GUIDANCE

GLOBAL GUIDANCE ON
CRITERIA AND PROCESSES FOR VALIDATION:

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

SECOND EDITION
2017

MONITORING AND EVALUATION

World Health Organization

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FOREWORD

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* (EMTCT). In 2015, the Global Validation Advisory Committee for EMTCT was established and, as of October 2017, eleven countries or territories have been validated for achieving elimination of mother-to-child transmission (MTCT) of HIV and/or syphilis as a public health problem. This second edition of the EMTCT global validation guidance document captures the learning from these validation efforts to date, and reflects WHO's commitment to the global effort to eliminate MTCT of HIV and syphilis, and expand the capacity of maternal and child health services to address vertical transmission of other communicable diseases. Even as we celebrate the achievement of these first countries, we must continue to strive to make this remarkable accomplishment a reality for all.

We welcome the revitalized global interest in this and other maternal, newborn and child health issues. We applaud 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 the determination to dedicate significant resources and attention towards achieving the Sustainable Development Goals for Health (SDGs), which promote universal access to health coverage and to sexual and reproductive health-care services. We support the new *Start Free, Stay Free, AIDS Free* framework to accelerate efforts to prevent and treat HIV among children and adolescents and young women, launched in 2016 by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and US President's Emergency Plan for AIDS Relief (PEPFAR). We are also 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. Countries in different phases of their HIV and syphilis response can learn from each other. 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, and ensure the involvement of women in service planning and delivery. Essential EMTCT services include testing for HIV and syphilis in antenatal care (ANC) clinics, prompt and efficacious interventions to treat women who test positive and prevent transmission of either infection; counselling for women and their partners to reduce transmission risk and ensure appropriate treatment; attended, safe delivery; appropriate follow up of exposed infants; optimal infant-feeding; and lifelong treatment and care for mothers living with HIV. In all countries, success depends on the combined efforts of advocates, policy-makers, health providers and community representatives to ensure that services are non-coercive, and the human rights of women, children and families affected by HIV are protected.

This second edition of the EMTCT global validation guidance document provides standardized processes and consensus-developed criteria to validate EMTCT of HIV and syphilis, and to recognize high-HIV burden countries that have made significant progress on the path to elimination. The guidance places strong emphasis on country-led accountability, rigorous analysis, intensive programme assessment and multilevel collaboration, including the involvement of communities of women living with HIV. It provides guidance to evaluate the country's EMTCT programme, the quality and accuracy of its laboratory and data collection mechanisms, as well as its efforts to uphold human rights and equality of women living with HIV, and their involvement in decision-making processes. 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 and syphilis. WHO is pleased with the initial progress of this elimination initiative, and anticipates ongoing success by countries and regions in achieving the elimination targets.

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We thank our partners, both our external partners and UN partners – the Joint United Nations Programme on HIV/AIDS (UNAIDS), United Nations Children's Fund (UNICEF) and United Nations Population Fund (UNFPA) – for their support in preparing this revised global guidance document. We thank the World Health Organization (WHO) regional advisors, regional validation committees, the Global Validation Advisory Committee and WHO HIV and STI technical staff for their valuable contributions.

Experience from the first countries validated for EMTCT – Cuba, Thailand, Belarus, Republic of Moldova (syphilis only) and Armenia (HIV only), as well as the next six countries and territories of Anguilla, Montserrat, Cayman Islands, Bermuda, Antigua and Barbuda, and St Christopher and Nevis – has been of great assistance in development of the second edition of the global guidance. We particularly thank the programme managers, health-care providers and women living with HIV and syphilis who have enabled countries to start making the impossible possible – ushering in a generation free of HIV and syphilis.

WHO EMTCT WEBSITES

Updates on progress and guidance on EMTCT of HIV and syphilis, as well as key source documents and tools, are available on the WHO EMTCT websites:

HIV/AIDS

http://www.who.int/hiv/topics/mtct/emtct-validation/en/

Congenital syphilis elimination

http://www.who.int/reproductivehealth/congenital-syphilis/en/

EMTCT processes and tools

http://www.who.int/reproductivehealth/congenital-syphilis/emtc-gvac/en/

http://www.who.int/reproductivehealth/congenital-syphilis/WHO-validation-EMTCT/en/

http://www.who.int/reproductivehealth/publications/rtis/emtct-hiv-syphilis/en/

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

WHO Regional Office for the Western Pacific

http://www.wpro.who.int/hiv/topics/emtct/en/

Additional EMTCT resources

http://www.dualelimination.org

ABBREVIATIONS AND ACRONYMS

ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral
CDC	U.S. Centers for Disease Control and Prevention
CS	congenital syphilis
CSF	cerebrospinal fluid
EID	early infant diagnosis
EMTCT	elimination of mother-to-child transmission
EQA	external quality assessment
GAM	UNAIDS Global AIDS Monitoring
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GIPA	greater involvement of people living with HIV
GVAC	global validation advisory committee
HBsAg	hepatitis B surface antigen
HIV	human immunodeficiency virus
M&E	monitoring and evaluation
MCH	maternal and child health
MDGs	Millennium Development Goals
MTCT	mother-to-child transmission
NVC	national validation committee
PEPFAR	United States President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission
QC	quality control
RVC	regional validation committee
RVS	regional validation secretariat
SDGs	Sustainable Development Goals
SRH	sexual and reproductive health
STI	sexually transmitted infections
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VDRL	Venereal Disease Research Laboratory
WHO	World Health Organization

EXECUTIVE SUMMARY

The global community has committed to eliminating mother-to-child transmission (EMTCT) of HIV and syphilis as a public health priority. At national level, efforts to eliminate mother-to-child transmission (MTCT) of HIV and syphilis focus on taking a harmonized and integrated approach to improving health outcomes for women and children. International and regional goals have been set, and countries are scaling up programmes towards EMTCT of HIV and syphilis. In addition, an emerging area of work that is under active development in several WHO regions is to move from dual elimination to "triple elimination" by incorporating the EMTCT of hepatitis B into maternal and child health (MCH) programmes and the EMTCT framework.

In 2007, the WHO-led initiative for the elimination of MTCT of syphilis was launched with *The global elimination of congenital syphilis: rationale and strategy for action*. This initiative was based on a foundation of quality MCH services that supported the Millennium Development Goals (MDGs) and aimed at reducing child mortality and improving maternal health. Soon after, initiatives in the WHO regions of the Americas, Asia and the Pacific, and Africa approached the control of MTCT of HIV and syphilis as an integrated process.

Following a global consultation in 2012, 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 2014, and launched the dual EMTCT initiative. *The Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive* (Global Plan) and WHO recommendations to move to lifelong treatment for pregnant women with HIV ("Option B+") and, more recently, treatment for all persons living with HIV, provided further support for global elimination goals and country-led efforts. Building in part on the legacy of the Global Plan, and the new treatment and prevention approaches, in October 2015, the Joint United Nations Programme on HIV/AIDS (UNAIDS) adopted a new strategy to end the AIDS epidemic as a public health threat by 2030. For women and children, there are interim goals that call for 95% coverage with antiretroviral therapy in pregnant women, and <20 000 new paediatric HIV infections a year by 2020.

In May 2016, the World Health Assembly endorsed three new WHO global health strategies on HIV, sexually transmitted infections and hepatitis. These strategies call for Member States and WHO to work together towards the goals of zero new HIV infections in infants by 2020, elimination of congenital syphilis as a public health threat by 2030, and less than 0.1% prevalence of hepatitis B surface antigen (HBsAg) among children by 2030.

The types of interventions required to prevent MTCT of HIV are similar to those needed for preventing vertical transmission of syphilis, which makes an integrated approach to dual EMTCT highly feasible. Indeed, an integrated approach is necessary to improve the efficiency and quality of MCH services, offer women more comprehensive primary care, and ultimately reduce preventable adverse birth outcomes.

At the same time, the specific strategies in any particular country for dual elimination of MTCT of HIV and syphilis are greatly influenced by differences in HIV and syphilis epidemiology, service delivery models, coverage of health services and available resources.

Since June 2015, when Cuba became the first country to be validated for EMTCT of HIV and syphilis as public health problems, and as of October 2017, a total of 11 countries or territories have achieved validation for EMTCT of HIV and/or syphilis.[1] The momentum created by this process has galvanized a large number of countries in all regions of the world to strengthen programme performance and commit to dual elimination.

The processes and criteria to validate EMTCT of HIV and/or syphilis described in this document were developed to apply a standard approach across a wide range of epidemiological and programmatic contexts. These elimination criteria must be achieved in a manner that protects and respects the human rights of women and promotes gender equality. The criteria also seek to ensure that representatives of civil society and of communities of women living with HIV are involved in the validation effort.

A harmonized approach to eliminating MTCT of both HIV and syphilis is encouraged. However, depending on the progress of national MTCT efforts, countries may choose to validate the elimination of MTCT of HIV, syphilis or both.

This second edition was developed by WHO and the Global Validation Advisory Committee (GVAC), and is intended for use by national and regional validation committees as they prepare or review national submissions requesting validation of EMTCT of HIV and/or syphilis.

The first edition of this global EMTCT guidance document sought to outline the minimum global processes and criteria that countries should address to achieve validation of EMTCT. This second edition includes changes, clarifications or new guidance in the following topic areas:

[i] revised validation criteria for EMTCT of HIV;

[ii] expanded description of surveillance case definition of congenital syphilis;

[iii] guidance on how to assess countries with small numbers of HIV- or syphilis-positive pregnant women;

[iv] criteria for the recognition of progress in countries with a high burden of HIV or syphilis (Path to Elimination);

[v] guidance on selection of low-performing subnational administrative units;

[vi] criteria for evaluation of human rights, gender equality and community engagement;

[vii] guidance on defining and evaluating special populations, including transient, marginalized and vulnerable populations;

[viii] selecting breastfeeding versus non-breastfeeding HIV MTCT targets;

[ix] assessment and reporting in the non-public (i.e. private) sector;

[x] maintenance requirements of validation; and

[xi] data reporting on HIV- and syphilis-exposed infants.

1 As of October 2017, countries/territories validated for elimination of HIV and syphilis, in order of validation are: Cuba, Thailand, Belarus, Armenia (HIV only), Republic of Moldova (syphilis only), Anguilla, Montserrat, Cayman Islands, Bermuda, Antigua and Barbuda, St Christopher and Nevis.

In addition, tools and checklists for use by validation teams in the areas of (i) surveillance and data evaluation, (ii) laboratory services, (iii) programme assessment, and (iv) human rights and community engagement have been updated and are available as online supplements to this document.

In public health, elimination is generally defined as reduction to zero of the incidence of a disease or infection in a defined geographical area. However, because both HIV and syphilis remain public health issues and PMTCT measures are highly but not 100% effective, currently it is not feasible in most settings to reduce MTCT of either infection to zero. Therefore, the goal for EMTCT initiatives is to reduce and ensure services to maintain MTCT of HIV and syphilis at a very low level, such that it is no longer a public health problem. This achievement requires strong political and public health commitment to maintain surveillance, prevention, and treatment programmes so that performance of the required indicators is preserved.

Of special note, this second edition of the global guidance presents a new approach to recognizing high-burden countries that may not have reached elimination targets but are on the "Path to Elimination". The approach and defining criteria for the Path to Elimination were developed during a series of consultations with countries in the Africa Region in 2016 and early 2017. They are designed for countries with a high prevalence of HIV and/or syphilis which have made tremendous progress in preventing MTCT but cannot as yet reach elimination targets due to the high prevalence of HIV and syphilis in antenatal care (ANC) attendees. The Path to Elimination comprises three tiers of accomplishment, each with its own set of process and outcome indicators. Moving to a higher tier brings a country progressively closer to elimination.

In developing this revised document, WHO and the GVAC considered the input of national programmes, regional validation teams and committees, and experts in the areas of programme, data quality, laboratory standards, human rights, gender equality and community engagement. Topic areas that needed revision were also discussed during face-to-face meetings of the GVAC held in Geneva in June 2016 and June 2017.

WHO hopes that this second edition of the EMTCT global guidance, popularly known as the "Orange Book", will further standardize and catalyse regional and country progress toward achieving the validation of EMTCT of HIV and syphilis as public health problems.

1 INTRODUCTION

Mother-to-child transmission (MTCT) of HIV is a significant contributor to the HIV pandemic, accounting for 9% of new infections globally. The Joint United Nations Programme on HIV/AIDS (UNAIDS) reported that in 2016 an estimated 160 000 children were newly infected with HIV, and an estimated 3.1 million children were living with HIV globally *(1)*. Although this is still a large number of new infections, at the peak of the HIV epidemic, there were close to 500 000 children infected with HIV through MTCT each year.

MTCT of HIV occurs when HIV is transmitted from a woman living with HIV to her baby during pregnancy, labour or delivery, or after delivery through breastfeeding. Without treatment, approximately 15–30% of infants born to HIV-positive women will become infected with HIV during gestation and delivery, with a further 5–15% becoming infected through breastfeeding. HIV infection of infants results in early mortality for many or creates a lifelong chronic condition that greatly shortens life expectancy and contributes to substantial human, social and economic costs.

Globally, an estimated 1.3 million women living with HIV become pregnant every year *(2)*. Primary prevention of HIV, prevention of unintended pregnancies, effective access to HIV testing and counselling, initiation of lifelong antiretroviral therapy (ART) with support for adherence, retention and viral suppression for mothers living with HIV, safe delivery practices, optimal infant-feeding practices and access to postnatal antiretroviral (ARV) prophylaxis for infants all contribute to the prevention of mother-to-child transmission (PMTCT), thereby reducing maternal and child mortality. With the global shift to highly effective and simplified interventions based on lifelong maternal ART, it is now feasible to virtually eliminate new HIV infections in infants, while assuring the health of the mother *(3)*.

In 2012 (the most recent global data), WHO estimated that over 900 000 pregnant women were infected with syphilis. These maternal infections resulted in more than 350 000 estimated adverse pregnancy outcomes, over 200 000 of which were stillbirths or neonatal deaths *(4)*. 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 early in pregnancy (*in utero* infection). If the infection remains untreated, adverse pregnancy outcomes are frequent. Indeed, over half of the pregnancies among women with active syphilis will result in stillbirth, early neonatal death, a preterm or low-birth-weight infant, or serious neonatal infection *(5)*. Screening for maternal syphilis early in pregnancy and prompt treatment of seropositive mothers with intramuscular benzathine benzylpenicillin, a long-acting penicillin, cures syphilis in both mother and infant, and prevents most complications associated with MTCT of syphilis *(6)*.

Dual elimination serves to improve a broad range of maternal and child health (MCH) services and outcomes. This achievement directly contributes to Sustainable Development Goals (SDGs) 3, 5 and 10, which aspire to ensure health and well-being for all, achieve gender equality and empower women and girls, and reduce inequalities in access to services and commodities *(7)*. Additionally, the similarity of the control interventions necessary to prevent transmission of HIV and syphilis in pregnancy adds to the feasibility and benefit of such an integrated approach to the elimination of MTCT (EMTCT) of both infections. Indeed, building on an integrated MCH platform, several WHO

regions are moving to "triple elimination" by incorporating hepatitis B into the EMTCT framework. The Pan American Health Organization is promoting a strategy of "EMTCT Plus", which includes the EMTCT of hepatitis B and Chagas disease, in addition to the EMTCT of HIV and syphilis (see Regional websites).

The processes and criteria to validate EMTCT of HIV and syphilis described in this document were developed to apply across a wide range of epidemiological and programmatic contexts. They also seek to ensure that representatives of civil society, including women living with HIV, are involved in the validation effort, and that elimination goals are achieved in a manner that protects and respects the human rights of women, and particularly women living with HIV and/or syphilis.

A harmonized approach to eliminating MTCT of HIV and syphilis is encouraged. However, depending on the progress of national EMTCT efforts, countries may choose to validate the EMTCT of HIV, syphilis or both. Elimination must be achieved while protecting human rights and with the involvement of women and affected communities in all interventions, including in planning and designing programmes, implementation, and monitoring and evaluation (M&E).

This revised document was developed by WHO and the Global Validation Advisory Committee (GVAC) in order to clarify existing guidance, update checklists and tools, and provide new guidance on the Path to Elimination for high-burden countries. The document is intended for use by national and regional validation committees as they prepare or review national submissions for validation of EMTCT of HIV and/or syphilis. In developing this revised document, WHO and the GVAC considered the input of national programmes, regional validation teams and committees, and external experts, including in the area of human rights. Suggestions for topic areas that needed revision were collected by WHO from global validation team members during country validation missions and during face-to-face meetings of the GVAC held in Geneva in June 2016 and June 2017.

The first edition of this global EMTCT guidance document was released in 2014 and sought to outline the minimum global processes and criteria that countries should address to achieve validation of EMTCT *(8)*. This second version includes changes, clarifications or new guidance in the following topic areas:

[i] revised validation criteria for EMTCT of HIV;

[ii] expanded description of surveillance case definition of congenital syphilis;

[iii] guidance on how to assess countries with small numbers of HIV- or syphilis-positive pregnant women;

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[vii] guidance on defining and evaluating special populations, including transient, marginalized and vulnerable populations;

[viii] selecting breastfeeding versus non-breastfeeding HIV MTCT targets;

[ix] assessment and reporting in the non-public (i.e. private) sector;

[x] maintenance requirements of validation; and

[xi] data reporting on HIV- and syphilis-exposed infants.

In addition, tools and checklists for use by validation teams in the areas of (i) surveillance and data evaluation, (ii) laboratory services, (iii) programme assessment, and (iv) human rights, gender equality and community engagement have been updated, and are available as online supplements to this document.

In public health, elimination is generally defined as reduction to zero of the incidence of a disease or infection in a defined geographical area *(9)*. However, because both HIV and syphilis remain public health issues and PMTCT measures are highly but not 100% effective, currently it is not feasible in most settings to reduce MTCT of either infection to zero. Therefore, the goal for EMTCT initiatives is to reduce and ensure services to maintain MTCT of HIV and syphilis at a very low level, such that it is no longer a public health problem. This achievement requires strong political and public health commitment to maintain surveillance, prevention, and treatment programmes so that performance of the required indicators is preserved.

In this revised document, WHO also proposes criteria for validation of three levels of achievement – bronze, silver and gold – on the Path to Elimination. Countries with a high burden of maternal HIV and/or syphilis, which have demonstrated significant and sustained reductions in MTCT rates as well as population case rates of the number of children born with HIV and/or congenital syphilis, are encouraged to apply for validation of being on the Path to Elimination. This new category has been added specifically to recognize the tremendous accomplishments of high-burden countries in markedly reducing their MTCT rates and the numbers of infected infants born each year. In many of these countries, the high prevalence of HIV-positive or syphilis-positive pregnant women makes it very difficult to reach the full validation targets for elimination without sustained efforts over many years to prevent new HIV and syphilis infections in women, especially adolescents and young women, to achieve reduced prevalence in pregnant women.

The term "validation" is used to attest that a country has successfully met the criteria for EMTCT or for one of the three levels of achievement on the Path to Elimination of HIV and/or syphilis. Successful prevention of MTCT is dependent on sustaining lifelong treatment for women with HIV of childbearing age, and the early detection and cure of those diagnosed with syphilis. Countries that achieve validation still need to maintain ongoing, routine and effective programme interventions, as well as quality surveillance systems to monitor elimination status.

A key consideration for validation of a country is that the interventions to reach the targets have been implemented in a manner consistent with international, regional and national human rights standards. These standards include human rights in relation to equitable access to sexual and reproductive health (SRH) services and antenatal care (ANC), pregnant women's autonomy in decision-making, informed consent for HIV testing, respect for their privacy and confidentiality, freedom from violence, abuse and coercive practices, decriminalization of HIV and syphilis transmission, and ensuring meaningful participation of people living with HIV in the design and delivery of programmes.

Gender equality considerations are particularly pertinent in the context of vertical transmission of HIV and syphilis, as gender norms and practices can significantly shape SRH and the rights of women, and the health outcomes for their children. Promoting and ensuring gender equality can significantly influence the opportunities of women and girls to access necessary information and services, make autonomous decisions about their sexuality and reproduction, and protect themselves against HIV and other sexually transmitted infections (STIs).

Greater involvement of people living with HIV (GIPA) is a principle that aims to help realize the human rights of people living with HIV, including their right to health, and the right to participate in decision-making processes that affect their lives *(10)*. There is consensus in the global community that engaging people living with HIV has many benefits, and that involvement should be multidimensional, including in the policy-making process, programme development and implementation, advocacy and service delivery. Engagement and participation of women living with HIV, in particular, in the formulation of health laws, policies, programmes and M&E systems that affect them results in better, more effective programmes, and helps to ensure that women living with HIV and infected with syphilis get the treatment they need to keep themselves well and their children free from infection.

In 2015, following the release of the first version of this global guidance (popularly known as the "Orange Book"), the GVAC was established and Cuba became the first country to receive validation for EMTCT. As of October 2017, eleven countries and territories have been validated for EMTCT of HIV and/or syphilis, and many more are in the process of evaluating their programmes and preparing to submit for full validation or for the Path to Elimination. WHO hopes that this second edition of the EMTCT global guidance will further standardize and catalyse regional and country progress towards achieving the validation of EMTCT of HIV and syphilis as public health problems.

2 RATIONALE FOR STANDARDIZED CRITERIA FOR EMTCT OF HIV AND/OR SYPHILIS

A. QUALIFYING REQUIREMENTS FOR EMTCT OF HIV AND/OR SYPHILIS

Before initiating the validation process, countries should be confident that they can meet the global minimum criteria. Any country that feels it can meet the qualifying global requirements, as well as any additional regional requirements, is encouraged to apply for validation. Before applying for validation of EMTCT of HIV and/or syphilis, candidate countries must meet the following global minimum criteria:

[1] National-level evidence of achievement of the EMTCT validation process indicator targets for two years and achievement of validation impact indicator targets for one year. In countries where impact targets can be collected every year, achievement of validation impact indicator targets for two or more years is recommended before applying for EMTCT validation.

[2] Evidence that EMTCT of HIV and/or syphilis has been adequately addressed in the lowest-performing subnational administrative units. The lowest-performing subnational administrative units are those known to perform poorly on relevant health indicators (e.g. those with the highest disease burden, lowest levels of service coverage, or an estimated MTCT rate of HIV and/or congenital syphilis rate that may not meet the global EMTCT validation targets). This approach is similar to that used by the maternal and neonatal tetanus elimination programme *(11)*. It helps to ensure that the validation process addresses equity in health service coverage. Where specific key populations are important for EMTCT, assessment of EMTCT efforts in these groups should be part of the process. Countries are encouraged to work with the regional validation committee to determine an appropriate selection process for the subnational administrative unit. This is described further in section 4.3.

[3] Existence of an adequate "validation standard" national monitoring and surveillance system that can capture process data from both the public and private health sectors, and detect the great majority of cases of MTCT of HIV and/or syphilis.

[4] Validation criteria must have been met in a manner consistent with basic human rights considerations.

B. STANDARDIZED CRITERIA USED IN EMTCT OF HIV AND/OR SYPHILIS

The ability to achieve EMTCT of HIV and/or syphilis in a particular country will depend on the political and public health commitment, prevalence of infection, extent of antenatal and other sexual, reproductive and MCH service coverage, resources, availability of appropriate treatment, and whether women who belong to marginalized or key populations with high transmission risk can access health care. Successful national-level EMTCT of HIV and/or syphilis is possible only where there are sustained improvements in national and subnational public health systems

and services, including adequate infrastructure, well-trained and sufficient staff, quality-assured laboratory services, funding to procure commodities and high-quality monitoring/surveillance systems *(12,13)*.

Standardized criteria for validation of EMTCT of HIV and/or syphilis are needed for the following reasons:

- to provide national EMTCT programmes and participating stakeholders with a clear and consistent set of criteria for evaluating and monitoring programme achievements;
- to ensure that EMTCT of HIV and/or syphilis has been achieved in accordance with agreed standards;
- to strengthen national coverage and quality of HIV and/or syphilis interventions in MCH services;
- to strengthen national data collection and programme monitoring systems;
- to ensure quality-assured laboratory services;
- to ensure gender equality and the protection of human rights of women living with HIV and syphilis;
- to ensure that communities of people living with HIV, particularly women living with HIV, are meaningfully involved in programme implementation; and
- to measure global progress.

The criteria selected for measuring EMTCT of HIV and/or syphilis take into account the following aspects of HIV and syphilis epidemiology:

- HIV and syphilis infection can be asymptomatic, meaning that detection is often delayed, and depends on the initiative of the individual and/or the capacity of the health system to promote and facilitate testing for early detection.
- To date, there is no cure for HIV infection. However, ART can prolong and greatly improve quality of life, and greatly reduce the risk of transmission, including transmission from mother to child.
- Syphilis infection in pregnant women and unborn infants can be cured with intramuscular injection of benzyl benzathine penicillin (also known as benzathine penicillin) and adverse birth outcomes prevented if treatment is given to the mother early in pregnancy.

The following strategies are important components of successful EMTCT programmes:

- interruption of transmission through quality ANC and prevention services that provide timely identification and treatment of pregnant women infected with HIV or syphilis, their sexual partners, and their infants;
- reduction in the number of HIV and/or syphilis infections among pregnant women through:
  - prevention of HIV and/or syphilis infection in women of reproductive age, including in HIV-negative pregnant and breastfeeding women and their sexual partners;

  - promotion of a healthy reproductive life, including prevention of unintended pregnancies and support for safer conception among women with known HIV infection;
  - control of HIV and syphilis in the general and key populations (including sex workers, drug users, men who have sex with men) to decrease prevalence.
- promotion and protection of the human rights and gender equality of women living with HIV;
- greater engagement of women living with HIV in HIV programming, decision-making and service delivery.

3 INDICATORS AND TARGETS FOR VALIDATION OF EMTCT OF HIV AND/OR SYPHILIS

The goal of EMTCT programmes is to ensure that MTCT of HIV and/or syphilis is controlled and reduced to a very low level, such that it ceases to be a public health problem. The same principle has been applied to elimination programmes for several other diseases, including leprosy *(14)*, onchocerciasis *(15)*, lymphatic filariasis *(16)*, dracunculiasis *(17)*, and maternal and neonatal tetanus *(11)*.

Validation indicators and targets should be used to monitor achievement of EMTCT over a defined period of time. The processes in place for determination of validation are designed to assess the quality and ability of the national monitoring and surveillance system to detect the large majority of MTCT cases, in public and private health facilities. Finally, they should assess the capacity of national programmes and health systems to sustain the EMTCT targets and indicators for validation.

The measure of elimination of MTCT should not be limited to just those women who are attending clinics and connected to the health-care system. The indicators and targets are specifically set to be population-level indicators. Thus, they should be measured among the entire population of pregnant women and not just those who are part of a health programme.

3.1 IMPACT INDICATORS FOR VALIDATION OF EMTCT OF HIV

Countries should have achieved and maintained for at least 1 year both of the following impact targets for validating EMTCT of HIV:

- a population case rate of new paediatric HIV infections due to MTCT of ≤50 per 100 000 live births (see Box 1); and
- an HIV MTCT rate of <5% (breastfeeding countries) OR <2% (non-breastfeeding countries).
- Direct measurement of the HIV EMTCT impact indicators or estimation through a combination of modeling and triangulation with programme data requires knowledge of the number of delivering women living with HIV, the number and percentage treated with ART, and the results of infant testing. Infant testing is based on early infant diagnosis (EID) with nucleic acid testing (most commonly with PCR, but other direct viral assays and rapid tests are becoming available) at birth, at 4–6 weeks or as soon after as possible and final status serological testing at 18 months (or 3 months after the end of breastfeeding, if beyond 18 months) *(3)*.

Box 1
Rationale for use of the infant HIV case rate

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

1. It provides a measure that is comparable across different population sizes (e.g. 500 new child HIV infections has a different level of significance in a country with 50 000 HIV-infected pregnant women than in a country with 5000 HIV-infected women).

2. It incorporates both reduction in the number of HIV-positive pregnant women (through primary prevention of HIV and reducing unintended pregnancies among women with HIV) and treatment of all HIV-positive pregnant women.

3. It is a standardized measure that can be applied across all countries regardless of their starting point, as contrasted with a percentage reduction from baseline. For example, a 90% reduction for a very high-burden country can still amount to a large number of HIV infections that represent a sizeable public health problem. By contrast, a 90% reduction in a very low-burden country may be nearly impossible to achieve, but represents a small public health problem.

The use of the transmission rate (MTCT rate) provides an additional measure of the effectiveness of the programme for preventing infant infections in pregnant women living with HIV.

With effective interventions and a high level of maternal treatment coverage, the MTCT rate of HIV can be reduced to levels well below 5% in breastfeeding settings and below 2% in non-breastfeeding settings.

Therefore, in countries where HIV-infected mothers breastfeed, a target MTCT rate of <5% at the end of breastfeeding should be achieved for validation of EMTCT of HIV.

In contrast, where HIV-infected mothers do not breastfeed, a target MTCT rate of <2% at 6 weeks postpartum (using a direct viral assay such as polymerase chain reaction [PCR]) should be achieved for validation.

The period of breastfeeding is determined by national policy and may be up to 24 months or longer in keeping with revised WHO guidelines on infant feeding in the context of HIV (18).

Both the infant HIV population case rate and the MTCT rate must be measured at the population level to reflect all pregnant women in the country and not limited to those women accessing the health system. The national case rate and MTCT rate will likely be higher than the "programme rates" if access to services is limited due to high levels of stigma, financial barriers or gaps in coverage.

3.2 IMPACT INDICATOR FOR VALIDATION OF EMTCT OF SYPHILIS

Countries should have achieved and maintained for at least 1 year the following impact target for validating EMTCT of syphilis:

- a case rate of congenital syphilis of ≤50 per 100 000 live births.

EMTCT targets use a surveillance case definition for congenital syphilis rather than a clinical case definition. A surveillance case definition 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 (Box 2). A surveillance case definition may not always be consistent with a clinical case definition, and in the case of congenital syphilis is not intended to be used by health-care providers for making a clinical diagnosis or for determining treatment.

The global surveillance case definition for congenital syphilis is given below *(13)*:

[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*

**** Adequate maternal treatment is defined as at least one injection of 2.4 million units of intramuscular benzathine benzylpenicillin at least 30 days prior to delivery.***[2,3]

OR

[2] a live birth, stillbirth or child aged <2 years 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).

Laboratory and radiographic evidence consistent with a diagnosis of congenital syphilis 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 Venereal Disease Research Laboratory (VDRL) test, or elevated CSF cell count or protein;

c. long bone radiographs suggestive of congenital syphilis (e.g. osteochondritis, diaphyseal osteomyelitis, periostitis);

d. infant with a reactive non-treponemal serology titre fourfold or more than that of the mother;

e. infant with a reactive non-treponemal serology titre less than fourfold more than that of the mother but that remains reactive ≥6 months after delivery;

2 In pregnant women with late syphilis or unknown stage of syphilis, WHO recommends benzathine penicillin 2.4 million units intramuscularly once weekly for three consecutive weeks *(6)*.

3 A woman with a past history of syphilis diagnosis and for whom previous syphilis treatment can be confirmed should be evaluated for risk of reinfection. Those without physical (e.g. ulcer, unexplained rash) or laboratory evidence of syphilis (increasing non-treponemal titre) need not be classified as having current syphilis. However, women living in high-prevalence settings or who have personal or partner behavioural risk or whose partners were not treated for syphilis may warrant evaluation for reinfection later in pregnancy. An infant born to a woman with a documented history of adequate treatment for syphilis prior to the current pregnancy, with no physical or laboratory evidence of reinfection (e.g. increasing maternal non-treponemal titre), can be excluded from the country counts of congenital syphilis cases.

f. infant with a reactive non-treponemal serology test of any titre AND any of the clinical signs listed below born to a mother with positive or unknown serology, independent of treatment; [4]

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 early clinical signs listed below;

h. for stillborn infants, maternal syphilis serostatus should be determined. Any case with a reactive maternal test should be considered a congenital syphilis case (i.e. a syphilitic stillbirth).

Clinical signs associated with congenital syphilis

Early clinical signs that may be present in an infant with congenital syphilis include non-immune hydrops, hepatosplenomegaly, rhinitis (snuffles), skin rash, pseudoparalysis of an extremity or failure to thrive or 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.

Box 2.
Rationale for use of the surveillance case definition for congenital syphilis

Congenital syphilis is underreported for many reasons:

- Access to 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. Stillbirths are often not delivered in health facilities, and providers may not realize that stillbirths are the most common adverse pregnancy outcome caused by maternal syphilis.
- 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 or entirely overlooked. Not all facilities have providers able to diagnose congenital syphilis.

A consultation convened by WHO in 2012 reached consensus on a simplified global surveillance case definition for congenital syphilis intended to promote standardization and improve the sensitivity of case reporting (19). While in some settings the surveillance case definition may overestimate cases, for monitoring the control and elimination of congenital syphilis, 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 congenital syphilis is an important measure for programmes to monitor in order to identify failures of programmes in detecting and treating syphilis-infected pregnant women early enough to prevent adverse outcomes in the fetus and infant.

4 All neonates with **reactive** non-treponemal tests should have careful follow-up examinations and repeat non-treponemal tests every 2–3 months until the test becomes **non-reactive**. Infants with a non-reactive non-treponemal test at birth and whose mothers were reactive at birth should be retested at 3 months to rule out incubating syphilis. In an infant who was NOT treated because congenital syphilis was considered unlikely, non-treponemal antibody titres should decline by age 3 months and be non-reactive at 6 months. Any infant ≥6 months of age with a reactive non-treponemal serology titre should be considered a case of congenital syphilis. Syphilis-exposed infants should receive treatment according to WHO syphilis treatment guidelines *(6)*.

3.3 FOLLOW UP OF HIV-EXPOSED INFANTS TO DETERMINE MTCT CASE RATE

Whether or not to include an exposed infant as an HIV or syphilis MTCT case is often not apparent at birth. For HIV-exposed infants, the diagnosis is complicated by the different sensitivities of different assays, timing of infection (*in utero*, intrapartum and postpartum via breastfeeding) and the presence of maternal antibody for up to 12–15 months. For EMTCT, HIV-exposed infants (i.e. infants born to mothers who are HIV seropositive) should be followed for an appropriate period to determine their final infection status:

- For **HIV-exposed infants who are not breastfed**, ruling out HIV infection is generally based on two or more negative EID virological tests (e.g. nucleic acid testing such as PCR) obtained in the first 3 months of life OR two negative HIV antibody tests from separate specimens at >6 months of age. Final serological testing for confirmation can be done at 18 months of age *(3)*.
- For **HIV-exposed infants who are breastfed**, ruling out HIV infection is based on both EID testing in the first 3 months and follow-up serological testing (e.g. at 9 months) and final antibody testing at 18 months or 3 months after the cessation of breastfeeding, whichever is later. While nucleic acid testing at any age is highly sensitive and specific to identify infection in infants, it is generally recommended to confirm a positive test result *(3)*.
- For **HIV-exposed infants, high EID coverage and cohort monitoring** are needed to provide sufficient data on infant outcomes to determine the MTCT and population case rates. While there is no required level of HIV-exposed infant testing coverage to meet validation criteria, the data on infant outcomes should be robust and provide reasonable certainty for the impact indicators. For small-population and low-prevalence countries, it is reasonable to expect EID testing to be >95%; for high-prevalence countries, it is reasonable to expect EID testing (or EID and antibody testing) to be >80%. These data can be used to characterize the outcome of infection in the infants tested, and 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 for ongoing risk of transmission through 18 months *(20,21)*.

3.4 CLINICAL FOLLOW UP OF SYPHILIS-EXPOSED INFANTS

- The surveillance case definition of congenital syphilis should be used to calculate the case rate (Section 3.2, Box 2). All **syphilis-exposed infants** should have careful follow-up examinations every 2–3 months for 6 months, regardless of maternal or infant treatment.
  - Infants with **a reactive non-treponemal test** at birth should have a repeat non-treponemal test at 3 **and** 6 months, regardless of maternal treatment. For infants who were NOT treated because congenital syphilis was considered unlikely, non-treponemal antibody titres should decline by age 3 months and be non-reactive at 6 months.
  - Infants with **a non-reactive non-treponemal** test at birth and whose mothers may have had new syphilis (e.g. high titre, or new infection on repeat screening) during pregnancy should be retested at 3 months to rule out incubating syphilis.
  - Any infant ≥6 months of age with a reactive non-treponemal serology titre should be considered a case of congenital syphilis and receive appropriate treatment. These cases should be counted towards the congenital syphilis case rate if not previously included.

3.5 PROCESS INDICATORS FOR VALIDATION OF EMTCT OF HIV AND/OR SYPHILIS

- **Population-level ANC coverage (at least one visit) of ≥95%**
- **Coverage of HIV and/or syphilis testing of pregnant women of ≥95%**

Box 3
Rationale for testing coverage

Near-universal testing for HIV and syphilis in early pregnancy is necessary to identify positive women who can benefit from services to prevent MTCT, and is the entry point for providing treatment and preventive services. This is also an underlying measure of the strength of the MCH services.

- **Antiretroviral therapy (ART) coverage of HIV-positive pregnant women of ≥95%**

Pregnant women with HIV should receive treatment according to WHO HIV treatment guidelines *(3)*.

Box 4
Rationale for HIV treatment coverage

The risk of MTCT of HIV can be significantly reduced through the provision of maternal ART as early as possible during pregnancy or preconception.

- **Treatment coverage of syphilis-seropositive pregnant women of ≥95%**

Pregnant women with syphilis should receive treatment according to WHO syphilis treatment guidelines *(6)*.

Box 5
Rationale for syphilis treatment coverage

The treatment of seropositive women with at least one dose of intramuscular benzathine benzylpenicillin at least 30 days prior to delivery is necessary to prevent transmission of syphilis to the infant and to treat early syphilis in the mother.

NOTE. Countries should follow WHO-recommended processes and algorithms for HIV *(22)* and syphilis testing *(23)* among pregnant women. Newer technologies such as dual HIV/syphilis rapid diagnostic tests may be considered in some ANC settings to improve testing coverage and reduce missed opportunities for timely treatment *(24)*.

NOTE. Countries applying for validation of EMTCT or of reaching a level on the Path to Elimination of HIV alone will be required to report syphilis indicator data, even if validation for achievement of syphilis indicators is not sought. Similarly, countries applying for validation of EMTCT or of reaching a level on the Path to Elimination of syphilis alone will be required to report HIV indicator data, even if validation of achievement of HIV indicators is not sought. This is to ensure that activities to promote dual EMTCT of both HIV and syphilis are encouraged.

Box 6
Required indicators for global validation of EMTCT of HIV and syphilis

EMTCT of HIV and syphilis impact indicators (must be achieved for at least 1 year)

- MTCT rate of HIV of <2% in non-breastfeeding populations OR <5% in breastfeeding populations
- A case rate of new paediatric HIV infections due to MTCT of ≤50 cases per 100 000 live births
- A case rate of congenital syphilis of ≤50 per 100 000 live births

EMTCT of HIV and syphilis process indicators (must be achieved for 2 years)

- ANC coverage (at least one visit) (ANC-1) of ≥95%
- Coverage of HIV and/or syphilis testing of pregnant women of ≥95%
- ART coverage of HIV-positive pregnant women of ≥95%
- Adequate treatment (see Box 5) of syphilis-seropositive pregnant women of ≥95%

In addition to careful documentation of the required indicators, countries should review additional requirements to support validation of EMTCT of HIV and/or syphilis. **Tools and checklists to assist in calculating these indicators can be found in the EMTCT programme tools *(25)***. It is important, for example, to monitor HIV incidence among women of reproductive age and syphilis seropositivity among pregnant women to gauge the effectiveness of primary prevention programmes. In addition, programmes should monitor follow-up care and treatment of infants born to HIV- or syphilis-seropositive women *(12,13)*.

Regions may identify additional indicators that may provide important information for the regional programme review and validation process. Regional indicators are not required for global validation purposes.

4 ADDITIONAL REQUIREMENTS

See online EMTCT tools for data, laboratory, programme and human rights (25).

4.1 DATA QUALITY

Similar to what is required for most other elimination/eradication initiatives, countries must have a "validation standard" monitoring and surveillance system to be eligible for validation of elimination or being on the Path to Elimination of HIV and/or syphilis. A "validation standard" system is one that can accurately assess intervention coverage (both testing and treatment) and detect a large majority of cases of MTCT of HIV and/or syphilis in a timely manner. It should be able to capture service delivery and outcome data from both the public and private health sectors, and minimize sources of error.

Countries should ensure that indicators are clearly defined within M&E and surveillance tools, and that there are standard instructions on how to capture these data. Standardized case definitions should be applied. Data quality for each of the required global EMTCT validation impact and process indicators should be assessed for completeness, accuracy, consistency and timeliness. For example, underreporting of both paediatric HIV infections and congenital syphilis is a recognized problem and should be assessed before a country can be determined to have a "validation standard" monitoring and surveillance system.

Data quality standards for validation should build on existing protocols and tools used in countries and regions for MTCT, and those used to strengthen health reporting systems and improve overall data quality. WHO guidance is available for impact measurement of EMTCT of HIV *(26)* and syphilis *(13)*. 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 *(25)*.

Population-level estimates of HIV and syphilis among pregnant women and exposed infants should be used to complement country-level programme data on service and rate indicators. Population data are available through nationally representative surveys, models or other mechanisms to adjust programme data to reflect women that are not captured in health programme data, including those women that do not attend ANC or otherwise do not have access to HIV and syphilis testing.

4.2 LABORATORY QUALITY ASSURANCE

Meeting laboratory standards is critical in the validation process. Laboratories that contribute data to the surveillance system should have:

[1] a quality management system in place to ensure that tests are procured, stored and used according to international standards, such as WHO pre-qualification or other regulatory equivalent;

[2] personnel performing the tests who have been trained in accordance with nationally recommended algorithms; and

[3] a laboratory quality assurance mechanism which is routinely and consistently applied, and verified through participation in an external quality assessment (EQA) programme for HIV and syphilis testing, in addition to internal quality assurance. An example of an overall laboratory quality assurance programme for testing is the *Stepwise Laboratory Quality Improvement Process Towards Accreditation* (SLIPTA) *(27)*. An example of an EQA programme for syphilis testing is the WHO/Centers for Disease Control and Prevention (CDC) Syphilis Serology Proficiency Programme *(28)*. CDC also provides international assistance in EQA for HIV testing *(29)*.

When a point-of-care test is used, the quality and diagnostic performance of the kits should be verified in accordance with international standards 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 test kit performance. Laboratory quality management systems should capture proficiency testing of clinical and laboratory staff to ensure the quality of testing and monitor compliance with approved algorithms to ensure appropriate diagnosis based on test results. Additional laboratory criteria for review during validation missions are included in the laboratory tool *(25)*. 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 laboratory programme. In line with existing WHO laboratory guidance, it is proposed to assess 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 (QC) of HIV and syphilis testing among pregnant women. Other aspects assessed are supply chain management, including availability of HIV and syphilis testing materials during pregnancy, labour and delivery, and postpartum, especially if breastfeeding.

[2] **Quality of tests.** This is an assessment of tests to evaluate whether they have acceptable and operational characteristics as specified by international and national organizations such as WHO, United Nations Children's Fund (UNICEF), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) and the United States Agency for International Development (USAID). This assessment includes areas such as the existence of national HIV and syphilis testing algorithms appropriate for antenatal testing, and choice of sufficiently well-performing tests that are suitable for the country's clinical settings where antenatal services take place.

[3] **Quality of testing.** This is an assessment of staff competency in general through professional licensure as technologists or appropriate training of other health-care workers, and staff proficiency in performing the tests selected.

[4] **Laboratory data management.** This is an assessment of the laboratory information management, specifically focused on a functional laboratory information system for EMTCT of HIV and syphilis.

4.3 PROGRAMME ASSESSMENT

Programme components relevant to the elimination strategy include comprehensive ANC services, HIV and syphilis testing and treatment programmes, and treatment and care for infected pregnant and postpartum women, their infants and their male partners. To verify whether the 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 *(25)*.

To achieve validation of EMTCT, countries must provide evidence that high-quality services for PMTCT of HIV and syphilis occur in both the public and non-public health sector. Countries must also provide evidence that even in the lowest-performing subnational administrative units, there is a concerted effort to deliver high-quality services for PMTCT of HIV and/or syphilis. The lowest-performing subnational administrative units may be defined in a number of ways. For example, these may be regions in the country (identified by national or regional validation teams) that perform poorly on relevant health indicators, regions with the highest disease burden, regions with marginalized populations or those where some or all of the impact and process indicators have not been met. Countries are encouraged to work with the regional validation committee or regional validation secretariat to determine an appropriate selection process for the lowest-performing subnational administrative unit. To be eligible for validation, a country does not have to meet elimination targets in all subnational units, but there must be evidence that performance in subnational units has been reviewed and that substantial efforts are being made to address low-performing units. These efforts should include outreach to impoverished, remote or marginalized populations, 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

A key requirement for validation of a country for eliminating MTCT of HIV and syphilis is that the interventions to reach the targets have been implemented in a manner consistent with international, regional and national human rights standards, have engaged the community of women living with HIV and have taken gender equality into consideration *(25)*. A number of elements have recently been promoted to evaluate HIV programmes through the lens of human rights protection, gender equality promotion and the full engagement of the community of women living with HIV *(30,31)*. These include the following principles, which are manifestations of fundamental sexual and reproductive health and rights of all women that need to be comprehensively examined for rights-based EMTCT of HIV and syphilis:

[1] non-criminalization of HIV/syphilis transmission in law and policy, and in practice;

[2] ensuring voluntary HIV and syphilis testing and treatment in law and policy, and in practice;

[3] ensuring informed consent in law and policy, and in practice;

[4] ensuring the elimination of forced, coerced and otherwise involuntary sterilization, contraception and/or abortion in law and policy, and in practice;

[5] ensuring confidentiality and privacy of HIV and health information in law and policy, and in practice;

[6] ensuring gender equality and non-discrimination in law and policy, and in practice;

[7] ensuring accountability, community engagement and participation of people affected by HIV and other key populations;

[8] ensuring availability, accessibility, acceptability and quality of services in law and policy, and in practice;

[9] ensuring access to justice, remedies and redress in law and policy, and in practice.

A tool and checklist for objectively assessing human rights, gender equality and engagement of civil society is available for use during missions to validate EMTCT or to certify countries on the Path to Elimination *(25)*.

4.4.1 Human, sexual, and reproductive health and rights

In the context of HIV programmes, relevant human rights standards and protections include: human rights in relation to autonomy in decision-making; informed consent; respect of privacy and confidentiality; and freedom from violence, abuse and coercive practices. The United Nations and regional human rights systems have in place a significant body of legal instruments, including treaties, conventions, general comments, concluding observations and case law for the protection of human rights. These include the right to enjoyment of the highest attainable standard of health ("right to health"), for all people without discrimination, among them women and children, and all people living with HIV *(31)*. At the national level, constitutions, health-care laws, patients' rights laws and other legal instruments should ensure national protection of human rights and gender equality. All women have the right to SRH services, which should be available without discrimination or recrimination. Women living with HIV face unique challenges to their sexual and reproductive health, for which specific planning, development and programme monitoring should be considered *(32)*.

4.4.2 Gender equality

Gender equality considerations are particularly pertinent in the context of vertical transmission of HIV and syphilis, as gender norms and practices can significantly shape the enjoyment of SRH and rights of women, as well as health outcomes for their children. Promoting and ensuring gender equality can significantly influence the opportunities of women and girls to access necessary information and services, make decisions about their sexuality and reproduction, and protect themselves against HIV and other STIs.

4.4.3 Community engagement

Greater involvement of people living with HIV/AIDS (GIPA) is a principle that aims to realize the human rights of people living with HIV, including their right to health, and the right to participation in decision-making processes that affect their lives *(10)*. There is consensus in the global community that engaging people living with HIV has many benefits, and that involvement should be multidimensional, including in the policy-making process, programme development and implementation, advocacy and service delivery. Engagement and participation of women living with HIV, in particular, in the formulation of health laws, policies, programmes and M&E systems that affect them helps to ensure better, more effective programming that will help women living with HIV and syphilis to stay healthy and keep their children free from HIV and syphilis. Consequently, community engagement advances efforts towards the EMTCT of HIV and syphilis.

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

Most countries in sub-Saharan Africa have reported a maternal HIV seroprevalence of >2%, some much higher, and a maternal syphilis seroprevalence of >1%. These high HIV burden countries, especially in sub-Saharan Africa, have been unable to achieve EMTCT validation due to a high HIV prevalence among pregnant women, which results in a case rate of new infections in children that is above the threshold of 50 per 100 000 live births, even if the MTCT rate of <5% is achieved. 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 congenital syphilis.

However, many high-burden countries have made substantial progress in preventing new infections of both HIV and syphilis in children. In some countries, new cases of HIV in children have been reduced by more than 80% over the past 5 years, and several high-burden countries have achieved HIV MTCT rates of <5% *(33)*. However, due to the successful scale up of ART to HIV-positive pregnant women, resulting in improved maternal health and fertility in women living with HIV, prevalence rates among women of childbearing age are likely to remain stable in the near term.

WHO, in collaboration with the Africa regional validation secretariat and with the input of the GVAC, has developed a set of criteria for recognition of the impressive achievements of high-burden countries as they progress along the Path to Elimination. This approach and the defining criteria were developed over a series of consultations with multiple countries in the African Region, which took place in late 2016 and early 2017. Countries selected a three-tier system, which recognizes stages of progress on the Path to Elimination. Each tier requires progressively increasing levels of service coverage for pregnant women and progressively lower HIV and/or syphilis case rates of new infections in children per 100 000 live births (*see* Box 7). Moving to a higher tier brings a country closer to elimination.

A country seeking certification for being on the Path to Elimination will follow the same procedure as a country requesting validation of EMTCT. Each national programme will develop a country report and submit this to the respective WHO country office. The regional validation secretariat will identify a group of independent technical experts to assist with the review of the report and, if needed, arrange a mission to verify its findings. In addition to meeting the specific criteria, countries that wish to be certified as being on the Path to Elimination must have achieved the process indicators for 2 years and impact indicators for 1 year, show that low-performing subnational units for PMTCT services (identified by national or regional validation teams) are being addressed by the country programme, have a reliable laboratory service and a high-quality M&E system. Further, the programme must show that criteria have been met while respecting human rights, ensuring gender equality, and engaging civil society in the process. Missions to verify the country report should use the same programme, laboratory, data and human rights tools *(25)* that are used for missions for validation of elimination.

Box 7 shows the impact and process indicators for achieving each of the three tiers (or levels) on the Path to Elimination. 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).

Box 7
Indicators for certification on the Path to Elimination of MTCT of HIV and/or syphilis (high-prevalence countries)

Maternal HIV prevalence >2%
Maternal syphilis prevalence >1%

	Process indicators		Impact indicators
GOLD TIER	• Antenatal care (ANC) coverage (at least one visit) (ANC-1) of ≥**95%** • Coverage of HIV and/or syphilis testing of pregnant women of ≥**95%** • Antiretroviral treatment (ART) coverage of HIV-positive pregnant women of ≥**95%** • Treatment coverage of syphilis-seropositive pregnant women of ≥**95%**	**HIV**	• Mother-to-child transmission (MTCT) rate of HIV of <2% in non-breastfeeding populations OR <5% in breastfeeding populations • A case rate of new paediatric HIV infections due to MTCT of ≤**250 cases per 100 000 live births**
		Syphilis	• A case rate of congenital syphilis (CS) of ≤**250 per 100 000 live births**
SILVER TIER	• ANC coverage (at least one visit) (ANC-1) of ≥**90%** • Coverage of HIV and/or syphilis testing of pregnant women of ≥**90%** • ART coverage of HIV-positive pregnant women of ≥**90%** • Treatment coverage of syphilis-seropositive pregnant women of ≥**90%**	**HIV**	• MTCT rate of HIV of <2% in non-breastfeeding populations OR <5% in breastfeeding populations • A case rate of new paediatric HIV infections due to MTCT of ≤**500 cases per 100 000 live births**
		Syphilis	• A case rate of CS of ≤**500 per 100 000 live births**
BRONZE TIER	• ANC coverage (at least one visit) (ANC-1) of ≥**90%** • Coverage of HIV and/or syphilis testing of pregnant women of ≥**90%** • ART coverage of HIV-positive pregnant women of ≥**90%** • Treatment coverage of syphilis-seropositive pregnant women of ≥**90%**	**HIV**	• MTCT rate of HIV of <2% in non-breastfeeding populations OR <5% in breastfeeding populations • A case rate of new paediatric HIV infections due to MTCT of ≤**750 cases per 100 000 live births**
		Syphilis	• A case rate of CS of ≤**750 per 100 000 live births**

Interventions to meet targets must have been met in a manner consistent with protecting human rights and ensuring gender equality and the engagement of civil society for certification in all tiers.

6 THE VALIDATION PROCESS

Before initiating the EMTCT validation process (or certification on the Path to Elimination), countries should be confident that they can meet the global minimum criteria as well as any specific regional requirements.

6.1 STRUCTURE AND FUNCTION OF VALIDATION COMMITTEES

6.1.1 National validation committee (NVC)

The Ministry of Health will be responsible for establishing a national validation committee (NVC) and a national validation team (NVT). The NVT is an optional body that can collect and analyze national data. The NVC and NVT should be multidisciplinary teams comprising a wide cross section of professionals from various services and programmes, such as MCH, HIV, STIs, laboratory, health systems, surveillance/monitoring, human rights, community of women living with HIV, and other civil society representatives selected by their respective constituencies. The NVC will coordinate the data collection and verification, and writing of the country report.

The WHO country office has an important role in the validation process, as this office serves as the first point of contact with the national stakeholders. The country office, in collaboration with other partners, will provide technical support to the country for the development of reports. The country office will provide support for and serve as an intermediary between the regional level and the NVC.

6.1.2 Regional validation committee (RVC)

The RVC is convened by the WHO Regional Director and its main purpose is to advise the regional secretariat as to whether a candidate country has successfully achieved the EMTCT regional targets of HIV and syphilis and can be recommended for validation.

The RVC is responsible for:

- reviewing EMTCT reports from candidate countries to make a preliminary assessment regarding compliance with regional and global criteria for validation of EMTCT of HIV and syphilis;
- requesting additional information or clarification from NVTs to facilitate this determination;
- coordinating with the RVTs to support country validation assessments;
- coordinating the preparation of the regional validation report, which will inform national and global partners whether the country meets regional and global criteria for validation; and
- collaborating with the global validation secretariat and the regional secretariat to ensure monitoring and maintenance of validation, including re-evaluation of impact and process indicators.

6.1.3 Regional validation team (RVT)

- The main purpose of the RVT is to advise on whether a candidate country has successfully achieved the criteria for EMTCT of HIV and/or syphilis, and can be recommended for validation. The RVT reviews the country reports, makes requests for clarification or missing data from the country report, which would require a revised country report, and participates in validation missions. In addition to technical expertise and sound understanding of regional and national contexts, a key criterion for members of the RVT includes the ability to express independent opinions. Should there exist affiliations with the EMTCT programmes under review, the conflict of interest is to be addressed by recusing the expert from the respective RVT. Once an RVT is convened, a team lead will be selected. The team lead will be responsible for leading deliberations on whether a country has achieved elimination and any internal or external communication. At the completion of the validation mission, the RVT will produce a validation report, which will be submitted to the RVC and then to the WHO global secretariat.

The RVT is responsible for:

- reviewing EMTCT country reports from candidate countries to make a preliminary assessment regarding compliance with regional and global criteria for validation of EMTCT of HIV and syphilis;
- requesting additional information or clarification from NVTs to facilitate this determination;
- coordinating with the regional secretariat to support country validation missions;
- coordinating the preparation of a validation report, which will inform national and global partners whether the country meets regional and global minimum criteria for validation; and
- collaborating with the global validation secretariat to ensure monitoring and maintenance of validation, including re-evaluation of impact and process indicators.

6.1.4 Global secretariat

At the global level, the secretariat is managed by WHO and is responsible for coordination of the GVAC, and development of guidance and validation tools. The global secretariat provides official notification of validation of EMTCT of HIV and syphilis to a country, and monitors the maintenance of validation status.

6.1.5 Global validation advisory committee

The GVAC is coordinated and supported by WHO at global level. This expert committee provides advice to WHO regarding validation standards, tools and processes. The GVAC reviews validation reports from either an RVC or an RVT to ensure consistency and compliance with the minimum global criteria, and provides independent advice to WHO regarding validation of candidate countries. The GVAC also provides recommendations to a country (if needed) to support ongoing monitoring and maintenance of validation.

6.2 OPERATION OF VALIDATION COMMITTEES

It is the role of the validation secretariats at regional and global levels to oversee and support the validation process. WHO headquarters and regional offices assume validation secretariat functions, in partnership with UNAIDS, UNICEF and United Nations Population Fund (UNFPA). The secretariat collaborates with key global and regional partners, as well as other bilateral and implementing agencies that support PMTCT programmes for HIV and syphilis.

Once a country has internally verified that all the key impact and process indicators have been met and the other conditions for validation satisfied, the Ministry of Health should submit a request for validation of elimination or of being on the Path to Elimination to the WHO country office and convene an NVC to assess the national programme and develop the country report.

The country report is submitted to the WHO regional office and reviewed by the appropriate RVC, an independent group convened by the regional validation secretariat (RVS). Where there is no standing RVC, the GVAC serves the function of the RVC and reviews the country report.

The RVS or RVC commissions a validation team to undertake a mission to verify the information contained in the country report using the set of standardized EMTCT tools *(25)*. Based on the review, if the RVS determines that the country is eligible for validation of EMTCT or Path to Elimination, the country report and the RVT report are submitted to the global secretariat for review by the GVAC (Figure 1).

6.3 STEPS IN THE VALIDATION PROCESS

The steps in the validation process for EMTCT (or certification on the Path to Elimination), at country, regional and global levels are outlined below and illustrated in Fig. 1 and 2.

[1] The Ministry of Health initiates a letter of request for validation of EMTCT, which is sent to the regional secretariat.

[2] The Ministry of Health establishes an NVC and an NVT (optional), which will be responsible for collection of the national data and preparation of the national validation report. This report should describe the basic structure and functions of the national programme, including the monitoring and surveillance system.

[3] An RVT is established and convened by the RVC or regional secretariat:

a. The RVT reviews the country report and conducts a desk review of the data reported by the country. These data must meet the regional and global minimum criteria for EMTCT validation.

b. The RVT will decide whether the country is ready for a full team in-depth assessment and in-country visit.

c. In-country validation visit. If the candidate country is considered ready for validation, the RVT works with the Ministry of Health, the NVT and regional secretariat to plan an in-country visit and in-depth assessment, and debriefing and review of findings.

Figure 1
Organization and roles of the secretariats and validation committees

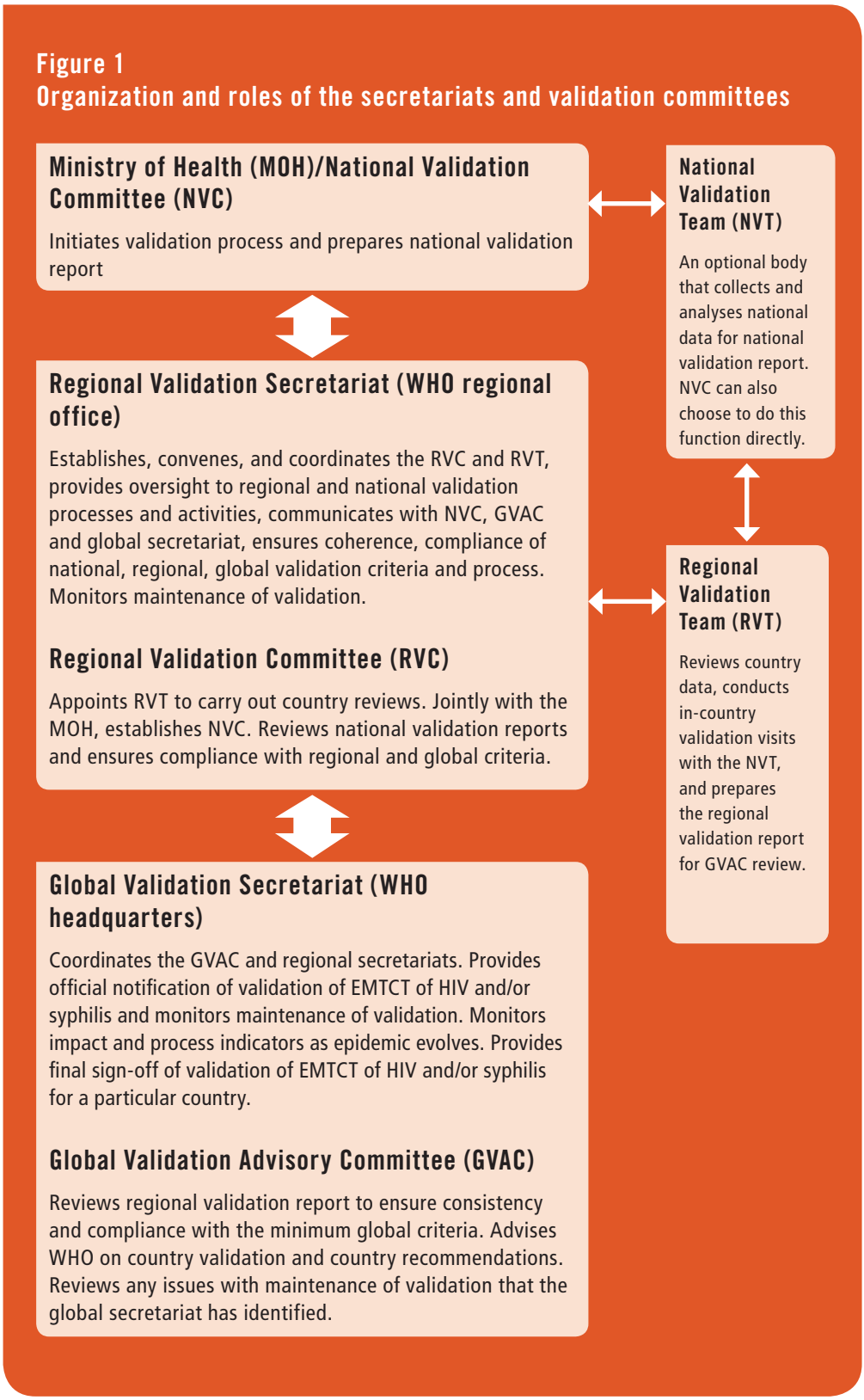

Figure 2
Summary of procedures for EMTCT of HIV and/or syphilis

Country pre-validation	• MOH submits a validation request to the regional secretariat. • MOH and the RVC jointly establish an NVC. • NVC decides whether to establish an NVT. • NVC (or NVT where active) collects, assesses, and summarizes data for national validation report. • NVC reviews national validation report and submits to the RVC.
Country validation	• RVC or RVS selects RVT for each candidate country. • RVT reviews national validation report. • RVT and NVT conduct in-country validation visit and interviews with key stakeholders. • RVT prepares and submits regional validation report to the regional secretariat.
Regional validation	• Regional secretariat convenes RVC. • RVC reviews national validation report for compliance with minimum regional and global criteria. • If approved, RVC prepares and submits regional validation report to the global secretariat. • If not approved, RVC notifies NVC and provides clear recommendations.
Global validation	• Global secretariat convenes GVAC. • GVAC reviews regional validation report for compliance with minimum global criteria. • GVAC advises WHO on validation and country recommendations.
Official validation	• Global secretariat issues letter officially notifying the candidate country of validation status and recommending follow-up actions for maintenance of validation status.
Maintenance of validation	• Global secretariat and the GVAC monitors maintenance of validation indicators through existing annual global reporting systems. • Global secretariat reports any concerns noted to RVC for follow-up and more in-depth assessment.

[4] Members of the RVT carry out the in-country assessment with the following objectives:

a. review and validate the process and impact indicators;

b. conduct an in-depth review of data sources and reports, and interview key programme stakeholders;

c. assess the design of the surveillance and monitoring system for completeness, quality and representativeness of the data;

d. assess the laboratory system for reliable quality control and assurance mechanisms, and the existence of an adequate laboratory network to support the essential services;

e. confirm the achievement of the regional and global EMTCT validation requirements in a manner that respects human rights;

f. assess the indicators and targets for reliability and integrity of data;

g. evaluate the case definitions and diagnostic algorithms to determine the reliability of the reported numbers;

h. assess whether the monitoring and surveillance system meets the "validation standard", i.e. has a national scope (both public and non-public health sectors) and is sufficiently sensitive to detect the great majority of cases of MTCT of HIV and/or syphilis;

i. assess the quality, completeness and representativeness of the data on each of the global impact and process indicators;

j. present a draft report and key findings to the RVC;

k. finalize the RVT report.

[5] The RVT report is submitted to the global secretariat at WHO, through the RVC. It is sent to the GVAC and a GVAC validation review (via Webex or direct meeting) is scheduled. The GVAC is responsible for reviewing the RVT report and advises WHO on whether the candidate country has reached elimination and should be validated.

[6] Official validation. The global secretariat (WHO headquarters) will issue a letter recognizing the candidate country's achievement of the validation of EMTCT of HIV and/or syphilis, and recommend follow-up actions for maintenance of EMTCT validation status. A validation letter or certificate is provided by the Director-General of WHO.

7 GUIDANCE ON SPECIAL CIRCUMSTANCES/SPECIAL POPULATIONS

7.1 SMALL NUMBERS OF HIV-POSITIVE AND/OR SYPHILIS-POSITIVE PREGNANT WOMEN

For countries with small populations and small numbers of HIV-positive and/or syphilis-positive pregnant women per year, national and regional validation committees may use alternative strategies to assess the MTCT rate and population case rates. In-depth review of each maternal case, and infant outcome, should be conducted and summarized in a standardized line-listing or case summary format. Data should be pooled from the prior 4 years to provide more stable estimates of MTCT and case rates. The clinical review should assess maternal treatment, infant outcome, social issues and, in cases where infant infection occurred, whether the programme had provided all appropriate measures to prevent infant infection.

If it is documented that all appropriate PMTCT measures were applied, but a transmission occurred anyway, such a case "may not count" against a country's achievement of EMTCT. In such situations of infant transmission, two members of the GVAC will be asked to perform an independent review of the cases, and present the case review to the GVAC for discussion and final decision. Examples of this situation include: a pregnant woman who was non-adherent with treatment despite appropriate programme efforts to initiate and maintain treatment (e.g. the mother elected not to take ART); a pregnant women who was lost to follow up due to migration out of the country; or a newly migrated pregnant women into the country who presented at delivery. Individual case reviews of congenital syphilis cases should also be conducted to evaluate the use of consistent and correct case definitions. This should be prioritized in situations where under- or overdiagnosis may have occurred that would affect case rates.

In summary, the country report should include a section describing how many infants were exposed, how many were infected/uninfected/of unknown status, and provide case studies for each one, including documentation of testing, treatment and adherence in the mother, breastfeeding status in the child, and determination of the final infant outcome. These data should be confirmed by the validation team during the validation mission.

7.2 TRANSIENT, MARGINALIZED AND VULNERABLE POPULATIONS

Many, if not most, countries experience challenges related to the delivery of health-care services to transient, marginalized and vulnerable populations, including migrant, internally displaced, immigrant, non-citizen residents and indigenous/aboriginal populations. Women belonging to these groups and their partners may be at higher risk for HIV or syphilis, and have relatively poorer access to health care. Vulnerable populations such as these may be disproportionately represented among pregnant women with late or no antenatal care. They may be harder to keep in follow up, and harder to reach by community outreach and contact tracing. Some may leave the country during the pregnancy or just after birth.

The country report should identify these vulnerable populations, describe the relevance of these populations to the epidemiology of HIV and syphilis in the country, describe policies related to EMTCT services for 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 and 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 and immigrants. Rates of service coverage may be lower in migrant, immigrant and other vulnerable populations but 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 transient, marginalized and vulnerable populations.

7.3 SELECTING BREASTFEEDING VERSUS NON-BREASTFEEDING HIV MTCT TARGETS

The target HIV MTCT rates for any country submitting for validation should be based on that country's national policy and practices for breastfeeding versus non-breastfeeding among HIV-positive mothers. The country report should include information on the national breastfeeding policies and protocols, including dates of implementation and degree to which national policy is followed. Validation teams should evaluate and verify this information during the country mission. The report on ANC 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 informed consent and autonomy is ensured. The country report should provide "final status" testing data (PCR or other nucleic acid amplification testing) at 6 weeks of age for HIV-exposed non-breastfed infants and at the end of 18 months (or 3 months after the end of breastfeeding, if longer than 18 months) for HIV-exposed breastfed infants to ensure that all possible infected infants are captured and recorded. Countries that are designated as non-breastfeeding must still consider each mother's choice of infant feeding practice and apply the appropriate clinical follow-up.

- For non-breastfed infants, additional data should be provided to validate the 6-week final status data (e.g. 18-month antibody data on a subgroup).
- For breastfed infants, a combination of programme and modelling data can be used, which should include EID testing (e.g. 6-week PCR testing and possibly birth testing) and final antibody testing at 18 months (or 3 months after the end of breastfeeding).

7.4 ASSESSING ANC EMTCT SERVICE COVERAGE IN NON-PUBLIC SETTINGS

In addition to public sector health services, ANC PMTCT services may be provided by private, nongovernmental organizations, faith-based organizations, correctional facilities and other non-public entities. 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 private sectors, it is expected that service coverage for EMTCT process indicators reach EMTCT targets in both the public and non-public sectors, and that data on performance of these service indicators be available to validation teams for assessment. Evaluation of EMTCT services in the private sector (i.e. non-public settings), including ANC, and HIV and syphilis testing and treatment with respect to access, delivery and payment, and how it compares to the public sector, should be included as part of the programme assessment.

8 MAINTENANCE OF VALIDATION

In countries that have been validated for the achievement of elimination and certified for being on the Path to Elimination, indicators for maintenance of elimination will be assessed every 2 years. The EMTCT levels of service coverage (process indicators) and impact criteria must remain in place to maintain validation status. Countries that fail to maintain required EMTCT-level performance of the service and impact indicators or that fail to maintain human, sexual or reproductive rights for women can lose validation status.

Maintenance of validation reports are expected to be submitted by countries every 2 years after initial validation. These reports will be submitted through the RVCs and reviewed by the GVAC and the global secretariat to verify maintenance of validation.

Experiences from other elimination and eradication programmes such as polio, maternal and neonatal tetanus, and malaria have shown that, to sustain eradication or elimination, a country requires comprehensive surveillance and monitoring systems (including among vulnerable and key populations at risk of acquiring HIV and STIs). Such strong systems are needed to provide accurate data on intervention coverage, and quickly detect changes in disease transmission trends. For MTCT of HIV and syphilis, these systems provide ongoing monitoring of the prevalence of disease in pregnant women and the coverage and effectiveness of treatment.

The global secretariat will maintain a list of countries that have achieved validation and maintain validation criteria and standards over time. A country may lose its validation status if coverage of services falls or if impact indicators such as case rate or MTCT rate exceed the global validation targets.

To maintain validation status, data should be reported through global reporting mechanisms such as the UNAIDS Global AIDS Monitoring (GAM) system. Indicators that are not captured in the GAM should be reported directly to the WHO country office.

At the time of assessment of maintenance of validation, countries will be required to prepare a report that should include data tables on validation targets (process and impact indicators for the previous 2 years). For countries with small populations and small numbers of HIV-positive and/or syphilis-positive pregnant women per year, 4 years of pooled data can be used to assess maintenance of validation. Human rights, gender equality and civil society engagement must be reassessed and included in the report at this time to ensure that there are no violations or changes in laws pertaining to this component of validation since the last validation review. Maintenance reports should include updates on any programmatic, data, laboratory and human rights recommendations provided by the GVAC at the time of validation. Maintenance reports should be submitted to the RVS, which will review the report and, if the validation criteria are still being met, will submit the report to the RVC (if applicable) and the GVAC for final review.

ANNEXES

Annex A. REQUIRED COMPONENTS OF VALIDATION REPORTS

[1] Executive summary

[2] Country context

- Geography
- Demography
- Basic health indicators, including MCH indicators
- Brief description of the NVT and goals of the review
- Epidemiological profile of HIV and/or syphilis prevalence and incidence trends in the general population and in ANC clinics
- HIV and syphilis prevalence trends in the general population, by age group and sex
- HIV and syphilis prevalence trends in the antenatal population, by age group
- Modes and drivers of HIV transmission
- Other information, e.g. pregnancy trends and rates; overall prevalence of HIV and syphilis
- Stillbirth trends and contributing factors

[3] Description of the health systems present in the country. This should include specifics on

- Provincial and district health services;
- Health-care needs and access for transient populations, including: internally displaced and stateless persons, refugees, migrant workers, immigrants, non-citizens and other marginalized populations;
- Laboratory services (MCH, HIV, family planning, public and non-public);
- Case definitions used for (i) HIV diagnosis in adults and infants, (ii) congenital syphilis, (iii) syphilis diagnosis in adults.

[4] Methodology and use of tools and checklists to evaluate key areas:

- Data verification and impact assessment, including sources of data, modelling and triangulation;
- Assessment of programmes and services;
- Laboratory assessment, including EQA, HIV and syphilis testing in pregnant women, EID;
- Assessment of human rights, gender equality and civil society engagement.

[5] Limitations of evaluation methods

[6] Key findings

- Country context for assessing the EMTCT programme
- Report on the key elimination indicators. What systems and data sources were used for the EMTCT process and outcome data?

- Overall achievements, national level, subnational levels
- Assessment of strengths for sustaining EMTCT
- Potential risks to sustaining EMTCT.

[7] Describe the following:

- National HIV EMTCT policies and programme
- National syphilis EMTCT policies and programme
- National breastfeeding policy, in general and for HIV-infected women. Choices women are given and if they are counselled on the risks and benefits of breastfeeding with and without formula. Are HIV-infected women offered universal lifelong ART?
- Are women living with HIV offered universal lifelong ART? Evidence for maintenance on treatment.
- Status of EMTCT services
  - What proportion of ANC and delivery services are public versus non-public, and are services similar in each system?
- Equity of EMTCT services
  - Are women living with HIV involved in national planning and evaluation of EMTCT services?
  - Are there laws and policies that force HIV and syphilis testing and treatment?
  - Are there laws and policies in place that criminalize HIV transmission?
  - Is stigma in facilities addressed?
  - Are there reports of human rights abuses, e.g. Forced testing, forced birth control/ sterilization or forced termination of pregnancy, and is there due diligence to identify and address such abuse?
- Consistency of achievements across geographical areas
  - How was the lowest-performing subnational unit identified?
  - Report specific indicators in that lowest-performing subnational unit
  - If indicators in the lowest-performing subnational unit do not meet validation criteria, what evidence is there that the programme is actively seeking to address inequities?
- Completeness and representativeness of data used in EMTCT indicators
  - How are coverage and impact indicators determined? Programme data must be used to model the reliability of the annual HIV and congenital syphilis rate impact indicator.
- Description of data inputs used for any model-based estimates of EMTCT of HIV and syphilis impact indicators, including how these inputs were measured to ensure that they are population based.

In addition to the above report components, there are several data tables that are required. ***See online national validation report (country report) and regional validation report templates (25).***

Annex B. INDICATORS TO SUPPORT VALIDATION OF EMTCT OF HIV AND/OR SYPHILIS

Indicators
1. Shared Indicators
1.1 ANC 1—Percentage of pregnant women visiting ANC clinic at least once
1.2 ANC 4—Percentage of pregnant women visiting ANC clinic at least four times
1.3 Percentage of pregnant women with early first ANC visit (first or second trimester)
2. Congenital syphilis
Impact Indicators
2.1 Congenital syphilis rate
2.2 Stillbirth rate
2.3 Percentage of stillbirths attributable to maternal syphilis
Other Programme Indicators
2.4 Percentage of ANC attendees tested for syphilis at least once
2.5 Percentage of ANC attendees tested for syphilis • at the first visit • during first trimester of pregnancy • at any point during pregnancy
2.6 Percentage of ANC attendees seropositive for syphilis
2.7 Percentage of syphilis-seropositive ANC attendees who receive adequate treatment
2.8 Of infants born to syphilis-seropositive women, the percentage who receive adequate treatment
2.9 Estimated percentage of all syphilis-seropositive pregnant women who receive treatment by 24 weeks
2.10 Country has a national congenital syphilis policy (Y/N)
2.11 Percentage of syphilis-seropositive ANC attendees whose partners are appropriately treated
2.12 Percentage of ANC clinics routinely testing for syphilis
2.13 Percentage of clinics that have experienced a stock-out of syphilis testing materials in the last 6 months
2.14 Percentage of clinics that have experienced a stock-out of benzathine penicillin in the last 6 months

Annex B. INDICATORS TO SUPPORT VALIDATION OF EMTCT OF HIV AND/OR SYPHILIS (continued)

Indicators	
3. HIV	
Impact Indicators	
3.1	• Number of new child HIV infections • Case rate: new paediatric HIV infections due to MTCT per 100 000 live births
3.2	MTCT (population rate, based on final infection status)
Other Programme Indicators	
3.3	New HIV infections in women ages 15–49 years
3.4	Unmet need for family planning (all women)
3.5	Unmet need for family planning (HIV-positive women)
3.6	Percentage of pregnant women who know their HIV status
3.7	Percentage of pregnant women attending ANC whose sexual partners were tested for HIV in the last 12 months
3.8	Seroconversion during pregnancy and post partum period
3.9	Percentage of HIV-positive pregnant women who received ARV drugs to reduce MTCT, disaggregated by ARV regimen
3.10	Percentage of infants born to HIV-positive women receiving ARV prophylaxis for prevention of MTCT in the first 6 weeks
3.11	Percentage of infants born to HIV-positive women who are provided with ARVs to reduce the risk of HIV transmission during breastfeeding
3.12	Percentage of infants born to HIV-positive women receiving a virological test for HIV within 2 months of birth
3.13	Percentage of infants born to HIV-positive women started on co-trimoxazole prophylaxis within 2 months of birth
3.14	Percentage of pregnant women (and breastfeeding women in settings with breastfeeding of HIV-exposed infants) known to be alive and on treatment 12 months after ART initiation.
3.15	Outcomes for birth cohort of HIV-exposed infants at 18 months (in settings where national guidelines support breastfeeding of HIV-exposed infants)
3.16	Health facility availability • Number and percentage of health facilities providing ANC services • Number and percentage of health facilities providing ANC services that also provide ART • Number and percentage of health facilities that offer paediatric ART • Percentage of health facilities that provide virological testing services (e.g. polymerase chain reaction, PCR) for diagnosis of HIV in infants on site or from dried blood spots (DBS)

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