Regional Initiative for the Elimination of
Mother-to-Child Transmission of HIV and Congenital Syphilis
in Latin America and the Caribbean

REGIONAL MONITORING STRATEGY

Pan American Health Organization
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LATIN AMERICAN CENTER FOR PERINATOLOGY WOMEN AND REPRODUCTIVE HEALTH CLAP/WR

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aecid Agencia Española de Cooperación Internacional para el Desarrollo

Canadian International Development Agency

2010

PAHO HQ Library Catalog-in-Publication

Pan American Health Organization
"Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean: Regional Monitoring Strategy"
Washington, D.C.: PAHO, © 2010

Author: Alonso González, Mónica

ISBN: 978-92-75-13111-4

I. Title

1. INFECTIOUS DISEASE TRANSMISSION VERTICAL – prevention & control
2. HIV INFECTIOUS – transmission
3. PREGNANCY COMPLICATIONS, INFECTIOUS
4. PRENATAL CARE – statistics & numeral data
5. SYPHILIS, CONGENITAL – transmission
6. ACQUIRED IMMUNODEFICIENCY SYNDROME – prevention & control
7. DELIVERY OF HEALTH CARE – statistics & numeral data
8. LATIN AMERICA
9. CARIBBEAN REGION

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This publication is part of a project funded by the Spanish Agency for International Development Cooperation (AECID) and by the Canadian International Development Agency (CIDA). The contents of this publication are the sole responsibility of the Pan American Health Organization.

Acknowledgments

This document was developed based on consultative processes with PAHO member states for the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean. PAHO/FCH/HI and CLAP-SMR thank the many organizations and people who provided input and resources for this publication. Special thanks are given to Mónica Alonso González for the development and writing of this document and coordination of all inputs, Suzanne Jacob Serruya (CLAP/SMR/PAHO) and Raúl González Montero (PAHO) for their comments and for their leadership in the conceptual development of the Elimination Initiative; Oriana Ramírez Rubio as contributor to writing several sections of the document, and the M&E peer-review group for their guidance and review of the development of the technical content of this document: Wilson Benia (CLAP/SMR), Nathalie Broutet (WHO), Sonja Caffe, (PHCO), Carolina Danovaro (PAHO), Amalia Del Riego (PHCO), Marie-Marcelle Deschamps (Geskio), Christopher J. Drasbek (PAHO), Gottfried Hirnschall (PAHO), Ricardo Fescina (CLAP/SMR), Jesús María García Calleja (WHO), Bertha Gómez (PAHO), Perry Gómez (The Bahamas MOH), Chika Hayashi (WHO), Geoffrey Ijumba (UNICEF), Jerry Jacobson (PAHO), Mary Kamba (CDC), Fátima Marinho (PAHO), Jennifer Mark (CDC), Victor Mejía (PAHO), Steve Nesheim (CDC), Carla Partridge (UNICEF), María Dolores Pérez-Rosales (PAHO), Matilde Pinto (PAHO), Cecilia Sánchez (UNICEF), Cristina Schneider (PAHO), Omar Sued (PAHO), Freddy Tinajeros (CDC), Luis Villa (PHCO), Marianela Villalta (UNICEF), and the experts from the following countries with whom this framework was shared and discussed: Argentina, Brazil, Colombia, Dominican Republic, Ecuador, Paraguay, and Uruguay.

ACRONYMS

AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care services
ARV	Antiretroviral
CLAP	Centro Latino Americano de Perinatologia y Salud de la Mujer y Reproductiva
CS	Congenital syphilis
HIV	Human immunodeficiency virus
L&D	Labor and delivery
LAC	Latin America and the Caribbean
M&E	Monitoring and evaluation
MTCT	Mother-to-child transmission of HIV
NGO	Nongovernmental organization
PAHO	Pan American Health Organization
PHCO	PAHO HIV Caribbean Office
PMTCT	Prevention of mother-to-child transmission of HIV
STI	Sexually transmitted infection
UA	Universal Access
UN	United Nations
UNAIDS	United Nations Joint Program on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization

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Executive Summary

Latin America and the Caribbean (LAC) has the highest syphilis rate worldwide. In this region, it is estimated that more than 164,000 children are born with congenital syphilis each year. An estimated 6,400 children will be newly infected with HIV, most of them via mother-to-child transmission (MTCT). Both conditions are preventable in LAC countries with effective, low-cost, and technically available interventions. However, progress in Latin America and the Caribbean is lagging, and gaps in access to and provision of these services for mothers and children persist.

PAHO and UNICEF are providing countries with strategies and tools to support the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis. This regional monitoring strategy is a companion document to the recommendations provided for the programmatic integration and scale up of prevention of mother-to-child transmission of HIV and congenital syphilis and the clinical guidance in support to this programmatic approach[1,2].

The current document provides the rationale for establishing a common monitoring strategy and why this framework is needed to track progress of the elimination initiative at regional level. This document is intended for national AIDS and sexually transmitted infection (STI) program managers, maternal and child health program managers, and monitoring and evaluation (M&E) specialists in Latin America and the Caribbean.

Specifically, this document recommends a common set of indicators that should be present in country monitoring and evaluation plans for the elimination of vertical transmission of HIV and congenital syphilis, enabling the monitoring of regional efforts and comparisons across countries of progress toward common goals. The document also provides a structured description for generation and interpretation of each of the essential regional indicators at the national level. Each indicator is accompanied by an indicator reference sheet that provides detailed information on measurement, data sources, frequency, and rationale.

As stated in the elimination initiative concept paper, the overall goal is to eliminate mother-to-child transmission of HIV and congenital syphilis in Latin America and the Caribbean

1 PAHO. *Concept Paper on the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean.* CLAP, Montevideo, 2009.

2 The guideline is available in Spanish: Guía clínica para la eliminación de la transmisión maternoinfantil del VIH y de la sífilis congénita en Latino America y el Caribe. Washington, DC, 2009.

by 2015. In order to measure progress toward this goal, PAHO and UNICEF propose two impact targets:

1. Reducing the rate of mother-to-child transmission of HIV to 2% or less
2. Reducing the incidence of congenital syphilis (including stillbirths) to 0.5 cases per 1,000 live births or less

Five main objectives need to be met to achieve these targets:

1. Increasing the coverage of antenatal care and skilled attendance at birth to 95% or more by 2015
2. Increasing the coverage of HIV and syphilis screening of pregnant women to 95% or more by 2015
3. Increasing the coverage of adequate HIV prophylactic management and treatment of syphilis in pregnant women and HIV prophylactic management of HIV in children to 95% or more by 2015
4. Increasing the percentage of first-level health care centers that provide services for prevention and diagnosis of HIV and other STIs in an integrated manner with other services (antenatal care, sexual and reproductive health, services for adolescents, gender violence) to more than 95%
5. Increasing the percentage of countries that have information systems to measure progress toward the elimination of mother-to-child transmission of HIV and congenital syphilis and support decision making to more than 95%

PAHO will track progress based on the proposed set of indicators laid out in this document and lead the process of country certification of the elimination of mother-to-child transmission of HIV and congenital syphilis. PAHO and UNICEF will support countries in their reporting requirements and contribute to strengthening of information systems as another key element of the success of the initiative.

1. Introduction

With less than a decade remaining to reach the commitments stated by countries in the Millennium Development goals, there is increasing recognition of the burden of HIV and syphilis on mothers and children in Latin America and the Caribbean. It is estimated that every year in Latin America and the Caribbean, approximately 6,400 children are newly infected with HIV, the majority through mother to child transmission and over 164,000 children will be born with congenital syphilis (CS)[3,4]. The Pan American Health Organization and UNICEF, committed to support countries in eliminating both preventable conditions in the region, have launched the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis as a public health problem. This document provides a basic foundation and guidance for tracking progress toward the regional initiative.

Latin America and the Caribbean has the highest syphilis rate worldwide. The World Health Organization (WHO) estimates that of the 12 million new infections that occur each year, 3 million occur in Latin America and the Caribbean (LAC).[5] Congenital syphilis is one of the most serious forms of illness caused by syphilis infection. Pregnant women with active syphilis will present serious complications of pregnancy, and up to 80% of these cases will result in preterm fetal death, perinatal death, or serious neonatal infection. In LAC, this burden of disease occurs in a context in which most countries have low-cost diagnostic tools and effective treatments. Congenital syphilis could be eliminated in the region with available technology and the existing health services infrastructure. Specifically, maternal syphilis screening early in pregnancy and prompt treatment of positive mothers with intramuscular benzathine penicillin will cure syphilis in infants and prevent most complications. Screening should ideally occur prior to 20 weeks gestation and at the first antenatal visit. Therefore, new cases of congenital syphilis should be considered as a marker of health system failure.

Mother-to-child transmission (MTCT) of HIV occurs when an HIV-positive woman passes the virus to her infant. Infants born to women living with HIV can become infected during pregnancy, labor and delivery, or postpartum through breastfeeding. Without prophylactic treatment, approximately 15%–30% of infants born to HIV-positive women will become infected with HIV during pregnancy and delivery. A further 5%–20% will become infected

3 UNAIDS/WHO. 2008 Report on the Global AIDS Epidemic. Geneva: UNAIDS, 2008.

4 Schmidt G, Stoner B, Hawkes S, Broutet N. The Need and Plan for Global Elimination of Congenital Syphilis. *Sexually Transmitted Diseases*. 2007;34(7):S5–S10.

5 World Health Organization. Global prevalence and incidence of selected curable sexually transmitted diseases: Overview and estimates. Geneva: World Health Organization, 2001 (WHO/CDS/CSR/EDC/2001.10). Retrieved from: http://www.who.int/hiv/pub/sti/pub7/en/.

through breastfeeding.[6] In some countries of the world, MTCT has been virtually eliminated thanks to effective testing and counseling, access to antiretroviral therapy, safe delivery practices, and the widespread availability and safe use of breast-milk substitutes. In contrast, coverage of MTCT preventive services in Latin America and the Caribbean is still surprisingly lagging. In 2007, there were an estimated 36,000 (30,000–45,000) HIV-infected pregnant women in LAC, and only 13,000 were reported to have received antiretrovirals (ARVs) for prevention of mother-to-child transmission (PMTCT).

PAHO/WHO and UNICEF have laid out technical strategies to advance toward elimination of mother-to-child transmission of HIV and CS in an integrated fashion. This integrated strategy calls for coherent and comprehensive surveillance and monitoring and evaluation (M&E) systems at the country level that will permit establishing a baseline situation and measure progress toward elimination. PAHO will track progress and lead the process of country certification of the elimination of mother-to-child transmission of HIV and congenital syphilis.

This document is intended for national AIDS and sexually transmitted infection (STI) program managers, maternal and child health program managers, and M&E specialists in Latin America and the Caribbean. It provides a basic set of indicators that should be present in countries' information systems. Each indicator is accompanied by a reference indicator sheet that provides the rationale, structured descriptions and interpretations of each indicator, and detailed information on measurement, data sources, and frequency. Common definitions and methods will permit the monitoring of regional progress and enable comparisons over time and across countries.

This document:

1. Provides a recommended set of indicators for monitoring country and regional progress toward elimination of MTCT of HIV and CS
2. Facilitates ultimate use of data and indicators for program planning and evaluation.
3. Enables comparisons among countries and over time of progress toward the elimination goal.
4. Provides key elements for the certification of elimination of MTCT of HIV and CS.

6 De Cock KM, Fowler M, Mercier E, et al. Prevention of mother-to-child HIV transmission in resource-poor countries: Translating research into policy and practice. *JAMA.* 2000;283(9):1175–1182.

2. The Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean: Historical Review

In 1994, the XXIV Pan American Sanitary Conference called for the elimination of congenital syphilis as a public health problem in the Americas. Efforts to address this situation culminated in 1995 with the formulation of the "Plan of Action for the Elimination of Congenital Syphilis" during the 116th Meeting of the Executive Committee of the Pan American Health Organization.[7] This document set out standard definitions for congenital syphilis and clearly determined the feasibility of eliminating congenital syphilis in the region as a public health problem. It presented specific strategies and methods that, if implemented, would lead to elimination of congenital syphilis in the LAC region.

Progress throughout the region up to 2003 was limited. In 2004, technical consultations took place that led to the publication of a regional framework for action called "Elimination of Congenital Syphilis in Latin America and the Caribbean: Framework for Implementation."[8] In the area of HIV, the "Regional HIV/STI Plan for the Health Sector, 2006–2015" was published with the main objective of halting and beginning to reverse the spread of HIV and other sexually transmitted infections by 2015.[9]

In 2006, Central American countries and the Dominican Republic, with support from PAHO and UNICEF, joined efforts to create the PMTCT Alliance with the objective of eliminating mother-to-child transmission of HIV and syphilis.

Some countries have made significant progress toward the elimination of mother-to-child transmission of HIV and syphilis as public health problems, while in other countries important gaps persist.

In 2008 and 2009, technical consultations with public health authorities and experts on HIV, maternal and child health, and reproductive health concluded that the joint elimination of mother-to-child transmission of HIV and syphilis in the region is feasible and necessary to achieve regional goals and commitments. An integrated approach is deemed necessary to overcome the barriers and challenges in provision of services, including verticality of programs and resource allocation.

7 PAHO. Plan of Action for the Elimination of Congenital Syphilis (PAHO/WHO/CE116/14), 1995.

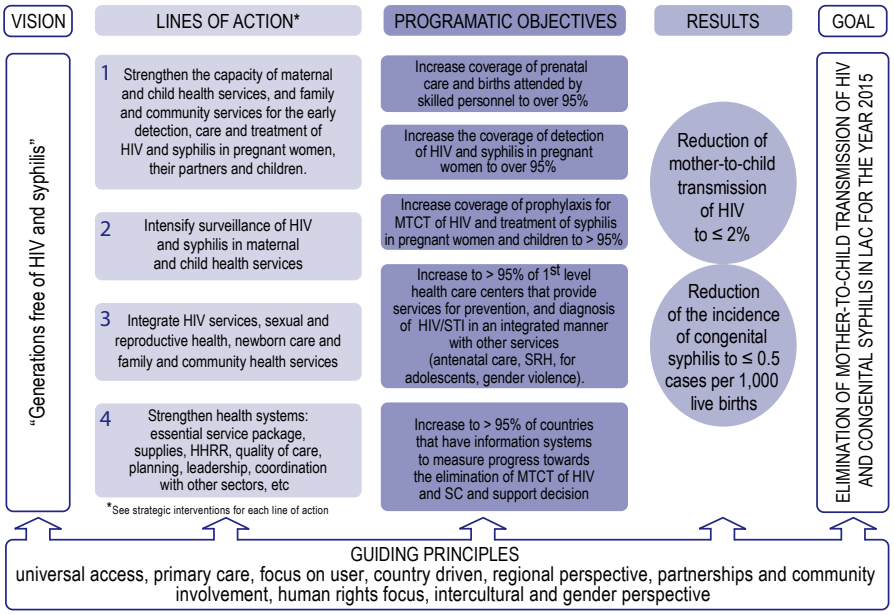
8 OPS. Eliminación de Sífilis Congénita en América Latina y el Caribe: Marco de Referencia para su Implementación. Washington DC, OPS, 2005. Retrieved from http://www.paho.org/Spanish/AD/FCH/AI/EliminaSifilisLAC.pdf

9 PAHO. Regional HIV/STI Plan for the Health Sector 2006-2015, Pan American Health Organization, 2004.

PAHO and UNICEF have developed clear programmatic and clinical guidance for countries to support the initiative of joint elimination of mother-to-child transmission of HIV and congenital syphilis. A companion document[10] addresses the programmatic implications and presents the conceptual framework for the regional elimination initiative (Figure 1). A second companion document provides clinical guidance for integrated HIV and syphilis clinical management from a public health approach.[11] This programmatic framework and clinical guidance includes a regional adaptation of the WHO strategy presented in "The Global Elimination of Congenital Syphilis: Rationale and Strategy for Action," a global reference document for the elimination of congenital syphilis.

The current document is a third element of the regional elimination initiative. This monitoring strategy builds on the programmatic framework of the elimination initiative to facilitate ultimate use of data and indicators for program planning and evaluation by governments, the Pan American Health Organization, and regional partners.

Figure 1. Conceptual framework of the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean



10 PAHO. *Concept Paper on the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean.* CLAP, Montevideo, 2009.

11 The guideline is available in Spanish: Guía clínica para la eliminación de la transmisión maternoinfantil del VIH y de la sífilis congénita en Latino América y el Caribe.

3. Monitoring of the regional elimination initiative

Monitoring and evaluation[12] is the backbone of public health systems with respect to providing essential information and evidence regarding the best practices and lessons learned in health programs. In this context, M&E is an indispensable management function that helps to strengthen program planning and improve effectiveness of actions and interventions directed toward the elimination of both mother-to-child transmission of HIV and congenital syphilis as public health issues. In addition to monitoring HIV/STI trends, which largely involves surveillance, there is interest in a second type of monitoring: monitoring of program indicators. Most indicators are not designed to explain why a situation has changed or has failed to change because they are designed only to measure the change itself. Thus, the analysis should focus on linking indicators from different levels of measurement (input, output, outcome, impact); for example, program outputs should be interpreted in relation to program inputs, and program outcomes should be analyzed in relation to changes in program inputs.

Objectives of monitoring of the regional initiative

The main objective is assessment of progress toward eliminating mother-to-child transmission of HIV and CS in Latin America and the Caribbean. As access and quality of integrated services improve, regional and national surveillance and monitoring systems will need to be strengthened. Clarity and standardization of the basic core recommended indicators for the initiative will facilitate strengthening of information systems. It will also guide ultimate use of data and indicators for program planning and evaluation, including an appropriate assessment of the magnitude of syphilis and HIV in pregnant women, congenital syphilis, and the effectiveness of PMTCT interventions. Common indicators will enable country and regional comparisons over time and between countries, contributing to increased regional visibility and sharing of lessons learned.

The regional monitoring strategy sets the basis for forthcoming certification processes in the region. PAHO will lead efforts to monitor progress at the regional level and coordinate the process of certification of elimination once countries have achieved established targets and sustained them over a span of years.

A reliable regional picture of the baseline situation and progress toward goals can be acquired with the country information provided based on this monitoring strategy. PAHO will support

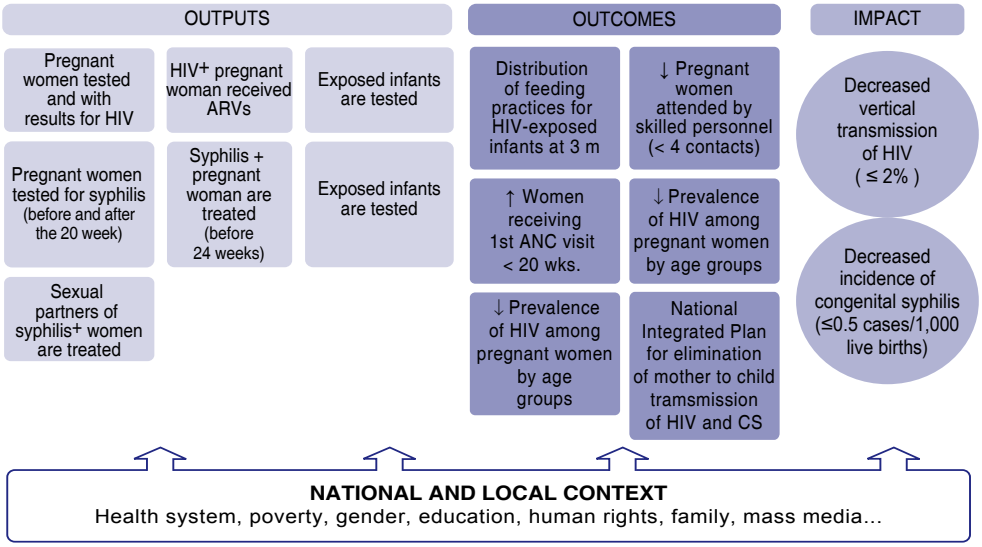
12 Monitoring and evaluation are two different management tools that are closely related and interactive functions. Where evaluation efforts tend to support monitoring, monitoring represents an ongoing activity (e.g., adequate planning, practical implementation mechanisms, results, regular reporting, baseline data, and indicators of performance) to track progress against planned tasks.

countries in their monitoring efforts and lead regional reporting strategies on an annual basis. Regional data will be collected annually in order to provide situation assessments and identify gaps and areas for improvement. Analysis, interpretation, and sharing of lessons learned with countries at the regional and subregional levels will be important elements in monitoring and evaluating progress and informing programmatic decisions toward meeting the goals of the elimination initiative.

4. Targets and indicators

As stated in the elimination initiative concept paper, the overall goal is to *eliminate mother-to-child transmission of HIV and congenital syphilis in Latin America and the Caribbean by 2015.* Among the multiple points for measuring progress at the country level, a small set of key indicators are designated as markers of regional progress in eliminating mother-to-child transmission of HIV and CS. A structural map of these indicators is presented in Figure 2.

Figure 2. Map of selected M&E indicators for the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean



Output indicator is a quantitative or qualitative measure of activities, work products, or actions.
Outputs generally "count things" produced by the resources of the program or health service. They are intended to measure the products of a program's implementation or activities. They may also be referred to as process measures.
Outcome indicator measures the observable benefits or changes for individuals, communities, or society as a result of the program that will potentially contribute to improvements in public health.

As described in the document "Concept Paper on the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean," two goals are proposed[13]:

1. Reducing mother-to-child transmission of HIV to 2% or less
2. Reducing the incidence of congenital syphilis (including stillbirths) to 0.5 cases per 1,000 live births or less

Five main objectives need to be met in order to achieve the above-mentioned goals. These key programmatic objectives are as follows:

1. Increasing the coverage of antenatal care (ANC) and skilled attendance at birth to 95% or more by 2015
2. Increasing the coverage of HIV and syphilis screening of pregnant women to 95% or more by 2015
3. Increasing the coverage of adequate HIV prophylactic management and treatment of syphilis in pregnant women and HIV prophylactic management of HIV in children to 95% or more by 2015
4. Increasing the percentage of first-level health care centers that provide services for prevention and diagnosis of HIV and other STIs in an integrated manner with other services (antenatal care, sexual and reproductive health, services for adolescents, gender violence) to more than 95%
5. Increasing the percentage of countries that have information systems to measure progress toward the elimination of mother-to-child transmission of HIV and congenital syphilis and support decision making to more than 95%

13 The global congenital syphilis elimination strategy also identifies two important additional goals (see The global elimination of congenital syphilis: Rationale and strategy for action. Geneva: WHO, 2008): (1) 90% of pregnant women positive for syphilis adequately treated prior to 24 weeks gestation (this requires collection of the following: syphilis screening by gestational age, test result, and, for positive tests, treatment by gestational age) and (2) under 2% syphilitic stillbirths (this requires initiation of stillbirth surveillance).

Table 1. Impact indicators*

Indicator	Numerator	Denominator	Observations
1.1 Congenital syphilis cases per 1,000 live births	Reported CS cases according to national case definitions	Estimated number of live births	PAHO will calculate this indicator based on standardized methodology for estimated live births
1.2 Reported HIV mother-to-child transmission rate: percentage of infants born to HIV-infected mothers who are positive for HIV	Number of infants born to HIV-infected mothers positive for HIV as reported via virological testing or serological testing at 18 months	Reported number of Infants born to HIV-infected mothers	In breastfed infants: testing should take place 6 weeks after termination of breastfeeding practices

* The Strategy for Global Elimination of Congenital Syphilis recommends an additional impact indicator: percentage of stillbirths attributed to congenital syphilis. The target for this indicator is set at <2% of stillbirths attributed to syphilis. The suggested period to monitor these indicators is per calendar year.

Key monitoring indicators

Fourteen recommended essential indicators are summarized in Table 2.[14] The recommended reporting time frame to evaluate progress at the regional level is by calendar year, and the numerator and denominator (where applicable) refer to the same defined year. Countries may choose to evaluate at shorter time periods depending on their information systems.

14 The indicators presented in Table 2 will enable the monitoring of key programmatic objectives 1, 2, and 3, as well as other intermediate outputs and outcomes necessary to achieve those targets. The monitoring of key programmatic objective 4 at the regional level will be done specifically through regional input indicator 4.6. Key programmatic target 5 will be monitored by the number of countries annually reporting to PAHO on the 16 indicators proposed in this M&E strategy.

Table 2. Key regional monitoring indicators for the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean

Indicator	*Numerator*	*Denominator*	*Observations*
2. Output indicators			
2.1 Percentage of pregnant women who were tested for HIV and received their result during pregnancy, during labor and delivery, and during the postpartum period (within 72 hours of delivery), including those with a previously known positive HIV status	Number of pregnant women who were tested for HIV and received their results-during pregnancy, during labor and delivery, and during the post-partum period (within 72 hours of delivery), including those with previously known positive HIV status	Estimated number of pregnant women	Universal Access indicator
2.2 Proportion of pregnant women first tested for syphilis during ANC visit a) before 20 weeks b) after 20 weeks	Number of women screened for syphilis during ANC a) before 20 weeks b) after 20 weeks	Estimated number of pregnant women	A similar Universal Access indicator exists. The differences are that this indicator is not disaggregated by gestational age and it refers only to those women accessing ANC. The numerator should refer only to initial tests conducted to avoid double counting of women.
2.3 Proportion of pregnant women tested for syphilis at the first ANC visit	Number of women screened for syphilis in the first ANC visit	Estimated number of pregnant women	
2.4 Percentage of HIV-infected pregnant women who received antiretrovirals to reduce the risk of MTCT*	Number of HIV-infected pregnant women who received antiretrovirals to reduce the risk of MTCT	Estimated number of HIV-infected pregnant women	Universal Access indicator Disaggregated as: a) On treatment with triple therapy due to mother's own health b) PMTCT prophylaxis with triple therapy c) Any other regimen
2.5 Percentage of infants born to HIV-infected mothers receiving ARVs for PMTCT	Number of infants born to HIV- infected mothers receiving ARVs for PMTCT	Estimated number of HIV-infected women giving birth	Universal Access indicator
2.6 Percentage of infants born to HIV-infected mothers who received testing to determine their HIV status by: a) virological HIV test in the first 2 months b) first virological HIV test after 2 months c) initial serological test between 9 and 12 months (infants without previous virological test) d) initial serological test after 12 months e) children lost to follow-up before an assessment of their HIV status	Number of infants, in the preceding 12 months, born to HIV-infected women who received an HIV test: a) viral load or qualitative PCR in the first 2 months b) viral load or qualitative PCR after the first 2 months c) initial antibody testing between 9 and 12 months d) tested after 12 months e) those not assessed (e.g., due to loss to follow-up by 12 months, death)	Estimated number of HIV-infected pregnant women giving birth	Universal Access indicator The numerator includes only the initial test in order to avoid double counting of infants.

Indicator	*Numerator*	*Denominator*	*Observations*
2.7 Proportion of syphilis-seropositive pregnant women who are appropriately treated at or before 24 weeks	Number of pregnant women with a positive syphilis serology *and* treated appropriately during pregnancy at or before 24 weeks	Number of pregnant women with a positive syphilis serology during pregnancy	Do not count if not tested or not treated.
2.8 Proportion of syphilis-infected pregnant women whose sexual contacts are appropriately treated for syphilis	Number of pregnant women with positive syphilis serology *and* whose sexual contacts are identified and treated for syphilis	Number of pregnant women with a positive syphilis serology during pregnancy	
3. Outcome indicators			
3.1 Proportion of pregnant women attended by skilled health personnel during at least four visits in the antenatal period	Number of pregnant women who have received at least four health care consultations during pregnancy provided by a trained health worker	Estimated number of pregnant women	
3.2 Proportion of pregnant women whose first antenatal care visit occurs before 20 weeks gestational age	Number of pregnant women with a first ANC visit provided by a trained health worker before 20 weeks gestational age	Estimated number of pregnant women	
3.3 Distribution of feeding practices at 3 months among infants born to HIV-infected mothers	Number of infants born to HIV-infected women assessed whose infant feeding practices (as recorded at 3 months) were: a) exclusive breastfeeding b) replacement feeding c) mixed feeding/other	Number of infants born to HIV-infected women with feeding practices assessed at 3 months	Universal Access indicator
3.4 HIV prevalence among pregnant women, disaggregated by age group (15–24 years, >24 years)	Number of HIV-positive pregnant women, disaggregated by age group (15–24 years, >24 years)	Pregnant women tested for HIV	This indicator can be derived from sentinel surveillance studies or programmatic data.
3.5 Syphilis prevalence among pregnant women, disaggregated by age group (15–24 years, >24 years)	Number of syphilis-positive pregnant women, disaggregated by age group (15–24 years, >24 years)	Pregnant women tested for syphilis	This indicator can be derived from sentinel surveillance studies or programmatic data.
3.6 Integrated congenital syphilis and mother-to-child transmission of HIV elimination plan/strategy at the country level	Existence of a single national integrated plan or strategy for mother-to-child transmission of HIV and congenital syphilis elimination		Qualitative assessment, yes/no indicator

*An additional programmatic quality of care indicator can be derived using as the denominator the actual number of pregnant women who access ANC and are diagnosed as HIV positive. It would be expected that this figure should always be equal or close to 100%.

Additional considerations for M&E systems

As part of larger-scale efforts to improve the health of women, infants, and young children, this monitoring strategy focuses on the component of prevention of mother-to-child transmission of HIV and congenital syphilis. Monitoring and evaluation of child and maternal health programs will also provide a broader understanding of progress in the health of women, infants, and children. In addition, different aspects of mother and child health programs must be functioning satisfactorily in order to achieve the desired results. In this document, essential key components have been selected but are not the only issues that countries would want to measure and monitor (e.g., monitoring of stock-outs of tests and/or treatment within countries, availability of critical HIV/syphilis commodities, number of ANC clinics providing syphilis screening). A broader organizing framework for a functional national HIV/STI M&E system covers additional aspects that should be in place to successfully control HIV and other STIs at country and regional levels.

As part of the "Three Ones," agreed upon in 2004, the "one national HIV monitoring and evaluation system" principle establishes the need to monitor progress across different sectors (e.g., Ministry of Health, Ministry of Education, Ministry of Social Welfare), different service delivery areas (e.g., prevention of mother-to-child transmission of HIV, antiretroviral treatment, palliative care), and different levels of implementation (e.g., national level, service delivery level). This monitoring strategy builds on that principle and provides an example of integration of efforts for control of HIV and congenital syphilis.

5. Indicator definitions and descriptions

1. Impact indicators

1.1 Congenital syphilis cases per 1,000 live births per year

What it measures
The incidence rate is the accumulated number of new cases of congenital syphilis in the defined time frame per live births in the same defined time frame. Therefore, this indicator is a measure of the risk of live-born infants developing congenital syphilis within a year.

Rationale
This indicator captures the impact of programs focusing on the elimination of congenital syphilis that aim to improve coverage of antenatal care and diagnosis and treatment of maternal syphilis.

Numerator
Reported CS cases according to the *national* case definition in a defined year.

Recommended congenital syphilis case definition (PAHO)
a) Newborn, stillborn, or spontaneous abortion of a woman with maternal syphilis who had not received appropriate treatment (see definition of adequate treatment in the document Guia clinica para la eliminación de la transmision maternoinfantil del VIH y de la sífilis congénita en Latino America y el Caribe)
b) Child with VDRL or RPR titers four times higher than maternal levels (equivalent to two dilutions; that is, mother, 1/4, child 1/16)
c) Child with clinical manifestations suggestive of congenital syphilis (see below) and positive serology regardless of the titer
d) Product of gestation or placenta with evidence of *Treponema pallidum* infection in histological studies

Clinical manifestations suggestive of CS
a) Clinical manifestations suggestive of early CS
Prematurity
Intrauterine growth retardation
Congenital pulmonary syphilis (pneumonia alba)
Hepatosplenomegaly
Generalized lymphadenopathy
Hematologic manifestations: anemia, leucopenia, leukocytosis, thrombocytopenia
Mucocutaneous manifestations: purpura, palmoplantar pemphigus, maculopapular rash, condylomata lata, rhagades, petechiae
Bone lesions, osteochondritis, periostitis
Renal manifestations: nephrotic syndrome
Central nervous system manifestations: aseptic meningitis, Parrot's pseudoparalysis
Ocular manifestations: chorioretinitis, retinitis
Other findings: fever, syphilitic rhinitis, pancreatitis, jaundice, gastrointestinal tract inflammation, hypopituitarism, myocarditis
Hydrops fetalis
b) Clinical manifestations suggestive of late CS
Hutchinson teeth
Interstitial keratitis
Saddle nose deformity, frontal bossing
Rhagades, cutaneous gumma
Central nervous system lesions: mental retardation, hydrocephalia, seizures, deafness, blindness
Osteoarticular lesions: Clutton's joints , sabre tibia, bone gumma, scapula in alar position
High palate, maxillary deformations, micrognathia, Mullberry molars

Denominator
Estimated live births in the same defined year.

Frequency
Annual.

Data sources and measurement tools

Numerator: Reported congenital syphilis cases according to the national case definition. In the majority of countries in Latin America and the Caribbean, CS is a mandatory notifiable disease.

Denominator: The denominator is generated through a population estimate of the number of live births in the preceding 12 months. This information can be obtained from national vital statistics offices. If there is not a specific national register of births, the annual birth average can be drawn from UN Population Division estimates[15] or PAHO's technical health information system.[16]

Additional considerations for countries

When possible, countries should try to follow the most complete definition of a congenital syphilis case, including having registers of stillbirths and spontaneous abortions. Furthermore, the Strategy for Global Elimination of Congenital Syphilis[17] recommends an additional impact indicator: percentage of stillbirths attributed to congenital syphilis. The target for this indicator is set at less than 2% of stillbirths attributed to syphilis.

Monitoring of both suspected and confirmed cases of congenital syphilis is recommended in order to evaluate the quality of surveillance and case reporting systems.

15 Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. World Population Prospects: The 2008 Revision. Retrieved from http://esa.un.org/unpp

16 Pan American Health Organization, Health Analysis and Statistics Unit. Regional Core Health Data Initiative. Washington, DC, 2007. Retrieved from http://www.paho.org/english/SHA/coredata/tabulator/newTabulator.htm

17 The global elimination of congenital syphilis: Rationale and strategy for action. WHO, 2007. Retrieved from http://www.who.int/reproductivehealth/publications/rtis/9789241595858/en/index.html

1.2 Reported HIV mother-to-child transmission rate: Percentage of infants born to HIV-infected mothers who are positive for HIV

What it measures
Progress toward eliminating mother-to-child HIV transmission by assessing, in a given year, the proportion of infants who are HIV infected relative to infants born to HIV-infected pregnant women.

Rationale
PMTCT programs aim to significantly reduce new pediatric HIV cases caused by mother-to-child transmission. The percentage of infants who are HIV infected should decrease as the coverage of PMTCT interventions and the use of more efficacious regimens increases.

Numerator
Number of infants who are born in a given calendar year to HIV-infected mothers and diagnosed as HIV positive.

HIV can be diagnosed via virological tests or serological tests (only among infants older than 18 months). Breastfeeding infants should be tested, with a virological test, 6 weeks after termination of breastfeeding practices in the given time frame.

Denominator
Reported number of infants born to HIV-infected mothers in the defined calendar year.

Frequency
Annual or more frequently, depending on a country's monitoring needs. Data will generally be referred to the 2 previous calendar years in order to ensure that all infants have been diagnosed (until virological testing practices are scaled up).

Data sources and measurement tools
Antenatal care or other health facility registers.

The goal of this indicator is to identify infants born (in a given calendar year) to HIV-infected mothers diagnosed who are HIV positive.

Strengths and weaknesses

Countries should try to monitor the impact of PMTCT using actual data on the HIV status of infants born to HIV-infected women gathered during follow-up health care visits with these infants. However, it is particularly difficult to follow up on mother-baby pairs, especially at the national level, because of the time lag in reporting and wide range of health facility sites and because loss to follow-up is relatively common. In countries where no confirmatory tests are available or being systematically conducted in children exposed to HIV, or where the HIV status of a significant number of pregnant women is not known, this indicator may underestimate mother-to-child transmission of HIV.[18]

18 Sensitivity analysis using losses to follow up could be used to estimate the range of underestimation.

2. Output indicators

2.1 Percentage of pregnant women who were tested for HIV and received their result during pregnancy, during labor and delivery, and during the postpartum period (within 72 hours of delivery), including those with a previously known HIV status

What it measures
This indicator assesses efforts to identify the HIV serostatus of pregnant women in the preceding 12 months.

Rationale
Identification of a pregnant woman's HIV serostatus provides an entry point for other PMTCT services and is needed to tailor prevention, care, and treatment to her needs.

Numerator
Number of pregnant women whose HIV status is known. This information is compiled from the number of women of unknown HIV serostatus attending ANC, labor and delivery (L&D), and postpartum services (within 72 hours of delivery) who were tested for HIV and know their results and the number of women with known HIV infection attending ANC for a new pregnancy in the preceding 12 months.

The numerator is the sum of categories a–d below:

a) Pregnant women who received an HIV test and result during ANC;
b) Pregnant women attending L&D with an unknown HIV status who were tested during L&D and received results;
c) Women of unknown HIV serostatus attending postpartum services within 72 hours of delivery who were tested and received results; and
d) Pregnant women with known HIV infection attending ANC for a new pregnancy.

The numerator is disaggregated by group, as follows: women attending ANC with known (positive) HIV infection at ANC, women tested and newly identified as HIV positive, and women testing HIV negative.

Denominator
Estimated number of pregnant women in the preceding 12 months.

Frequency
Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools
This is a Universal Access (UA) indicator (indicator 6: percentage of pregnant women who were tested for HIV and received their results).

Numerator: The numerator is calculated using national program records aggregated from facility registers for ANC, L&D, and postpartum care.

Health facility registers should record known HIV infection among newly pregnant women visiting ANC clinics so that they receive PMTCT services.

Efforts should be made to include all public, private, and NGO-run health facilities that provide testing and counseling for pregnant women.

Denominator: The denominator is generated through a population estimate of the number of live births in the preceding 12 months. This information can be obtained from national vital statistics offices. If there is not a specific national register of births, the annual birth average can be drawn from UN Population Division estimates[19] or PAHO's technical health information system.[20]

Strengths and weaknesses
This indicator enables a country to monitor trends in HIV testing among women attending ANC.

The reasons for dropouts that occur during the testing and counseling process are not captured by this indicator. It measures neither the quality of testing or counseling nor the number of women who received pretest or posttest counseling.

There is a risk of double counting with this indicator, as a pregnant woman can be tested more than once during ANC, L&D, or postpartum care. This is particularly true in cases where women are retested in different facilities, they do not have documentation of their previous results when they visit ANC or L&D services, or they are retested after a previous

19 Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. World Population Prospects: The 2008 Revision. Retrieved from http://esa.un.org/unpp

20 Pan American Health Organization, Health Analysis and Statistics Unit. Regional Core Health Data Initiative. Washington, DC, 2007. Retrieved from http://www.paho.org/english/SHA/coredata/tabulator/newTabulator.htm

negative test result during their pregnancy. Although it is not feasible to avoid double counting entirely, countries should ensure that a data collection and reporting system is in place to minimize it (e.g., using patient-held and facility-held ANC records to document that testing took place as well as the test results).

When live births are used in the estimation of the number of pregnant women, the total number of pregnancies in a given year may be underestimated. Although in theory all births should be included, in practice only live births are used owing to difficulty in obtaining information about non-live births and abortions. The exclusion of non-live births such as stillbirths, spontaneous and induced abortions, and ectopic and molar pregnancies underestimates the need for ANC in the population.

Additional considerations for countries

With respect to additional analyses and trends in testing and counseling uptake, countries may wish to disaggregate testing and counseling by ANC, L&D, and postpartum, as well as by type of health facility in the case of trends in testing uptake at different levels of the health care system.

2.2 Proportion of pregnant women tested for syphilis by gestational age

What it measures
This indicator assesses efforts to identify the syphilis serostatus of pregnant women in the preceding 12 months by gestational age.

Rationale
Identification of a pregnant woman's syphilis serostatus provides an entry point for prevention, care, and treatment services. *T. pallidum* is present in the blood in the early stages of the disease and can be transmitted to the fetus, especially between weeks 16 and 28 of pregnancy, though earlier transmission has been reported. Therefore, this indicator's objective is to measure the number of women screened by gestational age (before and after 20 weeks). PAHO strongly recommends screening for the first time before 20 weeks (in the first-trimester antenatal care visit), in order to minimize transplacental transmission, and then repeating the test in the third trimester and at delivery or during postpartum services (within 72 hours of delivery). If risk factors exist, tests could be repeated even more frequently.

Numerator
Number of pregnant women tested for syphilis with a serological test or other tests (such as anatomopathologic studies).

Disaggregation is by group, as follows: women screened *for the first time* before 20 weeks of pregnancy and women screened *for the first time* after 20 weeks of pregnancy.

The numerator refers only to initial tests; double counting of women should be avoided.

Denominator
Estimated number of pregnant women in the preceding 12 months.

Frequency
Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools

There is a similar UA indicator (indicator 37: coverage and prevalence of syphilis in ANC), with the difference that the UA indicator uses as a denominator pregnant women accessing ANC and is not disaggregated by gestational age.

Numerator: The numerator is calculated using national program records aggregated from facility registers for ANC, L&D, and postpartum care.

Denominator: The denominator is generated through a population estimate of the number of live births in the preceding 12 months. This information can be obtained from national vital statistics offices. If there is not a specific national register of births, the annual birth average can be drawn from UN Population Division estimates[21] or PAHO's technical health information system.[22]

Strengths and weaknesses

There is a risk of multiple counting with this indicator, as a pregnant woman can be tested more than once and in different settings during ANC, L&D, or postpartum care. While it is not feasible to avoid double counting entirely, countries should ensure that a data collection and reporting system is in place to minimize it (e.g., using patient-held and facility-held ANC records to document that testing took place as well as the test results).

When live births are used in the estimation of the number of pregnant women, the total number of pregnancies in a given year may be underestimated. Although in theory all births should be included, in practice only live births are used owing to difficulty in obtaining information about non-live births. The exclusion of non-live births such as stillbirths, spontaneous and induced abortions, and ectopic and molar pregnancies underestimates the need for ANC in the population.

21 Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. World Population Prospects: The 2008 Revision. Retrieved from http://esa.un.org/unpp

22 Pan American Health Organization, Health Analysis and Statistics Unit. Regional Core Health Data Initiative. Washington, DC, 2007. Retrieved from http://www.paho.org/english/SHA/coredata/tabulator/newTabulator.htm

2.3 Proportion of pregnant women tested for syphilis at the first antenatal care visit

What it measures
This indicator assesses the efforts of ANC services to identify, during the first visit, the syphilis serostatus of pregnant women in the preceding 12 months.

Rationale
Identification of a pregnant woman's syphilis serostatus provides an entry point for prevention, care, and treatment services. PAHO strongly recommends screening for the first time before 20 weeks, but women may not be captured by ANC services before the first trimester. Therefore, antenatal care services should perform a syphilis test at the first ANC visit or as soon as possible.

Numerator
Number of pregnant women tested for syphilis with a serological test at the first antenatal care visit.

The numerator refers only to initial tests; double counting of women should be avoided.

Denominator
Estimated number of pregnant women in the preceding 12 months.

Frequency
Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools
There is a similar UA indicator (indicator 37: coverage and prevalence of syphilis in ANC), with the difference that the UA indicator uses as a denominator pregnant women accessing ANC and does not specify that the screening must take place in the first antenatal care visit.

Numerator: The numerator is calculated using national program records aggregated from facility registers for ANC, L&D, and postpartum care.

Denominator: The denominator is generated through a population estimate of the number of live births in the preceding 12 months. This information can be obtained from national vital

statistics offices. If there is not a specific national register of births, the annual birth average be drawn from UN Population Division estimates[23] or PAHO's technical health information system.[24]

Strengths and weaknesses

This indicator measures the performance of services and not necessarily efforts in capturing women early in their pregnancy.

There is a risk of multiple counting with this indicator, as a pregnant woman can be tested more than once and in different settings during ANC. While it is not feasible to avoid double counting entirely, countries should ensure that a data collection and reporting system is in place to minimize it (e.g., using patient-held and facility-held ANC records to document that testing took place as well as the test results).

When live births are used in the estimation of the number of pregnant women, the total number of pregnancies in a given year may be underestimated. Although in theory all births should be included, in practice only live births are used owing to difficulty in obtaining information about non-live births. The exclusion of non-live births such as stillbirths, spontaneous and induced abortions, and ectopic and molar pregnancies underestimates the need for ANC in the population.

23 Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. World Population Prospects: The 2008 Revision. Retrieved from http://esa.un.org/unpp

24 Pan American Health Organization, Health Analysis and Statistics Unit. Regional Core Health Data Initiative. Washington, DC, 2007. Retrieved from http://www.paho.org/english/SHA/coredata/tabulator/newTabulator.htm

2.4 Percentage of HIV-infected pregnant women who received antiretrovirals to reduce the risk of mother-to-child transmission

What it measures
Progress in providing antiretrovirals to HIV-infected women to prevent mother-to-child transmission. HIV-infected pregnant women who are eligible for antiretroviral treatment and receive an ARV treatment regimen will also benefit from the prophylactic effect for prevention of mother-to-child transmission and thus are included in this indicator.

Rationale
The risk of mother-to-child transmission can be significantly reduced through the complementary approaches of providing antiretrovirals (as treatment or as prophylaxis) for the mother and antiretroviral prophylaxis to the infant, implementation of safe delivery practices, and safer infant-feeding practices.

Numerator
Number of HIV-infected pregnant women who received antiretrovirals during the preceding 12 months to reduce mother-to-child transmission.

The numerator can be disaggregated as follows: treatment with triple therapy as a result of the mother's own health status, PMTCT prophylaxis with triple therapy, and provision of any other regimen with ARVs.

HIV-infected pregnant women receiving any of these regimens meet the definition for the numerator.

Denominator
Estimated number of pregnant HIV-infected women in the preceding 12 months.

Frequency
Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools
This is an UNGASS (United Nations General Assembly Special Session on HIV/AIDS) and UA indicator.

Numerator: The numerator is calculated from national program records aggregated from facility registers. Antiretroviral drugs can be provided to HIV-infected women at various sites (ANC, L&D, and HIV care and treatment sites) during pregnancy, during labor, and shortly after delivery. The numerator can be calculated at the point of ARV provision or at the end-point of labor and delivery.

Efforts should be made to include all public, private, and NGO-run health facilities that provide ARVs to HIV-infected pregnant women for PMTCT.

Denominator: Two methods can be used to estimate the denominator:

a) Multiplying the total number of women who gave birth in the preceding 12 months (these data can be obtained from central statistics office estimates of births or UN Population Division estimates) by the most recent national estimate of HIV prevalence in pregnant women (which can be derived from HIV sentinel surveillance in ANC clinics).
b) Using a projection model such as the one provided by Spectrum Software (i.e., using as the output the number of pregnant women needing PMTCT). This method is indicated in countries with generalized epidemics.

Strengths and weaknesses

This indicator allows countries to monitor the coverage of antiretrovirals among HIV-infected pregnant women to reduce the risk of HIV transmission to the child.

When disaggregated, this indicator can monitor increased access to more efficacious ARV regimens for PMTCT in countries that are scaling up newer regimen categories.

Because the indicator measures ARVs dispensed and not ARVs consumed, it is not possible to determine adherence to the complete ARV regimen or distinguish between different ARV regimens and between pre- and intra-partum components. To check recommended ARV regimens, please refer to the elimination initiative's clinical guidelines.[25]

25 The guideline is available in Spanish: Guía clínica para la eliminación de la transmisión maternoinfantil del VIH y de la sífilis congénita en Latino América y el Caribe.

Additional considerations for countries

Countries are encouraged to track and report on the actual percentage distribution (or estimated percentage distribution, if actual data are unavailable) of the various regimens provided so that the potential impact of ARVs on mother-to-child transmission can be modeled based on the efficacy of corresponding regimens.

Countries may decide to include additional disaggregation elements to take into consideration early provision of ARV prophylaxis for PMTCT (categories for commencement of ARVs can be as follows: from week 14 to week 28 of gestation, after week 28, and during labor). This may provide information on barriers to the maximal efficacy of ARV use for PMTCT.

An additional programmatic quality of care indicator can be derived using as the denominator the actual number of pregnant women accessing ANC and diagnosed as HIV positive. It would be expected that this figure should always be equal or close to 100%.

2.5 Percentage of infants born to HIV-infected mothers receiving ARVs for PMTCT

What it measures

Progress in the prevention of mother-to-child transmission of HIV through the provision of antiretroviral prophylaxis to HIV-exposed infants.

Rationale

The risk of mother-to-child transmission can be significantly reduced through the complementary approaches of providing antiretrovirals (as treatment or as prophylaxis) for the mother and antiretroviral prophylaxis to the infant, implementation of safe delivery practices, and safer infant-feeding practices. This indicator allows countries to monitor the coverage of antiretroviral regimens dispensed or initiated among HIV-exposed infants to reduce the risk of maternal HIV transmission.

Numerator

Number of infants born to HIV-infected women during the preceding 12 months who began antiretroviral prophylaxis within 72 hours of birth[26] to reduce mother-to-child transmission of HIV.

Denominator

Estimated number of HIV-infected pregnant women giving birth in the preceding 12 months (as a proxy for the estimated number of infants born to HIV-infected women).

Frequency

Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools

This is a UA indicator (percentage of infants born to HIV-infected mothers receiving any ARV prophylaxis for PMTCT).

Numerator: The numerator is calculated from national program records aggregated from facility registers.

26 See ARV regimens and durations in the clinical guideline Guía clínica para la eliminación de la transmisión maternoinfantil del VIH y de la sífilis congénita en Latino América y el Caribe.

Antiretroviral drugs can be provided to HIV-exposed infants shortly after delivery, and this can take place at L&D facilities (for infants born at these facilities), at the outpatient postnatal care or child clinic (for infants born at home and brought to the facility within 72 hours), or at HIV care, antiretroviral therapy, or other sites, depending on the country context.

Three methods for calculating the numerator should be considered:

- *Counting at the point of ARV provision:* In settings with low facility delivery rates, data for the numerator should be compiled from sites where ARVs are dispensed and where the data are being recorded. There is a risk of double counting in cases where ARVs are provided during more than one visit or at different health facilities. Countries should establish data collection and reporting systems to minimize the potential for double counting.
- *Counting at the end-point of labor and delivery:* In settings where a high proportion of women give birth in health facilities, countries can estimate the numerator using only the L&D register, by counting the number of HIV-exposed infants receiving a specific ARV regimen prior to their discharge from the L&D ward. This may be the most reliable and accurate method of calculating this indicator in settings with a high proportion of facility deliveries, as the corresponding ARV regimen dispensed is counted at the time of provision to the infant.
- *Counting at postnatal or child health sites:* Countries can count and aggregate the number of HIV-exposed infants receiving a specific ARV regimen within 72 hours of birth, recorded at postnatal or child health clinics, if attendance is high and the exposure status of the child and any ARV regimen completed are likely to be known (e.g., from postnatal registers or standalone or integrated registers of HIV-exposed infants).

To prevent mother-to-child transmission, efforts should be made to include all public, private, and NGO-run health facilities that provide ARVs to HIV-exposed infants.

Denominator: Two methods can be used to estimate the denominator:

- Multiplying the total number of women who gave birth in the preceding 12 months (these data can be obtained from central statistics office estimates of births or UN Population Division estimates) by the most recent national estimate of HIV prevalence in pregnant women (which can be derived from HIV sentinel surveillance in ANC clinics). If information exists on the number of live births, data should be adjusted to

derive a better proxy using live births and estimates of HIV prevalence in women.

- Using a projection model such as the one provided by Spectrum Software (i.e., using as a proxy the output number of pregnant women needing PMTCT). This method is indicated in countries with generalized epidemics.

Strengths and weaknesses

This indicator measures the extent to which ARVs were initiated for infants as prophylaxis. It does not capture whether the ARVs were consumed; thus, it is not possible to determine adherence to the ARV regimen, nor is it possible to determine whether the complete ARV treatment was completed. Countries are encouraged to monitor the quality of infant prophylaxis by registering how many children complete the regimens up to 4–6 weeks.

2.6 Percentage of infants born to HIV-infected women who received HIV testing

What it measures

The extent to which infants born to HIV-infected women are tested to determine their HIV status with an early virological test in the first 2 months, with a virological test after 2 months, or with initial antibody testing at 9 to 12 months.

Rationale

Infants infected with HIV during pregnancy, delivery, or early postpartum often die before they are recognized as having HIV infection. PAHO/WHO recommends that national programs be created to establish the capacity to provide early virological testing of infants for HIV and guide clinical decision making at the earliest possible stage. In instances in which virological testing is not available, initial antibody testing at 9 to 12 months is recommended to identify negative cases.

Numerator

Number of infants who received:

- Virological testing in the first 2 months of life
- Initial virological testing after 2 months of age
- Initial serological testing between 9 and 12 months of age
- Initial serological testing after 12 months of age

Infants should be counted only once. The numerator should include the initial test but not any subsequent tests. In addition, infants lost to follow-up by 12 months should be reported.

Denominator

Estimated number of HIV-infected pregnant women giving birth in the preceding 12 months. This is a proxy measure for the number of infants born to HIV-infected women.

Frequency

Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools

This is a UA indicator (indicator 12: percentage of infants born to HIV-infected pregnant women who received an HIV test within 12 months, where infant testing is measured at two

points: before 2 months with a virological test and before 12 months with a serological test).

Numerator: The numerator is calculated from national program records compiled from data collected in registers at facilities.

The number of infants tested, rather thanthe number of tests performed, should be counted, since many infants may be tested multiple times.

Data should be aggregated from the appropriate facility registers. The register used may vary depending on the country context. For example, in cases where follow-up of HIV-exposed infants takes place in care and treatment settings, countries may aggregate information from those sites; where HIV-exposed infant testing takes place in child health settings, countries may also aggregate and report information from these sites. Where possible, double counting should be minimized when aggregating data to produce national-level data. Efforts should be made to include all public, private, and NGO-run health facilities that provide HIV testing for HIV-exposed infants.

Countries should also collect and evaluate data on the number of infants not assessed as a result of loss to follow-up, by 12 months, including deaths.

Denominator: Two methods can be used to estimate the denominator:

a) Multiplying the total number of women who gave birth in the preceding 12 months (these data can be obtained from central statistics office estimates of births or UN Population Division estimates) by the most recent national estimate of HIV prevalence in pregnant women (which can be derived from HIV sentinel surveillance in ANC clinics). If information exists on the number of live births, data should be adjusted to derive a better proxy.

b) Using a projection model such as the one provided by Spectrum Software (i.e., using as a proxy the output number of pregnant woman needing PMTCT). This method is indicated in countries with generalized epidemics.

Strengths and weaknesses

This indicator allows countries to monitor progress in providing early HIV testing to HIV-exposed infants, a critical tool for appropriate follow-up care and treatment.

Ideally, the indicator captures infants born to known HIV-infected women, but it may not be feasible in some settings to exclude infants tested for HIV using virological or antibody testing through provider-initiated testing in pediatric wards, malnutrition centers, and other sites where infants may be identified as exposed to or infected with HIV.

A low value of this indicator could signal health system weaknesses, including poor country-level management of supplies of HIV test kits, poor data collection, and mismanagement of testing samples.

2.7 Percentage of syphilis-seropositive pregnant women who are appropriately treated at or before 24 weeks

What it measures

Progress in the prevention of mother-to-child transmission of syphilis and in maternal health care through the provision of penicillin G at or before 24 weeks in pregnant women identified as seropositive for syphilis.

Rationale

Pregnant women with untreated syphilis (maternal or gestational syphilis) can transmit the infection to the fetus in utero or by direct contact with lesions during childbirth; the resulting congenital syphilis is the most prevalent form of neonatal infection in the world. Untreated syphilis is associated with stillbirth, spontaneous abortion, low birth weight, and serious neonatal infections, which are in turn associated with an increased risk of perinatal death. Different kinds of diagnostic tests are available; some provide results in minutes, allowing for treatment at the same visit.

The appropriate treatment for syphilis during pregnancy is at least one dose of IM penicillin G, which should be provided as close as possible to the time at which a positive result is found in the screening tests. This is a programmatic indicator reflecting treatment coverage among those identified as seropositive for syphilis.

Numerator

Number of syphilis-infected pregnant women who received appropriate treatment at or before 24 weeks gestational age.

Denominator

Total number of pregnant women with positive syphilis serology during pregnancy.

Frequency

Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools

This is a subindicator of UA indicator 36 (proportion of pregnant women diagnosed with syphilis who are adequately treated using national or international WHO standards).

Numerator: The numerator is calculated from national program records aggregated from facility registers. Treatment can be provided to syphilis-infected women at various sites (ANC, sexual and reproductive health clinics) during pregnancy. Women should not be counted in the numerator if they have not been tested or treated.

Note that there is a risk of double counting in cases where treatment is provided at different points in time and/or in different health facilities. Countries should therefore ensure that a data collection and reporting system is in place to minimize the potential for double counting.

Denominator: The denominator is extracted from national program records aggregated from facility registers. If estimation is needed, the total number of women who gave birth in the preceding 12 months (these data can be obtained from central statistics office estimates of births or UN Population Division estimates) can be multiplied by the most recent national estimate of syphilis prevalence in pregnant women.

Strengths and weaknesses

This indicator allows countries to monitor early treatment coverage among syphilis-infected pregnant women to reduce the risk of transmission to the child and as an assessment of the women's own health.

The indicator does not measure further quality of care, for example, penicillin allergy management. Also, treated women need to be reevaluated with quantitative serologic tests every 1 to 3 months in order to assess treatment failures, reinfection, or neurosyphilis (the last of which requires a lumbar puncture).

Additional considerations for countries

A population-based indicator may be calculated using the number syphilis-infected pregnant women who received appropriate treatment divided by the *expected* number of seropositive pregnant women. The expected number of pregnant women can be estimated by multiplying the estimated number of pregnant women in the preceding 12 months by the most recent national estimate of syphilis prevalence in pregnant women.

2.8 Proportion of syphilis-infected pregnant women whose sexual contacts are appropriately treated

What it measures
Progress in the prevention of mother-to-child transmission of syphilis through the provision of penicillin G to all sexual contacts of syphilis-infected pregnant women.

Rationale
Treating sexual partners of pregnant women is an important component of prevention of vertical transmission of congenital syphilis given that failure to treat sexual partners is the most common source of reinfection among pregnant women. Testing and treating male partners is an important tool for increasing male involvement and a critical entry point for ongoing and family care, as part of comprehensive care and treatment programs and efforts to reduce the overall burden of syphilis in a population.

Numerator
Number of pregnant women who have positive syphilis serology *and* whose sexual contacts are identified and treated. This numerator requires providing the pregnant woman with counseling and identifying all of her sexual contacts. She can be included in the numerator only if all of her reported sexual partners are being treated.

Denominator
Total number of pregnant women with a positive syphilis serology during pregnancy.

Frequency
Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools
Numerator: The numerator is calculated from national program records aggregated from facility registers.

Syphilis treatment can be provided to a syphilis-infected pregnant woman and her partners at various sites (ANC, sexual and reproductive health clinics). The facility that treats the pregnant woman is responsible for the diagnosis, treatment, and follow-up of her sexual partners as well. It is recommended that this information also be recorded in the pregnant woman's clinical history.

Denominator: The denominator is extracted from national program records aggregated from facility registers. If estimation is needed, the total number of women who gave birth in the preceding 12 months (these data can be obtained from central statistics office estimates of births or UN Population Division estimates) can be multiplied by the most recent national estimate of syphilis prevalence in pregnant women.

Strengths and weaknesses

This indicator allows countries to monitor efforts aimed toward increasing the involvement, testing, and treatment of male partners of pregnant women attending ANC services.

Data on the indicator may be difficult to gather as not all sites may be collecting data on male partner testing and treatment.

Additional considerations for countries

Measuring this indicator may require additional investment and resources to revise data collection tools and summary reporting forms.

3. Outcome indicators

3.1 Proportion of pregnant women attended by skilled health personnel during at least four visits in the antenatal period

What it measures
Progress made by countries in scaling up antenatal coverage for pregnant women.

Rationale
Antenatal care coverage is an indicator of access and utilization of care during pregnancy. At least four visits per pregnancy are recommended as an indicator of quality of care with an impact in terms of reducing maternal and infant mortality.

Numerator
Number of pregnant women in a given year who have completed at least four health care consultations during their pregnancy provided by a trained health worker.

Health care consultation during pregnancy is defined as health care services focusing on the control and monitoring of pregnancy and ambulatory care for associated morbidity; it does not include either direct vaccination activities or the health care services rendered immediately before delivery.

A skilled health attendant (sometimes referred to as a skilled attendant) is defined as an accredited health professional—such as a midwife, doctor, or nurse—who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth, and the immediate postnatal period and in the identification, management, and referral of complications in women and newborns. This definition excludes traditional birth attendants, whether trained or not, from the category of skilled health workers.

Denominator
Estimated number of pregnant women in the preceding 12 months.

Frequency
Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools

This indicator is based on the WHO/PAHO basic indicator (percentage of women who utilized antenatal care provided by skilled birth attendants for reasons related to pregnancy at least once during their pregnancy among all women who gave birth to a live child in a given time period).

Numerator: The numerator can be calculated from national program records aggregated from facility registers.

Denominator: The denominator is generated through a population estimate of the number of live births in the preceding 12 months. This information can be obtained from national vital statistics offices. If there is not a specific national register of births, the annual birth average can be drawn from UN Population Division estimates[27] or PAHO's technical health information system.[28]

Strengths and weaknesses

The main purpose of an indicator of antenatal care involving four visits is to provide information on the proportion of women who use antenatal care services that include a quality component including at least four consultations.

This indicator does not capture antenatal coverage that does not fulfill the requirements (e.g., three visits instead of four), nor does it measure the timing of the first visit, which is critical for preventing mother-to-child transmission of HIV and syphilis.

When live births are used in the estimation of the number of pregnant women, the total number of pregnancies in a given year may be underestimated. Stillbirths and miscarriages will not be included in the final figure. Although in theory all births should be included, in practice only live births are used owing to difficulty in obtaining information about non-live births. The exclusion of non-live births such as stillbirths, spontaneous and induced abortions, and ectopic and molar pregnancies underestimates the need for ANC in the population.

27 Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. World Population Prospects: The 2008 Revision. Retrieved from http://esa.un.org/unpp

28 Pan American Health Organization, Health Analysis and Statistics Unit. Regional Core Health Data Initiative. Washington, DC, 2007. Retrieved from http://www.paho.org/english/SHA/coredata/tabulator/newTabulator.htm

Additional considerations for countries

Countries may want to disaggregate this indicator by gestational age, location (urban/rural, major regions/provinces), and socioeconomic characteristics (e.g., women's educational level and wealth quintile) in order to monitor social inequalities and determinants of health.

3.2 Proportion of pregnant women whose first antenatal care visit occurs before 20 weeks gestational age

What it measures
Progress made by countries in recruiting women for early antenatal coverage.

Rationale
Antenatal care coverage is an indicator of access and utilization of care during pregnancy. In order to achieve this elimination strategy's goals, early screening, prophylaxis, and/or treatment of both syphilis and HIV in pregnant women are needed. Antenatal care services should attempt to recruit women early in their pregnancy.

Numerator
Number of pregnant women in a given year who have received an antenatal care consultation from a trained health worker before 20 weeks gestational age.

Health care consultation during pregnancy is defined as health care services focusing on the control and monitoring of pregnancy and ambulatory care for associated morbidity; it does not include either direct vaccination activities or the health care services rendered immediately before delivery.

A skilled health attendant (sometimes referred to as a skilled attendant) is defined as an accredited health professional—such as a midwife, doctor, or nurse—who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth, and the immediate postnatal period and in the identification, management, and referral of complications in women and newborns. This definition excludes traditional birth attendants, whether trained or not, from the category of skilled health workers.

Denominator
Estimated number of pregnant women in the preceding 12 months.

Frequency
Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools

This indicator is based on the WHO/PAHO basic indicator (percentage of women who utilized antenatal care provided by skilled birth attendants for reasons related to pregnancy at least once during their pregnancy among all women who gave birth to a live child in a given time period), though the latter does not take into account gestational age.

Numerator: The numerator can be calculated from national program records aggregated from facility registers.

Denominator: The denominator is generated through a population estimate of the number of live births in the preceding 12 months. This information can be obtained from national vital statistics offices. If there is not a specific national register of births, the annual birth average can be drawn from UN Population Division estimates[29] or PAHO's technical health information system.[30]

Strengths and weaknesses

The main purpose of this indicator of antenatal care (i.e., first visit occurring before 20 weeks gestational age) is to provide information on the proportion of women who are captured by ANC services early in their pregnancy. The indicator is critical in measuring how well ANC services are working toward the elimination of mother-to-child transmission of HIV and congenital syphilis.

The indicator does not capture full antenatal coverage (at least four visits), which has proved to have an impact with respect to reducing maternal and infant mortality.

When live births are used in the estimation of the number of pregnant women, the total number of pregnancies in a given year may be underestimated. Stillbirths and miscarriages will not be included in the final figure. Although in theory all births should be included, in practice only live births are used owing to difficulty in obtaining information about non-live births. The exclusion of non-live births such as stillbirths, spontaneous and induced abortions, and ectopic and molar pregnancies underestimates the need for ANC in the population.

29 Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. World Population Prospects: The 2008 Revision. Retrieved from http://esa.un.org/unpp

30 Pan American Health Organization, Health Analysis and Statistics Unit. Regional Core Health Data Initiative. Washington, DC, 2007. Retrieved from http://www.paho.org/english/SHA/coredata/tabulator/newTabulator.htm

Additional considerations for countries

Countries may want to disaggregate this indicator by gestational age, location (urban/rural, major regions/provinces), and socioeconomic characteristics (e.g., women's educational level and wealth quintile) in order to monitor social inequalities and determinants of health.

3.3 Distribution of feeding practices at 3 months among infants born to HIV-infected mothers

What it measures

Feeding practices among HIV-exposed infants at 3 months of age, using 24-hour recall. Infants are measured at the time of the DPT3 vaccination visit, at or around 3 months of age, or the closest visit after 3 months.

Rationale

HIV transmission can occur through breastfeeding, even in settings where 100% of pregnant women in need receive antiretrovirals for PMTCT. Mixed feeding (provision of both breast milk and other foods and liquids) increases the risk of HIV transmission. Thus, the current WHO/PAHO recommendation is exclusive replacement feeding (formula) for 6 months unless this is not acceptable, feasible, affordable, sustainable, and safe (AFASS). In this case, exclusive breastfeeding is recommended up to 6 months, when exclusive breastfeeding or provision of formula only is no longer recommended as infants and young children need complementary foods.

Coverage for DPT3 vaccination close to the recommended age of 14 weeks is high in most countries. It is proposed that data be collected at this time because most infants are seen then, and it is midway from birth to the point at which exclusive breastfeeding would end.

Numerator

Number of infants born to HIV-infected women in different of feeding practice categories, disaggregated as follows:

a) Number of HIV-exposed infants exclusively breastfeed at or around 3 months.
   - Exclusive breastfeeding: An infant receives only breast milk and no other liquids or solids, including water, with the exception of drops or syrups consisting of vitamins, mineral supplements, or medicines for up to 6 months. The definition of breast milk includes milk from a wet nurse and a mother's expressed milk.

b) Number of HIV-exposed infants with replacement feeding (no breast milk) at or around 3 months.
   - Replacement feeding: the process of feeding a child who is not receiving any breast milk with a diet that provides all of the nutrients the child needs until the child is fully fed on family foods. During the first 6 months, this should be with a suitable breast-milk substitute. The suitable breast-milk substitute would normally be commercial

infant formula, as home-modified animal milk is no longer recommended for feeding infants during the first 6 months of life, except as an emergency measure. Replacement feeding excludes breastfeeding.

c) Number of HIV-exposed infants with mixed feeding at or around 3 months.
   - Mixed feeding: feeding both breast milk and other foods or liquids to infants 0–6 months of age.

Denominator

The denominator is the same for all three indicators: the number of HIV-exposed infants 3 months of age whose feeding practice was assessed.

Frequency

Annual or more frequently, depending on a country's monitoring needs.

Data sources and measurement tools

This is a UA indicator (indicator 13: distribution of feeding practices [exclusive breastfeeding, replacement feeding, mixed feeding/other] among infants born to HIV-infected women).

Numerators: The numerators are calculated from national program records aggregated from facility registers or through special assessments of a sample of clinical records.

Ideally, data should be aggregated from appropriate sites and registers such as standalone or integrated registers of HIV-exposed infants, depending on where the services were provided and where data were recorded. During each visit, the health care provider should inquire about infant-feeding practices during the previous 24 hours: "What did you give your infant to eat or drink yesterday during the day and during the night?" After each response, the health provider should ask "Anything else?" The response will be recorded as one of the following: exclusively breastfeeding (EBF), replacement feeding (RF), or mixed feeding (MF). While this information is collected and recorded at every visit on the child health card, providers need to record it in the register only once, during the DPT3 vaccination visit. This record will be used for national-level compilation and reporting.

Denominator: The denominator is calculated from the total number of exposed infants whose infant-feeding practices were assessed. Exposed infants who did not attend facilities are not included in the denominator.

Efforts should be made to include all public, private, and NGO-run health facilities that provide follow-up services for HIV-exposed infants.

Strengths and weaknesses

The indicators measure important progress in safer infant-feeding practices among HIV-infected women and their exposed infants. They can also be used to indicate the quality of counseling related to infant feeding (with low rates of mixed feeding likely to indicate adequate counseling and support).

It should be noted that the indicators say nothing about quality of replacement feeding or the impact of feeding practices on child survival.

Some pitfalls of the indicators in reflecting the actual distribution of infant-feeding practices of HIV-exposed infants at the national level can be that they do not include HIV-exposed infants who may have already died, infants whose exposure status is unknown, or HIV-exposed infants whose mothers did not attend a facility with their infant for DPT3 or for another reason at or around 3 months.

Additional considerations for countries

To fully understand the extent and types of infant-feeding practices, countries may consider carrying out special studies with HIV-infected women who choose to replacement feed and exclusively breastfeed, examining the reasons why women who have chosen either breastfeeding or replacement feeding are or are not practicing the chosen option exclusively and whether the AFASS criteria are present.

3.4 Prevalence of HIV in pregnant women (disaggregated by age group)

What it measures
HIV prevalence among pregnant women attending ANC.

Rationale
To assess progress toward controlling HIV infection among women of childbearing age. This indicator should reflect efforts toward primary prevention of HIV in young women and women of childbearing age. It is calculated using data from pregnant women attending antenatal care clinics in HIV sentinel surveillance sites.

Numerator
Number of pregnant women tested whose HIV test results are positive, disaggregated by age group (15–24 years, >24 years).

Denominator
Number of pregnant women tested to determine their HIV infection status.

Frequency
Annual or biennial.

Data sources and measurement tools
Preferably, the numerator and denominator will be derived from sentinel surveillance studies. In situations where PMTCT program coverage is high, including HIV testing, programmatic data (extracted from national program records aggregated from facility registers) are a possible alternative.

Strengths and weaknesses
This indicator will be most useful when it is analyzed over time. Thus, consistency in the sites and methods used are important to enable appropriate comparisons.

The sample from which the prevalence of HIV among pregnant women is drawn is not necessarily representative of all pregnant women; rather, it is representative only of women who choose to attend antenatal care. Therefore, the higher the ANC coverage, the more reliable this indicator.

Additional considerations for countries

This indicator is used as a proxy for HIV incidence (especially if only women 15–24 years old are taken into account). The incidence of HIV infection is the preferred indicator to monitor the course of the HIV epidemic and the impact of interventions in generalized epidemics.[31] In countries where first sexual intercourse typically occurs at older ages and/or levels of contraception use are high, the HIV prevalence among pregnant 15–24-year-old women will differ from the prevalence among all women in that age group.

Countries may want to further disaggregate this indicator by location (urban/rural, major regions/provinces) and socioeconomic characteristics (e.g., women's educational level and wealth quintile) in order to monitor social inequalities and determinants of health.

31 More information is available in "Reproductive Health Indicators: Guidelines for Their Generation, Interpretation and Analysis for Global Monitoring." WHO, 2006. Retrieved from http://www.who.int/reproductivehealth/publications/monitoring/RHT_98_28/en/index.html

3.5 Prevalence of syphilis in pregnant women (disaggregated by age group)

What it measures
Prevalence of syphilis among pregnant women attending ANC.

Rationale
To assess progress in controlling syphilis infection among women of childbearing age. This indicator should reflect efforts toward primary prevention of syphilis in young women and other women of childbearing age. It is calculated using data from pregnant women attending antenatal care clinics at HIV/STI sentinel surveillance sites.[32]

Numerator
Number of pregnant women with positive serology for syphilis,[33] disaggregated by age group (15–24 years, >24 years).

Denominator
Pregnant women tested for syphilis in the same defined year.

Frequency
Annual or biennial.

Data sources and measurement tools
The numerator and denominator will be derived from sentinel surveillance studies. In situations where PMTCT program coverage is high, including testing pregnant women for syphilis, programmatic data (extracted from national program records aggregated from facility registers) are a possible alternative for this indicator.

Strengths and weaknesses
The sample from which the prevalence of syphilis among pregnant women is drawn is not necessarily representative of all pregnant women; rather, it is representative only of women who choose to attend antenatal care. In this context, studies that aim to determine the subregistration and subnotification of syphilis cases among pregnant women diagnosed in

32 The plan of action in the Region set the target for syphilis during pregnancy to less than 1%. See Plan of Action for the Elimination of Congenital Syphilis (PAHO/WHO/CE116/14), 1995.

33 According to the national diagnostic algorithm.

health care services may help to interpret the prevalence indicator and its quality.[34] This indicator will be most useful when it is analyzed over time. Thus, consistency in the sites and methods used is important to enable appropriate comparisons.

Additional considerations for countries

At both the national and international levels, this indicator is useful as a proxy of the STI burden in the general population and also as a marker of progress toward reducing this burden. If disaggregated, the 15–24-year-old age group may provide an idea of the incidence of new cases of syphilis, as most individuals this age are just beginning sexual activity. Of note, women attending antenatal clinics are believed to be a low-risk population since STIs are a major cause of infertility in developing countries. However, non-pregnant women include those who are not sexually active and therefore not at risk of STIs. Therefore, conclusions on syphilis prevalence in the general population based on sample surveys of pregnant women attending antenatal clinics should be made with caution.[35]

Countries may want to further disaggregate this indicator by location (urban/rural, major regions/provinces) and socioeconomic characteristics (e.g., women's educational level and wealth quintile) in order to monitor social inequalities and determinants of health.

34 For further information on the methodology of these studies, see the document Metodología para estudios de subnotificación de sífilis en embarazadas. PAHO, 2005. Retrieved from http://www.paho.org/Spanish/AD/FCH/AI/SubnotSifilisEmbarazo.pdf

35 More information is available in "Reproductive Health Indicators: Guidelines for Their Generation, Interpretation and Analysis for Global Monitoring." WHO, 2006. Retrieved from http://www.who.int/reproductivehealth/publications/monitoring/RHT_98_28/en/index.html

3.6 Integrated congenital syphilis and mother-to-child transmission of HIV elimination plan/strategy at the country level

What it measures
This indicator measures the existence of a national integrated plan or strategy for eliminating mother-to-child transmission of HIV and congenital syphilis that is in line with most recent international standards for the provision of PMTCT services.

PAHO recommends that national guidelines be available and include the following four lines of action from the conceptual framework of the elimination initiative:

1. Strengthen the capacity of maternal and child health, newborn care, and family and community services with respect to the early detection, care, and treatment of HIV and syphilis in pregnant women, their partners, and their children.

2. Intensify surveillance of HIV and syphilis in maternal and child services.

3. Integrate HIV, sexual and reproductive health, newborn care, and family and community health services.

4. Strengthen health systems by developing an essential package of services and ensuring adequate supplies, trained human resources, information systems, planning, leadership, coordination with other sectors, and so forth.

Rationale
PAHO has revised standards of prevention of mother-to-child transmission of HIV and congenital syphilis and recommends that national programs modify their guidelines accordingly and develop integrated plans and programs in order to successfully eliminate vertical transmission of HIV and congenital syphilis.

Qualitative indicator
This is a yes/no indicator. The response should be “Yes, plan or strategy exists” if national plans or strategies either exist in final or draft form or include all four above-mentioned lines of action.

Frequency
Annual.

Data sources and measurement tools

Self-reported from countries, key informants at the national level, and a detailed document review of existing plans.

Strengths and weaknesses

This indicator is not concerned with the quality of the plan or its implementation. However, the existence of such a plan demonstrates a country's intention to provide PMTCT services in line with international standards.

ISBN: 978-92-75-13111-4