GUIDANCE

GLOBAL GUIDANCE ON

CRITERIA AND PROCESSES FOR VALIDATION:

Elimination of Mother-to-Child Transmission of HIV and Syphilis

MONITORING AND EVALUATION

World Health Organization

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FOREWORD

Several countries are poised to validate the elimination of mother-to-child transmission (EMTCT) of HIV and/or syphilis as a public health problem; this will be a sentinel health system accomplishment for those countries. This global guidance document reflects the World Health Organization's commitment to facilitating these national validation efforts now and beyond 2015, as WHO places high priority on EMTCT of HIV and syphilis. As we celebrate making EMTCT of HIV and syphilis a realistic public health goal, we should remember a few key points.

We welcome the revitalised global interest in this and other maternal, newborn, and child health (MNCH) issues. We applaud the strong political will by countries to support the United Nations Secretary General's Global Strategy for Women's and Children's Health and to dedicate significant resources and attention towards achieving the Millennium Development Goals for HIV, reproductive health, and MNCH (MDGs 4, 5 and 6). We are also grateful to our United Nations partners—the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Population Fund (UNFPA), and the United Nations Children's Fund (UNICEF)—as well as our other partners, for their support in preparation of this global guidance document and their consistent efforts in the EMTCT effort worldwide.

However, while EMTCT of HIV and syphilis is on the horizon, it is not an "easy win". Countries are in different phases of their elimination of MTCT of HIV and syphilis efforts, with several yet to begin. We must continue to strengthen the capacity of health systems worldwide to prevent HIV and syphilis infection in the general population, including women of reproductive age, by implementing efficacious MTCT interventions and point-of-care syphilis testing and treatment strategies; delivering appropriate counselling for women and their partners; and encouraging safe delivery and infant feeding practices—all key components of these programmes. Success in all countries depends on the continued dedication from experts in HIV, syphilis, health policy, monitoring and evaluation, programme implementation and management, as well as from our civil society partners. We were delighted to work with many of these colleagues to develop the processes and criteria detailed in this document and we continue to depend on their expertise and leadership to make this programme a success.

Importantly, this document fills a critical gap by providing internationally standardized processes and criteria to validate EMTCT of HIV and syphilis. While the guidance document's strong emphasis on country-led accountability, analytic and programmatic rigour, and multi-level collaboration may be a challenge, we are convinced that setting the bar high will result in the best results for all, in particular the women and children at risk from HIV and syphilis.

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We thank our partners, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Population Fund (UNFPA), and the United Nations Children's Fund (UNICEF) for their support in preparation of this global guidance document. We also express our gratitude to our technical advisers and external reviewers for their invaluable contributions. In particular, we thank the experts in HIV, syphilis, health policy, monitoring and evaluation, programme implementation and management, and the civil society representatives who participated in the June 2012 'Global consultation on criteria and processes to validate the elimination of mother-to-child transmission of HIV and congenital syphilis' in Ferney-Voltaire, France, to discuss the criteria and processes for the dual elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. Furthermore, we are grateful for the input received from the countries who participated in the pilot exercises to develop processes and criteria for validation of EMTCT prior to the consultation: Botswana, Cambodia, Kazakhstan, Malaysia, Moldova, Saint Lucia, South Africa, and Sri Lanka. We thank the World Health Organization (WHO) regional advisors and technical staff for HIV, STI, and HIV Strategic Information for their wisdom and contributions. The experience in the regions, especially in the Americas, has been of great assistance in guiding development of the global process.

ABBREVIATIONS AND ACRONYMS

ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral (medication)
DBS	dried blood spot
EMTCT	elimination of mother-to-child transmission (of HIV and/or syphilis)
GVC	global validation committee
HIV	human immunodeficiency virus
M&E	monitoring and evaluation
MCH	maternal and child health
MNTE	maternal and neonatal tetanus elimination
MOH	Ministry of Health
MTCT	mother-to-child transmission (of HIV and/or syphilis)
NVC	national validation committee
NVT	national validation team
PCR	polymerase chain reaction
PMTCT	prevention of mother-to-child transmission
RVC	regional validation committee
RVT	regional validation team
STI	sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization

EXECUTIVE SUMMARY

The global community has committed itself to eliminating mother-to-child transmission (MTCT)[1] of HIV and syphilis as a public health priority. The initiative to eliminate mother-to-child transmission (EMTCT) of HIV and syphilis focuses on a harmonized approach to improving health outcomes for mothers and children. The global community has set international and regional goals, and countries are scaling up programmes towards EMTCT of HIV and syphilis.

The *Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive* provides the foundation for the country-led movement. The plan focuses on a series of specific policy and programmatic measures that countries will take to ensure rapid progress towards elimination of new HIV infections in children by 2015. In addition, in 2007 WHO launched an initiative for the global elimination of congenital syphilis, outlined in *The global elimination of congenital syphilis: rationale and strategy for action*. Initiatives in regions such as the Americas, Asia and the Pacific, and Africa have approached control of MTCT of HIV and syphilis as an integrated process.

The rationale for the elimination of MTCT of HIV and syphilis is that dual elimination will help to improve a broad range of maternal and child health (MCH) outcomes and also directly contribute to the Millennium Development Goals (MDGs), specifically MDGs 4 and 5, which aim to reduce child mortality and improve maternal health, and MDG 6, which aims to reduce the spread of HIV, malaria, and other diseases.

Additionally, the similarity of the control interventions necessary to prevent transmission of HIV and syphilis in pregnancy adds to the feasibility of such an integrated approach to the elimination of MTCT of both diseases. Indeed, this integrated approach is necessary to improve the efficiency and quality of MCH services and to offer women more comprehensive primary care services. However, activities in any specific country for dual elimination of MTCT of HIV and syphilis will be greatly influenced by differences in HIV and syphilis epidemiology and differences in service delivery models and coverage of health services.

Currently, there are no internationally standardized processes and criteria to validate EMTCT of HIV and syphilis. As the global community prepares to assess progress towards global health goals in 2015, standardized processes and criteria are needed to assess and validate EMTCT of HIV and syphilis, and to plan beyond 2015. These processes and criteria need to apply across widely varying epidemiologic and programmatic contexts. 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 elimination of MTCT of HIV, syphilis, or both.

This document outlines minimum global processes and criteria for validation of EMTCT of HIV and/or syphilis in a country; provides a description of global EMTCT validation targets and indicators; explains the operation of validation committees and secretariats; and reviews the

1 The term "congenital syphilis" has traditionally been used to describe the adverse outcomes of syphilis infection in pregnancy. However, expert consensus from a global consultation in 2012 suggested that, whenever possible, the term "mother-to-child transmission of syphilis" should be used in place of "congenital syphilis" in order to increase awareness of the full spectrum of adverse outcomes, including stillbirths, neonatal deaths, premature and low birth weight infants, as well as deformities at birth.

validation procedure itself, including maintenance of validation status. This document is intended for use by national, regional, and global validation committees for EMTCT of HIV and/or syphilis, national AIDS and sexually transmitted infection (STI) programme managers, maternal and child health programme managers, monitoring and evaluation (M&E) officers, policy-makers and staff of technical agencies, and international partners involved in supporting initiatives for EMTCT of HIV and/or syphilis.

The minimum EMTCT **impact** targets are:

- for HIV, ≤50 new paediatric infections per 100 000 live births and a transmission rate of either <5% in breastfeeding populations or <2% in non-breastfeeding populations;
- for syphilis, ≤50 cases of congenital syphilis per 100 000 live births.

Specific levels of service delivery also need to be met to accomplish EMTCT of HIV and syphilis. There are four **process** targets:

[1] antenatal care coverage (at least one visit) of ≥95%

[2] coverage of HIV and/or syphilis testing of pregnant women of ≥95%

[3] antiretroviral treatment coverage of HIV-positive pregnant women of ≥90%

[4] treatment of syphilis-seropositive pregnant women of ≥95%.

Countries can apply for validation of EMTCT of HIV and/or syphilis when they determine that they have met the impact targets for one year and the process targets for two years and that EMTCT has been achieved in at least one of the lowest-performing sub-national administrative units. A national team will collect data and prepare a report for review by a regional validation committee. The regional validation committee will assign a regional validation team to work with the country to review the quality of reported data. After validation, the request will be reported to the global validation committee. Regional and global validation committee functions will be performed by WHO Regional Offices and Headquarters, in partnership with UNAIDS, UNFPA and UNICEF. Subsequently, WHO headquarters will monitor maintenance of EMTCT of HIV and syphilis annually through routine global reporting mechanisms already in place.

As experience is gained through the establishment of the global and regional validation processes, additional guidance and tools will be provided to complement these initial minimum global standards.

1 INTRODUCTION

Mother-to-child transmission (MTCT) of HIV is an important contributor to HIV transmission. In 2012 an estimated 260 000 children were newly infected with HIV, and an estimated 3.3 million children were living with HIV (*1*).

MTCT of HIV occurs when an HIV-positive woman passes the virus to the baby during pregnancy, labour and delivery, or after delivery through breastfeeding. Without prophylactic 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 (*2*). HIV infection of infants creates a life-long chronic condition that potentially shortens life expectancy and contributes to substantial human, social, and economic costs.

Primary prevention of HIV, prevention of unintended pregnancies, effective access to testing, counselling, antiretroviral therapy (ART), safe delivery practices, and appropriate infant feeding practices[2] (including access to antiretroviral drugs to prevent HIV transmission to infants) all contribute to prevention of mother-to-child transmission (PMTCT) and also reduce child mortality.

Syphilis is transmitted sexually and across the placenta during pregnancy. If the disease remains untreated, adverse pregnancy outcomes are frequent. Indeed, over half of women with active syphilis will have a stillbirth, perinatal death, pre-term or low-birth-weight infant, or serious neonatal infection (*3*). Maternal syphilis screening early in pregnancy and prompt treatment of seropositive mothers with intramuscular benzathine penicillin or another effective regimen cures syphilis in both mother and infant and prevents most complications associated with MTCT of syphilis.

Achieving EMTCT goals will directly contribute to attainment of Millennium Development Goals (MDGs), particularly MDGs 4 and 5, which aim to reduce child mortality and improve maternal health, and MDG 6, which aims to reduce the spread of HIV, malaria, and other diseases. The *Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive* (*4*) and *The global elimination of congenital syphilis: rationale and strategy for action* (*5*) call for elimination of MTCT by 2015. Activities and initiatives in regions such as the Americas (*6*), Asia and the Pacific (*7*), and Africa (*8*) towards dual elimination of MTCT of HIV and syphilis have drawn attention to the need for standardized criteria and processes to validate EMTCT of HIV and syphilis.

Activities for dual elimination of MTCT of HIV and syphilis will be greatly influenced by (a) differences in HIV and syphilis epidemiology, (b) differences in service delivery models, and (c) coverage of health services. The similarity of the control interventions necessary to prevent transmission of HIV and syphilis in pregnancy makes it feasible to use an integrated approach to eliminate MTCT of both diseases and validate EMTCT. Indeed, this integrated approach can strengthen health systems, via improving the integration, efficiency, and quality of HIV and STI

2 National authorities should decide which infant feeding practice—namely, breastfeeding with antiretroviral drugs or avoidance of all breastfeeding—is more appropriate to promote and support in local health systems in order to improve HIV-free survival of infants born to HIV-infected mothers. This decision should follow consideration of population access to safe water and sanitation, availability of quality health services to treat child illnesses, the prevalence of under nutrition, and major causes of infant and child mortality.

programming within maternal and child health (MCH) prevention, treatment, and care services. Accordingly, EMTCT of HIV and syphilis can contribute to the improvement of a broad range of MCH outcomes.

Elimination is defined as reduction to zero of the incidence of disease or infection in a defined geographical area (*9*). However, because both HIV and syphilis remain a public health issue and PMTCT measures are highly but not 100% effective, currently it is not feasible to reduce MTCT of either infection to zero. Therefore, the goal for EMTCT initiatives is to reduce MTCT of HIV and syphilis to a very low level, such that it is no longer a public health problem (*9*).

The term "validation" is used to attest that a country has successfully met criteria for EMTCT of HIV and/or syphilis at a specific point in time. "Validation of EMTCT of HIV and/or syphilis" implies that countries will also need to maintain ongoing, routine, effective programme interventions and quality surveillance systems to monitor EMTCT of HIV and/or syphilis.

Efforts to eliminate MTCT of HIV and syphilis are in different stages in different countries. As part of its continued commitment to achieving MDG 4 and 5 in the post-2015 context, the World Health Organization (WHO), with the Joint United Nations Programme on HIV-AIDS (UNAIDS), the United Nations Population Fund (UNFPA) and the United Nations Children's Fund (UNICEF) and other international partners, will continue to support countries' efforts to scale up and improve programmes. Accordingly, countries may choose to validate EMTCT of HIV, syphilis, both or neither, depending on the progress of national EMTCT efforts.

This document is a result of a consultative process led by WHO, with support from UNAIDS, UNFPA and UNICEF, to come to consensus on processes and criteria for validation of EMTCT of HIV and/or syphilis across both high- and low-prevalence settings. For this purpose, eight countries conducted pilot exercises, and in 2012 WHO convened a meeting involving more than 70 participants with expertise in PMTCT of HIV and syphilis, health policy, monitoring and evaluation (M&E), programme implementation and management, and civil society.

This document reflects the input from that consultative process. It is intended for national, regional, and global validation committees for EMTCT of HIV and/or syphilis, national AIDS and sexually transmitted infection (STI) programme managers, MCH programme managers, M&E officers, policy-makers and staff of technical agencies, and international partners involved in supporting initiatives for EMTCT of HIV and/or syphilis. This document describes the key criteria and processes for validation of EMTCT of HIV and/or syphilis, including:

- global minimum targets and indicators for validation of EMTCT of HIV and/or syphilis
- an outline of the validation process
- requirements for maintenance of validation status.

The criteria and processes outlined here are intended to be global minimum standards for validation of EMTCT of HIV and/or syphilis. Global minimum standards allow harmonization and consistency among regions to ensure the credibility of the validation process. WHO anticipates that these criteria and processes may evolve as programmes evolve and experience with validation grows in countries. Consequently, regions have the freedom to establish additional criteria and processes that go beyond these global standards. Finally, it is important to note that while many countries are not able to meet the validation criteria at this time, they can still serve as goals to which these countries can aspire for 2015 and beyond.

2 CRITERIA FOR EMTCT OF HIV AND/OR SYPHILIS

Achieving EMTCT of HIV and/or syphilis will depend on the prevalence of disease, the extent of antenatal and other sexual, reproductive, maternal, and child health service coverage, and whether key populations with high transmission risk can access health services. Successful national level EMTCT of HIV and/or syphilis is intended to promote sustainable improvements in public health; develop health services infrastructure, well-trained staff, and high quality monitoring/surveillance systems; and enhance coordination among countries undergoing the validation process, partners, and potential funding sources (*10*).

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 monitoring and evaluating programme achievement;
- to ensure that EMTCT of HIV and/or syphilis has been achieved;
- to strengthen national monitoring, coverage, and quality of HIV and/or syphilis interventions in MCH services;
- to measure global progress.

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

- Transmission of HIV and syphilis generally takes place directly from person-to-person, without a vector or intermediary stage.
- HIV and syphilis infection can be asymptomatic, meaning that detection is often delayed, depending on the initiative of the individual and/or the capacity of the health system to promote and facilitate early detection.
- To date there is no cure for HIV infection. However, antiretrovirals (ARVs) can extend and improve life and greatly reduce the risk of transmission, including transmission from mother to child.
- Syphilis infection can be cured with intramuscular injection of benzathine penicillin or other effective regimen.

The following strategies are important components of successful EMTCT programmes:

- interruption of transmission through timely identification and appropriate treatment of pregnant women infected with HIV or syphilis, their sexual partners, and their infants;
- reduction of 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 pregnant 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.

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

The goal of initiatives for EMTCT of HIV and syphilis 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 (*9*). The same principle is used in elimination programmes for several other diseases including leprosy, onchocerciasis, lymphatic filariasis, dracunculiasis, measles, and maternal and neonatal tetanus.

Validation indicators and targets should be used to monitor achievement of EMTCT over a defined period of time and should measure the quality and ability of a monitoring and surveillance system to detect the vast majority of MTCT cases, in public and privately run health facilities. Finally, they should assess the capacity of national programmatic and health systems to sustain the EMTCT targets and indicators for validation.

3.1 IMPACT INDICATORS AND TARGETS FOR VALIDATION OF EMTCT OF HIV

The *Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive* and the corresponding *Global monitoring framework and strategy for the global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive* outline 10 targets for the EMTCT initiative—two overall targets, six targets related to the four prongs of the PMTCT, and two child-related targets (*4*, *10*) (Box 2).

It is essential that the minimum global targets for validating EMTCT of HIV capture the effects of all four prongs of PMTCT, build on the Global Plan targets, and are applicable across high- and low-prevalence epidemics. Global targets should also allow for comparisons among countries and provide a long-term, fixed end-point that all countries can strive for.

Countries should achieve both of the following targets for validating EMTCT of HIV:

- a case rate of new paediatric HIV infections due to MTCT ≤50 per 100 000 live births; and
- MTCT rate of HIV of <5% in breastfeeding populations **OR** MTCT rate of HIV of <2% in non-breastfeeding populations.

Rationale for use of case rate

The use of a 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 5 000 HIV-infected pregnant women).

[2] It incorporates the concept for EMTCT to both reduce the number of HIV-positive pregnant women (through primary prevention of HIV and reducing unintended pregnancies) and to treat most HIV-positive pregnant women (e.g. identifying and treating every HIV-positive pregnant woman is not enough if HIV incidence is high).

[3] It is a standardized measure that applies across all countries regardless of their starting point, as contrasted with reductions from different baselines (e.g. a 90% reduction for a very high burden country can still amount to a large number of HIV infections, whereas a 90% reduction in a country with fewer than 10 new paediatric HIV infections may be impossible to achieve).

With effective interventions and high levels of coverage the MTCT rate of HIV can be reduced to levels below 5% in breastfeeding populations and below 2% in non-breastfeeding populations. Therefore, in countries where HIV-infected mothers breastfeed, a target MTCT rate of <5% transmission should be achieved for validation of EMTCT of HIV; in contrast, where mothers do not breastfeed, a target MTCT rate of <2% transmission should be reached for validation of EMTCT of HIV.

For countries with small numbers of HIV+ pregnant women per year, validation committees may use alternative strategies to assess the MTCT rate, such as pooling data from multiple years and/or conducting in-depth investigation of each case of vertical transmission. In such small population settings, if it is documented that all possible PMTCT measures were applied, but transmission occurred anyway, such a case should not count against a country's achievement of elimination of MTCT of HIV as a public health problem.

3.2 IMPACT INDICATOR AND TARGET FOR VALIDATION OF EMTCT OF SYPHILIS

Technical consultations convened by WHO between 2007 and 2010 on monitoring and evaluation of the elimination of congenital syphilis identified a set of 3 core and 12 additional impact and process indicators that were considered important for efforts to prevent syphilis in pregnant women and monitor elimination of congenital syphilis (*11*).

In 2012, through the global process to identify validation criteria and processes, experts reached consensus that, to assess and validate the impact of efforts to eliminate MTCT of syphilis, it is important to monitor the congenital syphilis rate. Validation should be based on a global surveillance case definition for congenital syphilis. Such a definition is intended to standardize the reporting of similar cases across health facilities and at various levels of the health system—sub-national, national, and international. It is not intended for clinical management. Countries may use their national case definition for validation purposes, provided it is consistent with the global surveillance definition.

The global surveillance case definition for congenital syphilis is defined as:

- a stillbirth, live birth, or fetal loss at >20 weeks of gestation or >500 grams to a syphilis-seropositive mother without adequate syphilis treatment; **OR**
- a stillbirth, live birth, or child aged <2 years with microbiological evidence of syphilis infection.[3]

The target for validating EMTCT of syphilis is:

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

Rationale for use of congenital syphilis rate

The congenital syphilis rate is the most widely used measure of the adverse outcomes of syphilis infection in pregnancy. Although diagnosis of congenital syphilis can be challenging, it is essential to monitor in order to identify failures of programmes to eliminate MTCT of syphilis.

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

For validation of EMTCT of HIV and/or syphilis, the following process indicators and targets must be attained:

[1] **Antenatal care (ANC) coverage (at least one visit) of ≥95%**

3 Microbiological evidence of congenital syphilis includes any one of the following:
- demonstration by dark field microscopy or fluorescent antibody detection of *T. pallidum* in the umbilical cord, the placenta, a nasal discharge or skin lesion material;
- detection of *T. pallidum*-specific IgM;
- infant with a positive non-treponemal serology titre ≥ fourfold above that of the mother.

Rationale: Elimination targets for MTCT of HIV and syphilis cannot be attained unless ANC services are universal or nearly universal. If high ANC coverage is not attained, many of the pregnant women at greatest risk for HIV and syphilis infection will not receive critical services to prevent MTCT of HIV and syphilis including testing and treatment if positive.

[2] **Coverage of HIV and/or syphilis testing of pregnant women of ≥95%**

Rationale: Near-universal testing for HIV and syphilis in early pregnancy is necessary to identify women who can benefit from services to prevent MTCT and is the entry point for providing treatment and preventive services.

[3] **Antiretroviral (ARV) coverage of HIV-positive pregnant women of ≥90%**

Rationale: The risk of MTCT of HIV can be significantly reduced through the provision of an effective ARV regimen.

[4] **Treatment of syphilis-seropositive pregnant women of ≥95%**

Rationale: The treatment of seropositive women with at least one dose of intramuscular benzathine penicillin or other effective regimen is necessary to prevent transmission of syphilis to the infant and to treat primary or secondary syphilis in the mother. It is recognized that prevention of MTCT of syphilis is most effective before the end of the first trimester. This indicator should be complemented with assessment of what proportion of women receive early ANC and are treated early in pregnancy as part of the validation data quality assessment process.

Box 1 summarizes the global minimum required impact and process indicators for validation of EMTCT of HIV and/or syphilis.

Box 1
Required indicators for global validation of EMTCT of HIV and/or syphilis

HIV
Impact indicators
Case rate of new paediatric HIV infections due to mother-to-child transmission (MTCT) of HIV of ≤50 cases per 100 000 live births; **AND**
MTCT rate of HIV of <5% in breastfeeding populations **OR** MTCT rate of HIV of <2% in non-breastfeeding populations
Process indicators
Antenatal care (ANC) coverage (at least one visit) of ≥95%
Coverage of pregnant women who know their HIV status of ≥95%
Antiretroviral (ARV) coverage of HIV-positive pregnant women of ≥90%

Congenital syphilis
Impact indicator
Case rate of congenital syphilis ≤50 cases per 100 000 live births
Process indicators
ANC coverage (at least one visit) of ≥95%
Coverage of syphilis testing of pregnant women of ≥95%
Treatment of syphilis-seropositive pregnant women ≥95%

In addition to careful documentation of the required indicators, countries should review the full list of indicators to support validation of EMTCT of HIV and/or syphilis (see Annex A), as such indicators are important for assessing a national programme.

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 (*10*, *11*).

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.

Box 2
The Global Plan and Validation of EMTCT of HIV and Syphilis

The *Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive* covers all low- and medium-income countries, with a focuse on 22 priority countries where 90% of global mother-to-child transmission of HIV occurs: Angola, Botswana, Burundi, Cameroon, Chad, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, South Africa, Swaziland, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

It has 10 targets—2 overall targets, 2 child health targets, and 6 targets, all which are related to the four prongs of PMTCT.

The two overall global targets are:
Global target 1: Reduce the number of new HIV infections among children by 90% by 2015
Global target 2: Reduce the number of HIV-associated deaths to women during pregnancy, childbirth or puerperium by 50% by 2015.

The other eight targets are:
Child target: Under-5 deaths due to HIV
Child target: ART coverage among children
Prong 1 target: New HIV infections in women age 15–49
Prong 2 target: Unmet need for family planning
Prong 3 target 3.1: Mother-to-child transmission of HIV
Prong 3 target 3.2: Maternal ARV coverage
Prong 3 target 3.3: Breastfeeding ARV coverage
Prong 4 target: ART coverage among pregnant women

The 22 countries are working towards these targets and about a third of them are already halfway towards Global target 1. However, even if they reach this target, some countries will still have a large number of new HIV infections among children after 2015, albeit reduced by 90%. The next milestone for a country that achieves the Global Plan goal will therefore be achieving validation of EMTCT of HIV and syphilis, as outlined in this document. The criteria for validation are more stringent, and countries meeting them would have eliminated MTCT of HIV and/or syphilis to such a degree that they are no longer a public health problem for children. Therefore this document provides a useful framework for the 22 priority countries once they reach their Global Plan goals, as well as for other countries and provides a framework beyond 2015.

4 DATA QUALITY ASSESSMENT FOR VALIDATION OF EMTCT OF HIV AND/OR SYPHILIS

Similar to what is required for some other elimination/eradication initiatives,[4] countries must have a "validation standard" monitoring and surveillance system to be eligible for validation of EMTCT of HIV and/or syphilis. A "validation standard" system is one that can accurately assess intervention coverage and detect the vast 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 systematic bias.

Countries should ensure that indicators are clearly defined and that there are standard instructions on how to formulate them. 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, under-reporting 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 currently used in countries and regions to strengthen health reporting systems and improve overall data quality. General data quality assurance guidance for MTCT of HIV can be further developed[5] to be applicable to the validation process. WHO guidance is available for impact measurement of EMTCT of HIV (*12*) and syphilis (*11*). Additionally, laboratory standards are an important component to be verified in the validation process.

Operational tools and a checklist to ensure a minimum standard for data quality for the impact and process indicators will be developed as part of the required documentation in the validation process.

4 The criteria for "certification standard monitoring" of polio, for example, are available at: http://www.polioeradication.org/Dataandmonitoring/Surveillance.aspx.

5 WHO works with the Monitoring and Evaluation Working Group of the Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children.

5 THE VALIDATION PROCESS

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.

5.1 QUALIFYING REQUIREMENTS FOR VALIDATION

As discussed at the 2012 global validation consultation, 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.[6]

[2] Evidence that EMTCT of HIV and/or syphilis has been achieved in at least one of the lowest-performing sub-national administrative units. The lowest-performing sub-national 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 (MNTE) programme (*13*). 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 sub-national administrative unit.

[3] Existence of an adequate "validation standard" national monitoring and surveillance system that can capture process and 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.

5.2 OPERATION OF VALIDATION COMMITTEES

To ensure the credibility of the validation process, it is the role of the validation secretariat to assume ultimate responsibility for this global effort via oversight of the entire validation process. WHO Headquarters and Regional Offices assume validation secretariat functions, in partnership with UNAIDS, UNFPA and UNICEF. The secretariat will collaborate with other key global partners and other bilateral and implementing partners for EMTCT of HIV and syphilis. It is the responsibility of the global validation secretariat to ensure that linkages and adequate representation among and within the national, regional, and global validation committees are maintained and that the impact and process indicators are re-evaluated as the epidemics evolve. The global secretariat will appoint the global validation committee (GVC) and will work with the regional secretariats to appoint the regional validation committees (RVCs). At any one time at

6 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.

least one representative of an RVC from each region should serve as a member of the GVC, to facilitate communication in the validation process.

Membership of the national, regional, and global validation committees should consist of independent and multidisciplinary experts. Committee members should generally include:

- epidemiologists
- national HIV/AIDS and/or STI managers and programme officers
- managers/officers of maternal and child health care programmes
- experts on HIV and other STIs
- social scientists
- laboratory scientists
- statisticians
- public health officers
- advocates from civil society and nongovernmental organizations that work with at-risk and vulnerable groups, including people living with HIV
- human rights experts
- representatives of the private health sector.

Box 3 summarizes the organization and roles of the validation committees.

5.2.1 The national validation committee and team

The national validation committee (NVC) takes overall responsibility for the national validation process. The NVC is convened, chaired and led by the candidate country Ministry of Health (MOH). As such, the NVC is an extension of MOH efforts to rigorously and transparently document its national EMTCT efforts. The NVC's role is to:

- gather evidence and prepare the national validation report
- coordinate internal validation processes
- ensure strong communication with the MOH

The NVC can accomplish the tasks listed above directly. Alternatively, it can choose to convene a national validation team (NVT) as a subset of the NVC membership to perform these functions.

5.2.2 The regional validation secretariat

The regional validation secretariat takes overall responsibility for the regional validation process. The regional validation secretariat is provided by the WHO Regional Offices, and its functions will be performed in partnership with UNAIDS, UNFPA and UNICEF. The role of the regional validation secretariat (WHO regional office) is to:

- establish and convene the regional validation committee (RVC);
- serve as the focal point for communication between national, regional and global partners;
- convene and support the RVCs and regional validation teams (RVTs) in their assessment work;
- collaborate with the global secretariat to ensure monitoring and maintenance of validation, including re-evaluation of impact and process indicators as the epidemics evolve.

Box 3
Organization and roles of the secretariats and validation committees

Ministry of Health (MOH)/National Validation Committee (NVC)

Initiates validation process and prepares national validation report

National Validation Team (NVT)

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

Regional Validation Secretariat (WHO regional office)

Establishes, convenes, and coordinates the RVC and RVT, provides oversight to regional and national validation processes and activities, communicates with NVC, GVC and global secretariat, ensures coherence, compliance of national, regional, global validation criteria and process. Monitors maintenance of validation.

Regional Validation Committee (RVC)

Appoints RVT to carry out country reviews. Jointly with the MOH, establishes NVC. Reviews national validation reports and ensures compliance with regional and global criteria.

Regional Validation Team (RVT)

An optional body that reviews country data, conducts in-country validation visits with the NVT, and prepares the regional validation report for GVC review.

Global Validation Secretariat (WHO headquarters)

Coordinates the GVC and regional secretariats. Provides official notification of validation of EMTCT of HIV and/or syphilis and monitors maintenance of validation. Monitors impact and process indicators as epidemic evolves. Provides final sign-off of validation of EMTCT of HIV and/or syphilis for a particular country.

Global Validation Committee (GVC)

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

5.2.3 The regional validation committee and team

As described above, the regional validation secretariat is tasked with the establishment of a regional validation committee (RVC). The role of the RVC is to:

- work with NVCs to assess readiness for validation;
- assist countries with efforts to initiate/complete validation or prepare for future validation activities;
- review national validation reports to determine national compliance with regional and global criteria for validation of EMTCT of HIV and/or syphilis;
- review the country status report on elimination initiatives
- prepare the regional validation report
- prepare a regional validation report that will inform national and global partners whether the country meets regional and global minimum criteria for validation;
- ensure that the regional report includes clear explanations and suggestions for the areas requiring improvement in the event that a candidate country does not meet regional and global validation criteria.

In principle, the RVC can accomplish the tasks listed above directly by working with NVCs (or NVTs, where active). However, depending on the size and complexity of the tasks in a region, it may be more practical for the RVC to convene a regional validation team (RVT). This team is constituted from a roster of independent regional experts with the time, interest, and capability to conduct a detailed review of data for the national validation EMTCT of HIV and/or syphilis.

5.2.4 The global secretariat

The global secretariat takes overall responsibility for setting standards, establishing and coordinating the global validation committee (GVC), communicating with regional secretariats, and officially recognizing countries that achieve validation of EMTCT of HIV and/or syphilis. The global validation secretariat is provided by the WHO Headquarters, and its functions will be performed in partnership with UNAIDS, UNFPA and UNICEF. The role of the global validation secretariat (WHO headquarters) is to:

- establish and convene the GVC;
- upon receipt of the global validation report from the GVC, issue a letter officially notifying the candidate country of their achievement and recommending follow-up actions for maintenance of EMTCT validation;
- bring any problems noted with maintenance of validation to the attention of the GVC and the RVC;
- work with regional validation secretariats to ensure monitoring and maintenance of validation, including re-evaluation of impact and process indicators as the epidemics evolve.

5.2.5 The global validation committee

As listed above, the global validation secretariat is tasked with the establishment of a global validation committee (GVC). The role of the GVC is to:

- conduct a critical review of regional validation reports to ensure consistency and compliance with the minimum global criteria for EMTCT validation;
- make the final determination of validation of EMTCT of HIV and/or syphilis;
- provide clear recommendations if validation is not achieved or, if validation is achieved, submits a global validation report to the global secretariat;
- review the situation of any country noted to have problems with maintenance of validation.

5.3 VALIDATION PROCEDURES

Countries that are compliant with regional and global EMTCT validation requirements are encouraged to apply for validation. The time frame for the proposed sequence of events listed below will differ depending on the size of the candidate country and the availability and quality of data. The validation process will have the following stages:

[1] **Validation request**

The MOH of the candidate country initiates the validation process by submitting an application letter for validation of EMTCT of HIV and/or syphilis to the regional secretariat. The regional secretariat then shares the request with the RVC. The RVC decides whether it will convene an RVT to work with the MOH to establish an NVC.

[2] **Country pre-validation**

The NVC chooses whether it will convene an NVT to collect national data and prepare the national validation report. This report should describe the basic structure and functions of the national programme, including the monitoring and surveillance system (a sample outline of a country report is provided in Annex B). The NVC reviews the national validation report to ensure that it meets the regional and minimum global validation requirements. Once the NVC and MOH have reviewed the national validation report, they submit it to the regional secretariat.

[3] **Country validation**

The process for country validation consists of the following:

a. Review of the candidate country's national validation report

Following receipt of the national validation report, the RVC appoints an RVT, which is pooled from the RVC members with the inclusion of independent experts as required or appropriate. In both cases, the assessment reviews data on the candidate country's EMTCT programme and monitoring and surveillance system, and conducts a quality assessment of the national EMTCT data for accuracy, completeness, and reliability. These data must meet the regional and global minimum criteria for EMTCT validation. The RVT submits recommendations to the RVC indicating whether the country is ready for a full-team in-depth assessment and in-country visit. The RVT may request the NVC/NVT to provide additional information, clarification, and/or justification of data where indicated.

b. In-country validation visit

If the candidate country is considered ready for validation, the RVC works with the NVC and MOH to plan an in-country visit and in-depth assessment.

Members of the RVT and NVT (where active) carry out the in-country assessment jointly. Its main objectives are to:

- review and validate the process and impact indicators;
- conduct an in-depth review of data sources and reports and interview key programme stakeholders;
- assess the design of the surveillance and monitoring system for completeness, quality, and representativeness of the data;
- assess the laboratory system for reliable quality control and assurance mechanisms and the existence of an adequate laboratory network to support the essential services.

The RVT, NVC, and NVT (where active) will work together to compile the candidate country's national validation report for submission to the regional secretariat and the RVC.

[4] Regional validation

The RVC reviews the national validation report to develop regional recommendations on validation. The process for regional validation of EMTCT of HIV and/or syphilis includes:

- confirmation of the achievement of the regional and minimum global EMTCT validation requirements in a manner that respects human rights;
- assessment of indicators and targets for reliability and integrity of data;
- evaluation of case definitions and diagnostic algorithms to arrive at a conclusion regarding the reliability of the reported numbers;
- assessment of a "validation standard" monitoring and surveillance system that has a national scope (public and private health sectors) and is sufficiently sensitive to detect the great majority of cases of MTCT of HIV and/or syphilis;
- assessment of quality, completeness, and representativeness of the data on each of the global impact and process indicators.

On completion of review of the national validation report, if the candidate country meets regional and global EMTCT criteria, the RVC prepares and submits a regional validation report to the global secretariat.

If the RVC determines that EMTCT of HIV and/or syphilis has not been achieved, the RVC/regional secretariat formally advises the NVC and MOH of the candidate country about the reasons for their decision. Additionally, it provides appropriate recommendations for additional steps that the country must take to meet regional and global validation criteria.

[5] Global validation

The GVC prepares a global validation report based on a critical review of the recommendations and outcomes of the regional validation report. This report verifies whether the candidate country has met minimum global criteria for validation of EMTCT of HIV and/or syphilis and notes other comments that may be important to maintenance of validation. This report is submitted to the global secretariat with a request that WHO, in collaboration with UNAIDS, UNFPA and UNICEF, officially recognize the candidate country for EMTCT.

[6] Official validation

The global secretariat (WHO headquarters), in collaboration with UNAIDS, UNFPA and UNICEF, will issue a letter recognizing the candidate country's achievement of the validation of EMTCT of HIV and/or syphilis and recommends follow-up actions for maintenance of EMTCT validation status.

Box 4 summarizes the activities leading to validation of EMTCT of HIV and/or syphilis.

Box 4
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 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 national 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 GVC. • GVC reviews regional validation report for compliance with minimum global criteria. • GVC prepares global validation report and submits to global secretariat.
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 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.

Global validation of EMTCT of HIV and/or syphilis does not require a comprehensive programme review. However, regions may choose to use the validation exercise as an opportunity to perform a comprehensive programme review of a national health system and gather information on programmatic capacity to sustain the validation targets of EMTCT of HIV and/or syphilis.

6 MAINTENANCE OF VALIDATION STATUS OF EMTCT OF HIV AND/OR SYPHILIS

Validation of EMTCT of HIV and/or syphilis must be maintained, not only to ensure that transmission of infection no longer occurs, but also for the additional benefits of strengthening health systems and improving a broad range of other maternal and child health outcomes. 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 that can provide accurate data on intervention coverage and quickly detect changes in disease transmission trends as well as surveillance of high-risk groups and key populations.

The global secretariat will maintain a list of countries that have achieved validation and maintained validation criteria and standards. While a candidate country may achieve validation of EMTCT of HIV and/or syphilis at a specific time, it should be understood that ongoing programme interventions are required to maintain a country's EMTCT validation status in subsequent years. A country may lose its validation status if rates of MTCT of HIV and/or syphilis exceed or fall below the global EMTCT validation indicator targets. For this reason it is important for candidate countries to have a high-quality and sensitive "validation standard" surveillance and monitoring system.

To maintain validation status, two types of data should be reported through global health reporting systems:

- EMTCT validation impact targets and indicators, reviewed every three years (see pages 6–7, and Box 1, page 8);
- EMTCT validation process targets and indicators, reviewed annually (see pages 7–8, and Box 1, page 8).

The global secretariat will review maintenance of validation annually, based on a review of data provided through the global reporting system. Any potential issues noted will be communicated to the GVC and the RVC. The RVC will work closely with the NVC and the MOH of the country whose data are in question to clarify or address any issues noted.

ANNEXES

Annex A. 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)
Other relevant indicators (please fill in)
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 a first visit • ever
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
Other relevant indicators (please fill in)

Annex A. 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)
Other relevant indicators (please fill in)

Annex B. OUTLINE OF SUGGESTED CONTENT OF NATIONAL VALIDATION REPORT

Countries applying for validation will submit a national validation report to the regional validation committee (RVC). The national validation report should highlight the following:

[1] **Brief country context**

- geography
- demography

[2] **Epidemiological profile of HIV and syphilis incidence in the country**

- 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 of HIV transmission
- other information e.g.,
  - adolescent pregnancy trends and rates
  - stillbirth trends and contributing factors

[3] **Description of the health system and the programmatic components of the Elimination Initiative**

- health regions or districts
- health financing (MCH, HIV, family planning, syphilis)
- service availability and delivery (MCH, HIV, family planning, syphilis; public and private)
- laboratory (MCH, HIV, family planning, syphilis; public and private)
  - laboratory network (public and private)
  - case definition for congenital syphilis; HIV diagnoses in adults and infants; and syphilis diagnoses in adults and infants
- supply chain (MCH, HIV, syphilis)

[4] **Description of primary prevention programmes and treatment services for HIV and syphilis**

- antenatal care
- HIV prevention efforts
- HIV and syphilis screening during pregnancy
- HIV and syphilis treatment, care, and support
- management of sex partners

[5] **Description of the "validation standard" monitoring and surveillance system for the EMTCT initiative**

- data sources and formats
- protocols and mechanisms for data processing, analysis, and dissemination
- data quality assurance system and recent data quality assessments

[6] **Summary table of recent data for all required validation indicators**

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