and for maintenance of EMTCT validation status accompany a letter from the Director General that is sent to the WHO Regional Office for transmission to the country.

**Fig. 7.1. Process for validation of EMTCT or PTE certification, including the responsibilities of the health ministry, committees and secretariats at the national, regional and global levels**

<p><b>Health ministry</b></p>	<ol style="list-style-type: none"> <li>1. The health ministry sends a request for validation to the WHO country office or national validation secretariat.</li> <li>2. The health ministry establishes the national validation committee or task force for collecting the evidence and reporting on efforts to achieve EMTCT. It may also create a team or working group responsible for data collection and preparation of the final report.</li> </ol>
<p><b>National validation committee/ task force and secretariat</b></p>	<ol style="list-style-type: none"> <li>3. The national validation committee or task force conducts a preliminary assessment.</li> <li>4. The national validation committee or task force prepares an initial national report to apply for validation and submits it to the WHO regional director or regional validation secretariat.</li> </ol>
<p><b>Regional validation committee/ task force and secretariat</b></p>	<ol style="list-style-type: none"> <li>5. The WHO regional director or regional validation secretariat establishes and convenes a regional validation committee or task force. Any of these entities can create a regional team or working group.</li> <li>6. The assigned regional validation structure undertakes a desk review of the elements in the national validation report and conducts the regional validation assessment (via in-country mission or virtual assessment).</li> <li>7. The regional validation team, working group or committee submits the regional validation report to the regional validation secretariat.</li> </ol>
<p><b>Global Validation Advisory Committee and secretariat</b></p>	<ol style="list-style-type: none"> <li>8. The regional validation secretariat submits the regional validation report to the global validation secretariat, which reviews the report before sending it to the Global Validation Advisory Committee.  The Global Validation Advisory committee reviews the regional report and advises WHO whether the country has reached elimination targets and should be validated or certified for PTE.</li> <li>9. The Director-General of WHO signs a certificate recognizing the country's achievement of elimination. The certificate and recommendations for follow-up actions are sent with a letter from the Director-General to the WHO Regional Office for transmission to the country.</li> </ol>

## 8. MAINTENANCE OF VALIDATION

The experience of elimination programmes has shown that, to sustain elimination of a disease at such a level that it is no longer a public health problem, a country requires a monitoring and surveillance system that can accurately assess intervention coverage and detect the majority of cases of MTCT of HIV, syphilis and HBV in a timely manner (including among vulnerable and key populations at risk of acquiring HIV and STIs). For MTCT of HIV, syphilis and HBV, these systems provide ongoing monitoring of the prevalence of disease in pregnant women and the coverage and effectiveness of treatment and infant care, including HBV vaccinations and follow-up of HIV-exposed infants and young children through to final diagnosis. Reviews for maintenance of validation ensure that countries sustain the systems and responses for long-term prevention of new infections in infants and young children and maintain the health of mothers. (Table 8.1 shows the assessment time intervals.) Countries are expected to provide data sequential to that provided at the last review without omitting any years.

**Table 8.1. Time intervals for assessing maintenance of validation**

Type of country	Validation request	Maintenance review time interval
Standard (HIV/syphilis)	Single or dual	3 years
Standard (HBV)	Single	5 years
Country applying for triple elimination (HIV/syphilis/HBV)	Triple	3 years (HIV/syphilis) 6 years (HBV – reviewed at every other maintenance review)
Small population, low burden country (HIV/syphilis)	Single or dual	4 years
Small population, low burden country (HIV/syphilis/HBV)	Triple	5 years

See Chapter 3 for options for combining validation requests

The service delivery coverage (process indicators) and impact indicator targets must remain steady within the eligibility range or improve to maintain validation status. Countries that fail to maintain these, maintain the quality of achievement of the four foundational requirements of validation as described in Chapter 4 (data, laboratory, programme, human rights, gender equality and community engagement) and effectively implement recommendations made at validation, can lose their validation status. For substantial, sustained disruptions, like the COVID-19 pandemic, WHO may consider deferrals or extensions for maintenance.

## 8.1. Process of applying for maintenance of validation

The global secretariat maintains a list of countries that have achieved validation and have maintained validation criteria and standards over time. The global secretariat is responsible for notifying regional-level structures of the maintenance review schedules for countries. Countries should prepare reports on maintenance of validation using the maintenance report template in Web Annex J.

The national report should be prepared using the national component of the report template in Web Annex J and submitted to the regional secretariat. The national validation secretariat then submits the report to the regional validation secretariat, which convenes a meeting of the regional validation committee to determine whether the country has maintained the criteria for validation. The regional secretariat will then submit the report to the global secretariat with a written endorsement, using the regional component of the report template in Web Annex J.

### 8.1.1. Country report on maintenance of validation

In the report, countries are required to summarize significant changes to the EMTCT programme(s) since the previous review, update mandatory data tables with process and impact indicators for the period of review and report on progress made on recommendations (see maintenance report template in Web Annex J). Maintenance reports should include important new or emerging issues identified and addressed during the current period of review as follows:

- [1] A summary of the health system and services for EMTCT should indicate and briefly describe any significant changes to the health system within the four foundational areas of assessment since the last review:
  - **Data quality:** Demonstrate maintenance or improvement of quality or strength of the system.
  - **Laboratory:** Demonstrate maintenance or improvement of quality assurance [EQA/proficiency testing] and provide updates on the relevant laboratory tests used.
  - **Programme:** Update on any key changes in national guidelines and service delivery.
  - **Human rights, gender equality and community engagement:** Reassess for any changes at the national level in collaboration with the community of women living with HIV or HBV in the country to ensure that there are no worsening violations or negative changes in laws since the last validation review.
- [2] Required data for maintenance of validation in required data tables:
  - As for the validation process, data to be assessed for the maintenance review should have been verified and reported through global reporting mechanisms, such as the UNAIDS GAM system or the Global Hepatitis Reporting System. Indicators that are not captured in the GAM should be reported directly to the regional validation committee through the WHO country office.
- [3] Potential risks to sustaining EMTCT:
  - The report should also include a succinct narrative on any changes in the EMTCT programmes or environment that may affect the maintenance of targets. An example would be a description of service disruptions due to a major event, such as the COVID-19 pandemic or a natural disaster, and the resulting issues and interventions to address them.

- [4] Responses to recommendations and updates on requests for information made by the Global Validation Advisory Committee in the previous review.

The regional validation committee reviews the maintenance report to determine whether the country has maintained validation. The regional validation secretariat then submits the report to the global validation secretariat, accompanied by a separate regional endorsement document for maintaining validation or otherwise, along with relevant comments and recommendations from the regional review. Refer to the *Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis (14)* and Web Annex J for details.

### 8.1.2. Transfer to regions of reviews of continued maintenance of validation reviews

The Global Validation Advisory Committee recognizes the strong commitment and expertise of the regional validation structures. To that end, after two rounds of reviews of maintenance of validation reports by the Global Validation Advisory Committee, countries may be transferred to the regional level for continued reviews if the countries have continued to meet targets for maintenance of EMTCT of HIV, syphilis and HBV.

The decision to transfer a country from the global to the regional level for continuation of validation of maintenance reviews will be initiated and determined by the global validation secretariat, informed by a vote of the Global Validation Advisory Committee. The vote for transfer will occur preferably at the same time as completion of the maintenance review.

Reasons that the Global Validation Advisory Committee may vote to postpone or deny transfer of validation processes to the regional level may include:

- The country has not satisfactorily addressed major recommendations from the prior maintenance review.
- Issues in human rights and gender equality and lack of engagement of communities of women living with HIV remain uncorrected.
- The country's maintenance of validation was deferred pending additional information and clarifications from the country.
- The country has single validation only, and the Global Validation Advisory Committee would like to encourage dual or triple elimination.

Single validation of EMTCT of HBV is normally conducted at the regional level. However, in special circumstances where regions make requests for single validation of HBV EMTCT assessments at the global level, the process of evaluating maintenance will be carried out at the regional level.

Once responsibility for maintenance of validation has been transferred to the regional level, the Regional Validation Secretariat will be required to inform the global validation secretariat of the determination of the regional validation committee on whether the country has maintained the criteria for validation. If the need arises, the global secretariat can decide whether the next maintenance review should revert to the global level. Details of the process of transferring countries can be found in the *Governance guidance for the validation of elimination of mother-to-child transmission of HIV and syphilis (14)*.

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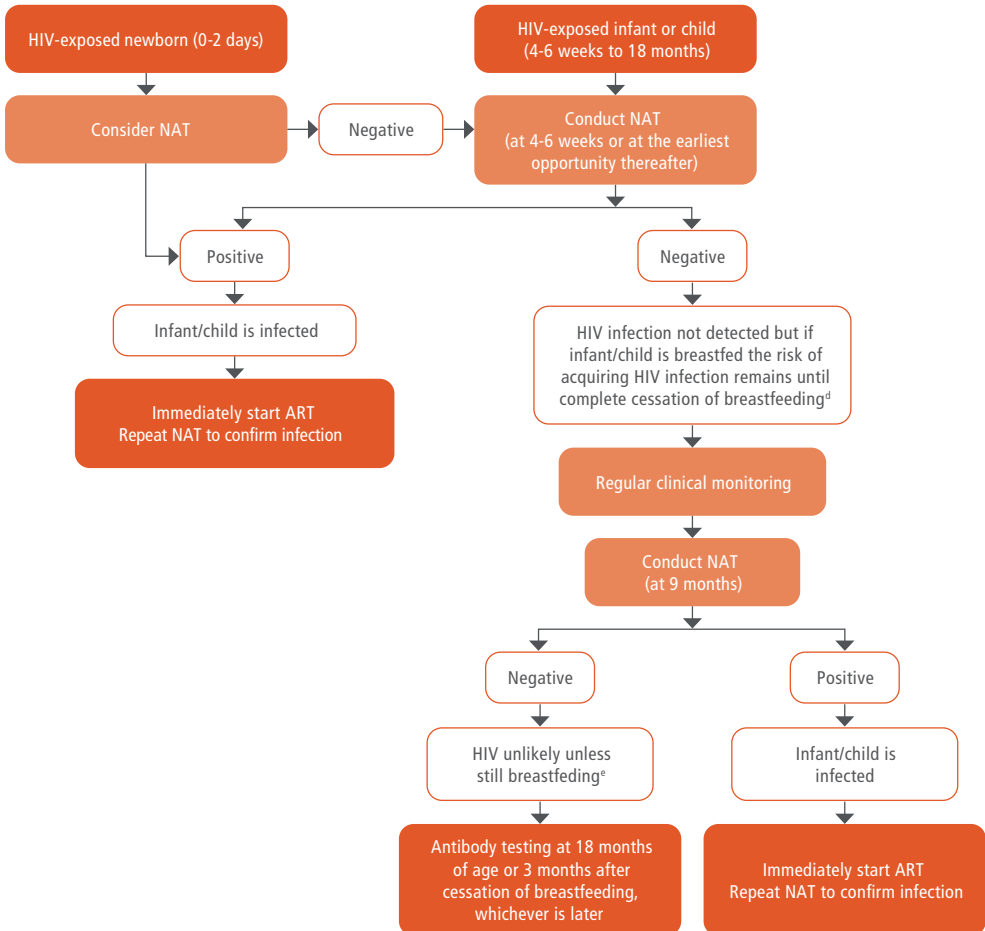
# ANNEXES

## ANNEX 1. CLINICAL FOLLOW-UP OF INFANTS AND YOUNG CHILDREN EXPOSED TO HIV, SYPHILIS OR HBV

### A1.1. Clinical follow-up of infants and young children exposed to HIV

The diagnosis of HIV infection in HIV-exposed infants and young children is complicated by the variable sensitivities of assays, ongoing HIV exposure (in utero, intrapartum and postpartum via breastfeeding) and the presence of maternal antibody for up to 12–15 months. For EMTCT, HIV-exposed infants and young children should be followed for an appropriate period to determine their final infection status.

**Fig. A1. Simplified infant diagnosis algorithm from WHO's Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring (1)**



<sup>a</sup> The addition to the existing testing algorithm of NAT at birth can be considered.

<sup>b</sup> Point-of-care NAT can be used to diagnose HIV infection as well as to confirm positive results.

<sup>c</sup> Start ART without delay. At the same time, retest to confirm infection. As maternal treatment is scaled up and MTCT transmission rates decrease, false-positive results are expected to increase: retesting after a first positive NAT is hence important to avoid unnecessary treatment, particularly in settings with lower transmission rates. If the second test is negative, a third NAT should be performed before interrupting ART.

<sup>d</sup> For children who were never breastfed, additional testing following a negative NAT at 4–6 weeks is included in this algorithm to account for potential false-negative NAT results.

<sup>e</sup> The risk of HIV transmission remains as long as breastfeeding continues. If the 9-month test is conducted earlier than 3 months after cessation of breastfeeding, infection acquired in the last days of breastfeeding may be missed. Retesting at 18 months or 3 months after cessation of breastfeeding (whichever is later) should be carried out for final assessment of HIV status.

<sup>f</sup> If breastfeeding extends beyond 18 months, the final diagnosis of HIV status can only be assessed at the end of breastfeeding. If breastfeeding ends before 18 months, the final diagnosis of HIV status with antibody testing can only be assessed at 18 months. Antibody testing should be undertaken at least 3 months after cessation of breastfeeding (to allow for development of HIV antibodies). For infants younger than 18 months of age NAT should be performed to confirm infection. If the infant is older than 18 months, negative antibody testing confirms that the infant is uninfected; positive antibody testing confirms infant is infected.

- For HIV-exposed infants, ruling out HIV infection is based on the algorithm in Fig. A1 (1).
- Nucleic acid testing is highly sensitive and specific to identify infection at any age. In infants it should be used to both diagnose and confirm infection (19, 21).
- For HIV-exposed infants, high infant HIV testing coverage at stipulated time points and birth cohort monitoring are needed to provide sufficient data on infant outcomes to determine the MTCT and population case rates. While there is no specified level of HIV-exposed infant testing coverage required to meet validation criteria per se, the data on infant outcomes should be robust and provide reasonable certainty for the impact indicators.
- For small-population and low HIV prevalence countries with strong health systems (see section 6.3), it is reasonable to expect EID testing coverage to be >95%. For high prevalence countries, it is reasonable to expect EID testing (or EID and final antibody testing) to be >80%. These data, although programmatic and not included as process indicators for EMTCT validation, can be used to characterize the outcome of exposure in the infants and young children tested, and they can be triangulated with maternal treatment data to estimate outcomes in the additional infants not tested. For MTCT and population case rates, a birth cohort estimation method is recommended. For breastfeeding infants, the cohort method needs to allow for follow-up through 18 months due to ongoing risk of transmission (75, 76).

## A1.2. Clinical follow-up of infants and young children exposed to syphilis

The surveillance case definition of CS should be used to calculate the case rate (see section 3.1.2). For the purpose of clinical follow-up, all syphilis-exposed infants should receive treatment when recommended according to WHO syphilis treatment guidelines (5) and managed and monitored as follows:

- Infants born to **inadequately treated mothers** should receive treatment for CS and have a non-treponemal test with titre at delivery as well as at six months post-treatment to evaluate treatment response (77).
- Infants born to **adequately treated mothers** with no signs of maternal reinfection do not require treatment or follow-up non-treponemal titres, but they should be evaluated for clinical signs suggestive of CS at delivery. If such clinical signs are identified, these infants should receive testing, recommended treatment and follow-up.
- Any previously **undiagnosed and untreated infant** ≥6 months of age who has a reactive non-treponemal titre should be considered a case of CS and receive treatment according to WHO syphilis treatment guidelines. These cases should be counted towards the CS case rate if not previously included.

## A1.3. Clinical follow-up of infants exposed to HBV

Follow-up of HBV-exposed infants, including PVST testing (anti-HBs with or without HBsAg), is important to identify children with, and to protect children from, HBV infections. For validation, PVST is part of the calculation of the MTCT rate for HBV; it is an additional impact indicator required for countries that provide targeted timely HepB-BD only (see section 3.1.3 and Annex 2).



The WHO policy on hepatitis B vaccination recommends that, where needed, PVST in exposed infants should be carried out at least 1–2 months after administration of the last dose of the hepatitis B vaccine series, when the antibody response is greatest (27). Routine PSVT testing for immunity (anti-HBs) is not necessary, as the primary 3-dose series induces protective antibody concentrations in >95% of healthy infants, but can be done in the context of HBV elimination in countries with targeted timely HepB-BD and in countries with low-prevalence settings, where it serves as a tool to confirm immunity against hepatitis B among infants of HBsAg-positive mothers (27).

Several scenarios may affect clinical follow-up of HBV-exposed infants. The exposed infant may be:

- **infected with HBV** (HBsAg-positive). The infant will need to be clinically followed during childhood and early adulthood for assessment to rule out progression to liver disease, with the possibility of treatment or eventual spontaneous HBsAg clearance. In infants and children, whether treatment is needed is a clinical decision. It is indicated in cirrhosis as well as for those with active hepatitis with high viral loads (58).
- **uninfected** (HBsAg-negative and anti-HBs-positive) and have responded adequately to the HBV vaccine series. No clinical follow-up is required.
- **uninfected, but may not have responded to the HBV vaccine** (HBsAg-negative and anti-HBs-negative). These infants need to be revaccinated. This group is usually a small percentage (<5%) of the vaccinated cohort.



# ANNEX 2. MEASUREMENT OF INDICATORS AND TARGETS FOR VALIDATION OF EMTCT OF HEPATITIS B VIRUS

## A2.1. Measurement of childhood prevalence of HBsAg in $\leq 5$ -year-olds

### A2.1.1. Preferred approach: measurement of childhood HBsAg prevalence in $\leq 5$ -year-olds

The preferred approach is to directly measure a proxy for chronic HBV incidence (that is, HBsAg prevalence in  $\leq 5$ -year-olds) with national-level biomarker surveys among young children. This is the gold standard recommended by WHO in  $\leq 5$ -year-olds for monitoring progress towards HBV control targets, but it requires large sample sizes in settings that have low prevalence (39). The focus should be on obtaining the best possible representative prevalence estimates with narrow confidence intervals in the 0–5-year-old age cohort.

The advantage of measuring HBsAg prevalence in  $\leq 5$ -year-olds is that it captures the effects of interventions on MTCT as well as early horizontal transmission. However, a limitation is that it reflects the impact of an intervention five years earlier. There is, therefore, flexibility for countries to include, for convenience, an age group of 1–5 years or a narrower age range such as one year of age to measure this indicator using representative serosurveys. This would capture the impact of recent interventions, although it would not reflect sustainability. However, there are logistical and cost constraints in undertaking serosurveys in a younger cohort of one year of age, given the requirement for household surveys and venous sampling. Conducting such surveys in  $\leq 5$ -year-olds also may be challenging in certain countries. Since many countries already conduct school-based HBV serosurveys or serosurveys among vaccinated cohorts across a wider age range, there could be flexibility to use these existing serosurveys in older children ( $> 5$  years as well as  $\leq 5$  years), especially if there is a long history and programmatic evidence of high sustained birth dose and infant vaccination coverage (for example, in the WHO Region of the Americas and in western Europe). This approach will capture the impact on both vertical and horizontal transmission.

The technical challenges of conducting a nationally representative biomarker survey can be minimized by complementing it with other, more focused surveys that:

- 1) target high-risk geographical areas or subpopulations likely to have a higher prevalence (for example, children from particular racial/ethnic groups or migrant communities);
- 2) are based on programmatic indicators such as HepB3 and HepB-BD and prevalence in pregnant women or women of reproductive age through multiphase methodology serosurveys (78, 79) (to reduce the required sample size and increase the power of the serosurvey to confirm elimination); or

3) integrate into existing national surveys for other disease areas (which are often performed using dried blood spot testing), such as the Demographic and Health Surveys and AIDS Indicator Surveys.

For countries with a small population size, such as the islands in the Pacific, their size need not be a hindrance to conducting a serosurvey to verify elimination, as it may be actually easier to conduct the survey and validate elimination. A finite population correction (FPC) factor can be calculated when estimating the required sample size. Even for verification of the control, an FPC factor can be applied to generate the sample size (80, 81).

### **A2.1.2. Additional approach: measurement of the MTCT rate through follow-up of HBV-exposed infants in settings using targeted timely HepB birth dose vaccination**

Measurement of the additional indicator and target of an MTCT rate of  $\leq 2\%$  may be indicated in low-HBsAg prevalence countries (low both in the overall population and in  $\leq 5$ -year-olds). Also, this may be done in countries using targeted timely HepB-BD where there are subpopulations with still high prevalence and so continuing vertical MTCT of HBV (for example, among Indigenous populations or migrant populations from high-HBsAg prevalence countries). It may also be considered in settings where population-based serosurveys may not be feasible.

The MTCT rate is calculated as the proportion of infants with CHB infection, that is, the number of HBsAg-positive infants (numerator) among those infants exposed, that is, infants of HBsAg-positive mothers (denominator). Calculation of this transmission rate requires both high-level coverage ( $\geq 90\%$ ) of antenatal HBsAg testing to identify positive mothers and PVST of exposed infants at 9–12 months of age to identify infected infants. Some countries, such as China, recommend PVST at 7–9 months of age.

Thus, countries providing targeted timely HepB-BD will need to have strong data collection systems and linkages between programmes in place to capture the data for calculation of the transmission rates.



## A2.2. Using mathematical modelling alongside empirical data to determine attainment of the elimination targets

Modelling is not a substitute for the collection of data, but it can be a tool for using existing data to yield new insights and identify data gaps. Where national empirical data are of sufficient quality and coverage, mathematical models<sup>1</sup> using existing in-country data as well as previously published literature may be useful to assess the progress of countries towards the achievement of the impact targets for perinatal and horizontal HBV elimination. They can also be used to project the potential impact of additional preventive (including immunization) and treatment interventions for CHB infections on progress towards the 2030 targets.

To determine if a country has achieved elimination, modelling could be used in the following specific applications:

- to set country-specific targets for programmatic coverage that can be used to guide a strategic response.
- using programmatic data, to determine whether it is likely that elimination has been achieved in any particular place. This could also inform the commissioning of a biomarker survey. The general assumption is that, where global targets for programmatic coverage indicators have been reached, it is also likely that elimination has been achieved. However, this assumption relies, in turn, on assumptions made in the course of various modelling exercises that may not apply to all epidemiological contexts. In addition, this methodology depends on high-quality programmatic data and robust reporting systems.
- to establish whether measurement of the MTCT rate alone may be sufficient to establish whether elimination has been achieved and whether measurement of MTCT may be converted to an estimate of the likely incidence rate for the whole population.
- to establish the required design of a biomarker survey and to convert a measure of HBV prevalence into an estimate of the likely incidence rate for the whole population. The standards for the calculation of these indicators for the EMTCT of HBV, comparable to the approach used by the Spectrum model for HIV (82), remain to be determined.

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<sup>1</sup> Mathematical models employed in the process should be independent and peer reviewed, as the regional validation task force will review inputs, assumptions, analysis and outputs in detail during its review of the national validation report. In addition, the models used might vary across countries.

# WEB ANNEXES

The following web annexes will be published in 2022. The current tools can be found at: <https://www.who.int/initiatives/triple-elimination-initiative-of-mother-to-child-transmission-of-hiv-syphilis-and-hepatitis-b/validation/process-and-tools>.

**Web Annex A. Checklist for preliminary assessment of EMTCT validation**

**Web Annex B. Congenital syphilis estimation tool**

**Web Annex C. Initial validation or Path to Elimination report template**

**Web Annex D. Data assessment and verification tool**

**Web Annex E. Laboratory assessment and verification tool**

**Web Annex F. Programme assessment and verification tool**

**Web Annex G: Human rights, gender equality and community engagement assessment and verification tool**

**Web Annex H. Analysis guidance for human rights, gender equality and community engagement in validation of EMTCT**

**Web Annex I. Sample case study form**

**Web Annex J. Maintenance of validation or Path to Elimination report template**

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