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*Until no
child has
AIDS.*

CRITERIA FOR IDENTIFICATION OF POORLY-PERFORMING DISTRICTS IN LINE WITH EMTCT PRE-VALIDATION REQUIREMENTS AND THE ACCELERATED ACTION PLAN FOR NATIONWIDE SCALE-UP OF INFANT, PEDIATRIC AND ADOLESCENT ART (AAP)

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ABBREVIATIONS AND ACRONYMS

AAP	Accelerated Action Plan for Nationwide Scale-up of Infant, Pediatric and Adolescent ART
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral (medication)
EMTCT	Elimination of Mother-to-Child Transmission (of HIV and/or syphilis)
HIV	Human Immunodeficiency Virus
M&E	Monitoring and Evaluation
MNCH	Maternal, Newborn and Child Health
MTCT	Mother-to-Child Transmission (of HIV and/or syphilis)
PMTCT	Prevention of Mother-to-Child Transmission
PPF	PMTCT Partnership Forum
TWG	Technical Working Group
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WHO AFRO	World Health Organization Africa Regional Office

1.0 BACKGROUND

1.1 INTRODUCTION

Mother-to-child transmission (MTCT) of HIV is an important contributor to HIV transmission. In 2012 an estimated 260,000 children globally were newly infected with HIV, and an estimated 3.3 million children were living with HIV¹. 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 breastfeeding². 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, and effective access to testing, counselling, antiretroviral therapy (ART), safe delivery practices, and appropriate infant feeding practices all contribute to prevention of mother-to-child transmission (PMTCT) and reduce child mortality.

Syphilis is transmitted sexually and across the placenta during pregnancy. If the disease remains untreated, adverse pregnancy outcomes are frequent. Over half of women with active syphilis will have a stillbirth, perinatal death, pre-term or low-birth-weight infant, or serious neonatal infection³. 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.

1.2 GLOBAL PLAN FOR EMTCT OF HIV AND SYPHILIS

Both the Joint United Nations Program on HIV and AIDS (UNAIDS) Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive⁴ and the World Health Organization (WHO) global elimination of congenital syphilis: rationale and strategy for action⁵ call for the elimination of MTCT of HIV and/or syphilis. Activities and initiatives in regions such as the Americas⁶, Asia and the Pacific⁷, and Africa⁸ towards dual elimination of MTCT (EMTCT) of HIV and syphilis have drawn attention to the need for standardized criteria and processes to validate EMTCT of HIV and syphilis. The similarity of 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 to validate EMTCT. EMTCT of HIV and syphilis can contribute to improvement of a broad range of maternal, newborn and child health (MNCH) outcomes.

Elimination is reduction to zero of the incidence of disease or infection in a defined geographical area⁹. However, because both HIV and syphilis remain major public health concerns and PMTCT measures are highly but not 100% effective, 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 problem⁹. Validation of EMTCT of HIV and/or syphilis implies that countries will need to maintain ongoing, routine, effective program interventions and quality surveillance systems to monitor EMTCT of HIV and/or syphilis. In 2014, the WHO, with support from UNAIDS, UNFPA and UNICEF, developed standard processes and criteria for validation of EMTCT of HIV and/or syphilis across both high- and low-prevalence settings, which are summarized below.

1.2.1 WHO-DEFINED CRITERIA FOR NATIONAL LEVEL VALIDATION OF EMTCT OF HIV AND SYPHILIS

Achieving EMTCT of HIV and/or syphilis will depend on the prevalence of disease, the extent of antenatal (ANC) 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 health¹⁰. Standardized criteria for validation of EMTCT of HIV and/or syphilis are needed for the following reasons:

- To provide national EMTCT of HIV and/or syphilis programs and participating stakeholders with a clear and consistent set of criteria for monitoring and evaluating program 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 MNCH services

1.2.1.1 IMPACT INDICATORS AND TARGETS FOR VALIDATION OF EMTCT OF HIV

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

Impact indicator	Rationale for use of case rate
A case rate of new pediatric HIV infections due to MTCT \leq 50 per 100,000 live births	It provides a measure that is comparable across different population sizes 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 It is a standardized measure that applies across all countries regardless of their starting point, as contrasted with reductions from different baselines
MTCT rate of HIV of $<$ 5% in breastfeeding populations OR MTCT rate of HIV of $<$ 2% in non-breastfeeding populations	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

1.2.1.2 IMPACT INDICATOR AND TARGET FOR VALIDATION OF EMTCT OF SYPHILIS

The global surveillance definition for congenital syphilis should be used for validation of EMTCT of syphilis. 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

Impact indicator	Rationale for use of congenital syphilis rate
A case rate of congenital syphilis of \leq 50 cases per 100,000 live births	The congenital syphilis rate is the most widely-used measure of 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 programs to eliminate MTCT of syphilis.

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

The following process indicators and targets must be attained for EMTCT validation:

Process indicator	Rationale
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Antenatal care (ANC) coverage (at least one visit) of $\geq 95\%$	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.
Coverage of HIV and/or syphilis testing of pregnant women of $\geq 95\%$	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.
Antiretroviral (ARV) coverage of HIV-positive pregnant women of $\geq 90\%$	The risk of MTCT of HIV can be significantly reduced through the provision of an effective ARV regimen.
Treatment of syphilis-seropositive pregnant women of $\geq 95\%$	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.

Countries should review the full list of indicators to support validation of EMTCT of HIV and/or syphilis; as such indicators are important for assessing a national program. Programs should monitor follow-up care and treatment of infants born to HIV- or syphilis-seropositive women^{10,11}.

1.2.1.4 WHO QUALIFYING REQUIREMENTS FOR EMTCT VALIDATION

Countries must meet the following minimum criteria for validation of EMTCT of HIV and/or syphilis:

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.
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. This approach helps to ensure that the validation process addresses equity in health service coverage.
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.

1.3 ELIMINATION OF MTCT OF HIV AND SYPHILIS IN ZIMBABWE

Zimbabwe is one of the 22 high-burden countries in sub-Saharan Africa hardest hit by the AIDS epidemic, with an adult HIV prevalence of approximately 16.7%¹². The adult HIV incidence rate decreased from 1.3% in 2011 to 1.1% in 2014^{14,15}. However, even as the percentage of HIV infections among adults has decreased, the number of new infections among infants has remained high; in 2013, there were approximately 11,000 new infant HIV infections and 64,000 AIDS-related deaths among children.¹³

In 2011, UNAIDS released a call to end pediatric HIV and AIDS through its Global Plan toward the elimination of new HIV infections among children by 2015 and keeping their mothers alive¹⁵. National adoption of the 2010 WHO PMTCT guidelines (Option A) in May 2010 helped Zimbabwe move closer to ending MTCT; in 2009, the MTCT rate was estimated to be approximately 30%, and by 2013, the rate had decreased to less than 13%.¹⁶ Scale up of

PMTCT service access resulted in 95% of health facilities in Zimbabwe offering PMTCT services. Zimbabwe achieved near universal PMTCT access coverage (94% of Zimbabwe's population had access to PMTCT services) in 2014.¹⁷

In 2014, Zimbabwe transitioned to Option B+, consistent with the 2013 WHO PMTCT guidelines, which recommended lifelong ART to all HIV-positive pregnant and breastfeeding women (regardless of CD4 count) and to all HIV-positive children of five years of age or younger.¹⁸ Successful national roll-out of Option B+ further accelerated progress toward elimination of MTCT. ART is now initiated among HIV-positive pregnant and breastfeeding women within all MNCH sites throughout the country.¹⁷

With the successes in reduction of HIV MTCT rate to approximately 6.7% by the end of 2014¹⁴, the current focus for Zimbabwe is to sustain the gains made in the PMTCT program and to direct efforts towards pre-validation of EMTCT of HIV and syphilis. The country is also focusing on accelerating the identification and treatment of HIV-infected children and adolescents. Universal treatment for children age five years or younger, as recommended by current global HIV guidelines, allows more permissive criteria to scale up pediatric ART. Today, an estimated 170,717 children (0–14 years) live with HIV in Zimbabwe, and approximately 27% of these are in need of treatment.¹⁹ HIV remains a major underlying cause of childhood mortality, accounting for 21% of under-five mortality in Zimbabwe²⁰. Program implementers in the country are shifting focus from scale-up of PMTCT to sustainability of PMTCT, scale-up of early identification of HIV-infected children and wider access to pediatric HIV care and treatment.²¹

1.4 PURPOSE OF THIS DOCUMENT

Despite recent strides towards achievement of EMTCT of HIV, Zimbabwe does not have a standard document to guide district level EMTCT performance. This document was thus developed by the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) in collaboration with the WHO, the Zimbabwe Ministry of Health and Child Care (MOHCC) AIDS and TB Unit, and the national monitoring and evaluation (M&E) technical working group (TWG). This document outlines the proposed selection criterion for identifying poorly-performing districts in Zimbabwe with respect to meeting EMTCT pre-validation status. The selection criteria will be used by MOHCC and its implementing partners at national and provincial levels to identify poorly-performing districts for targeted interventions or support to improve program performance. These criteria should be used by district level teams to categorize site performance and identify service delivery areas for targeted support.

1.5 STEPS IN DEVELOPMENT AND FINALIZATION OF THE SELECTION CRITERIA

This draft document has been developed in consultation with the MOHCC, WHO Africa Regional Office (AFRO), the M&E-sub-committee, and other implementing partners. WHO AFRO will provide overall guidance on the EMTCT pre-validation process, the process and impact indicators to be assessed, and their performance thresholds. In accordance with WHO AFRO guidance, the M&E sub-committee will finalize the selection criteria which will be presented to the national PMTCT Partnership Forum (PPF) before finalization and endorsement (sign-off) by the Permanent Secretary for Health. The document will then be printed and distributed to MOHCC national and subnational levels as well as implementing partners, and will be ready to use by the second quarter of 2016.

2.0 SELECTION CRITERIA FOR POORLY-PERFORMING DISTRICTS IN ZIMBABWE

The selection criteria outlined below were informed by WHO guidance on pre-validation of EMTCT of HIV and syphilis. Whereas WHO guidance focuses on ANC coverage, testing coverage for HIV and syphilis, ART coverage and syphilis treatment amongst pregnant women, it is critical to assess program performance across the care and treatment cascade. ARV prophylaxis for HIV-exposed infants is critical for prevention of postnatal MTCT. Final HIV

testing at 18 to 24 months is critical to determining the MTCT case rate which is one of the impact indicators for EMTCT pre-validation. Assessing ART coverage amongst children 0 to 14 years is critical in determining pediatric HIV care and treatment program performance. Assessment of retention of HIV-positive women and children on ART will provide a proxy for treatment adherence. The additional indicators included to cover these program aspects are;

- Percentage of HIV-exposed infants initiated on ARV prophylaxis
- Percentage of HIV-exposed infants < 2 months with DNA PCR sample collected
- Percentage of HIV-exposed infants aged 18 to 24 months with a final HIV test done
- Percentage of HIV-positive children aged 0 to 14 years initiated on ART
- Percentage of HIV-positive women retained on ART 6, 12 and 18 months after initiation during ANC.

2.1 PROCESS INDICATORS

Table 1 summarizes process indicators and performance thresholds for classifying district performance.

Table 1: Process indicators and performance thresholds for classifying district performance

Indicator	Numerator	Denominator	Performance Thresholds		
			Poor (Red)	Moderate (Orange)	Good (Green)
Scoring Matrix Indicators					
ANC coverage (at least 1 visit)	Pregnant women booking for first ANC visit (P1) ¹ PLUS Pregnant women arriving in labor and delivery (L&D) with unknown HIV status (P12)	Number of expected pregnancies in the program catchment area	<85%	85-90%	>90%
Coverage of HIV testing of pregnant women	Pregnant women HIV tested in ANC for the first time and received results (P2) PLUS Pregnant women booking for first ANC visit with a known HIV-positive result (P5) PLUS Women tested in L&D for the first time and received results (P13)	Number of expected pregnancies in the program catchment area	<85%	85-90%	>90%
Antiretroviral coverage of HIV-positive pregnant women	Pregnant women booking for first ANC visit already on ART (P8) PLUS HIV-positive pregnant women initiated on ART in ANC (P11) PLUS HIV-positive pregnant women initiated on ART in L&D (P18)	Number of HIV-positive women in need of PMTCT	<85%	85-90%	>90%
Antiretroviral coverage of HIV-exposed	HIV-exposed infants initiated on NVP within 72 hours (P27) PLUS HIV-exposed infants	Number of HIV-positive women in need of	<85%	85-90%	>90%

¹ Indicator code on the national monthly progress report form

infants	initiated on NVP from 73 hours to 24 months (P29)	PMTCT			
Additional Process Indicators					
6 month retention of pregnant women on ART	Number of women retained on ART 6 months after initiation in ANC	Number of pregnant women initiated on ART in ANC 6 months prior to reporting period	<85%	85-90%	>90%
12 month retention of pregnant women on ART	Number of women retained on ART 12 months after initiation in ANC	Number of pregnant women initiated on ART in ANC 12 months prior to reporting period	<85%	85-90%	>90%
18 months retention of pregnant women on ART	Number of women retained on ART 18 months after initiation in ANC	Number of pregnant women initiated on ART in ANC 18 months prior to reporting period	<85%	85-90%	>90%
6 month retention of children < 2 years on ART	Number of children retained on ART 6 months after initiation before 2 years of age	Number of children < 2 years initiated on ART 6 months prior to reporting period	<85%	85-90%	>90%
Early HIV infant diagnosis (EID) coverage for HIV-exposed infants	Infants ≤ 2 months with DNA PCR sample collected (P30)	Number of HIV-positive women in need of PMTCT	<85%	85-90%	>90%
Final HIV testing coverage for HIV-exposed infants	HIV-exposed infants aged 18 to 24 months with a final (rapid) HIV test done	Number of HIV-positive women in need of PMTCT	<85%	85-90%	>90%
ARV coverage for HIV-positive children 0 to 14 years	HIV-positive children aged 0 to 14 years initiated on ART	HIV-positive children aged 0 to 14 years	<85%	85-90%	>90%
Coverage of syphilis testing of pregnant women	Number of pregnant women syphilis tested during ANC	Number of expected pregnancies in the program catchment area	<85%	85-90%	>90%

Treatment of syphilis-seropositive pregnant women	Number of syphilis-seropositive pregnant women who received at least 1 dose of Benzathine penicillin	Number of syphilis-seropositive pregnant women	<85%	85-90%	>90%
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2.2 IMPACT INDICATORS

Table 2 summarizes impact indicators and performance thresholds for classifying district performance.

Table 2: Impact indicators and performance thresholds for classifying districts performance

Indicator	Numerator	Denominator	Performance Thresholds (Cases per 100 000 live births)		
			Poor	Moderate	Good
Case rate of new pediatric HIV infections due to MTCT of HIV	Number of new pediatric HIV infections due to MTCT of HIV	Total number of live births	>885*	885-50	<50
Case rate of congenital syphilis	Number of new cases of congenital syphilis	Total number of live births	TBD	TBD	TBD

* Assuming national HIV prevalence in ANC of 14%, MTCT rate of 5% and expected pregnancies of 447,000 per year (2015). Case rate per year will be 885 per 100,000 live births.

Program performance will be assessed by MOHCC and implementing partners on a quarterly basis using aggregate data at health facility, district, province and national levels for all process indicators in Table 1. Impact indicators will be assessed bi-annually. Performance for each of the process indicators will be calculated and ranked into any of the three categories namely Poor (Red), Moderate (Orange) or Good (Green). Officers will use data available at their level- e.g. the national level team will use data in DHIS 2 and related population-based denominators, and facility level health workers will use data in their report forms and registers. Although program performance will be assessed for all the process indicators, only four key indicators will be used for scoring district performance. A scoring matrix will be used to categorize district performance based on:

- ANC coverage
- HIV testing coverage amongst pregnant women
- ART coverage amongst HIV-positive pregnant women
- ART coverage amongst HIV-positive children aged 0 to 14 years

Table 3 outlines the scoring matrix for district performance across the four key process indicators.

Table 3: Scoring matrix for district performance

Category	Obtained Scores	Decision
Category 1	At least 1 red score in any of the 4 indicators	Poorly-performing (Red)
Category 2	4 orange scores	Poorly-performing (Red)
Category 3	3 orange and 1 green score	Poorly-performing (Red)

Category 4	2 green and 2 orange scores	Moderate (Orange)
Category 5	3 green and 1 orange scores	Moderate (Orange)
Category 6	4 green scores	Good (Green)

Additional Guidance for District and Facility Level Teams

District level teams should apply the criteria outlined above to assess performance of each health facility in their district regardless of the overall category of the district performance. Any health facility categorized as moderate and poorly-performing should be targeted with support. Some sites with overall good (green) performance might be poorly-performing in some service delivery areas and such sites should also be targeted with support. All districts should aim to have all their health facilities in the good (green) performance category across all service delivery areas.

2.3 ROUTINE DATA QUALITY ASSESSMENTS

To ensure full compliance with established WHO pre-validation requirements, the national M&E and surveillance system will be strengthened to ensure that it accurately assesses intervention coverage, detects the majority of cases of MTCT of HIV and syphilis in a timely manner, and generates high quality data in both public and private sectors. Data quality for each of the EMTCT validation impact and process indicators will be assessed by MOHCC and implementing partners quarterly for completeness, accuracy, consistency, and timeliness through routine data quality assessments (RDQA) conducted during supportive supervision in representative health facilities across all districts. A standard RDQA tool will be used for these assessments. RDQA findings will be used to determine districts and indicators with poor data quality. The average data quality scores for each indicator and district will be calculated and used for ranking. Districts with mean variance (Verification factor) between reported data and recounts from facility registers > 10% in any one out of the four key indicators verified will be considered to have poor data quality. Table 4 summarizes indicators for RDQA to classify district performance.

Table 4: Indicators for routine data quality assessments for classifying district performance

Indicator	Reported Data (DHIS 2)	Recounts from Facility Registers	Verification Factor ²
Pregnant women booking for first ANC visit (P1) ³			
Pregnant women HIV tested in ANC for the first time and received results (P2)			
HIV-positive pregnant women initiated on ART in ANC (P11)			
HIV-exposed infants initiated on nevirapine (NVP) (P27 PLUS P29)			
HIV-exposed infants ≤ 2 months with DNA PCR sample collected (P30)			
Number of pregnant women tested for syphilis during ANC			
Number of syphilis-seropositive pregnant			

² Verification Factor (VF) = (Reported-Recounts)/Reported*100

³ Indicator code on the national monthly progress report form

women who received at least 1 dose of Benzathine penicillin			
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2.4 POORLY-PERFORMING DISTRICTS IN ZIMBABWE

The selection criteria outlined above were used by EGPAF and MOHCC to identify currently poorly-performing EMTCT districts in Zimbabwe, using October to December 2015 aggregate service uptake data. EGPAF is currently working with MOHCC to develop a geospatial map outlining the district performance for the October - December 2015 period.

2.5 USE OF FINDINGS FROM APPLICATION OF SELECTION CRITERIA

After applying the selection criteria to each district, the national level team comprising MOHCC and implementing partners will develop geospatial maps to share with provinces and districts for use in quarterly data and program review meetings. Recommendations and action plans should be drawn from the review meeting and these should be implemented to address Identified performance gaps. Subsequent review meetings should start with a review of implementation of action plans from previous meetings. The subnational teams will be capacitated to apply these criteria and produce subnational geospatial maps that identify hot spots for targeted support. All poorly-performing districts should be visited for support and supervision by national and provincial teams. The moderate (orange) performing districts can be supported through virtual platforms such as Skype or other applications. The good (green) performing districts will be supported through virtual and physical visits to sustain their good performance as well as document best practices. Support for poorly-performing districts will include intensive joint support and supervision visits by MOHCC and implementing partners during which coaching and mentoring of site staff will be conducted to improve service uptake and data management, and to mobilize training resources as needed.

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