Field Guide for Implementation of the Strategy and Plan of Action for Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in the Americas

Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

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PAHO HQ Library Cataloguing-in-Publication Data

Pan American Health Organization.

Field Guide for Implementation of the Strategy and Plan of Action for Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in the Americas. Washington, DC : PAHO, 2014.

1. HIV Infections – prevention & control. 2. Women's Health. 3. Child Health. 4. Syphilis, Congenital. 5. Americas. I. Title.

ISBN 978-92-75-11804-7 (NLM Classification: WC 503.3)

Contents

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Acronyms and abbreviations

ART	Antiretroviral treatment
ARV	Antiretroviral(s)
BCG	Bacille Calmette-Guerin
CBO	Community-based organization
CDC	Centers for Disease Control and Prevention
CLAP	Centre for Perinatology and Maternal Health
CS	Congenital syphilis
CSF	Cerebrospinal fluid
EIA	Enzyme immunoassay
EMTCT	Elimination of mother-to-child transmission
HPV	Human Papilloma Virus
IHSDN	Integrated health service delivery network
IM	Intramuscular
IPT	Isoniazid preventive therapy
LAC	Latin America and the Caribbean
MDG	Millennium Development Goal
M&E	Monitoring and evaluation
MNCH	Maternal, neonatal and child health
MTCT	Mother-to-child transmission
NGO	Nongovernmental organization
PAHO	Pan American Health Organization
PCR	Polymerase chain reaction
PMTCT	Prevention of mother-to-child transmission
POC	Point of care
RDT	Rapid diagnostic test
RPR	Rapid Plasma Reagin test
RVC	Regional validation committee
SOP	Standard operating procedure
SRH	Sexual and reproductive health
STI	Sexually transmitted infection
TB	Tuberculosis
TPHA	Treponema pallidum hemaglutination assay
TPPA	Treponema pallidum particle agglutination assay
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
VDRL	Venereal Disease Research Laboratory test
WHO	World Health Organization

Preface

In September 2010, the Pan American Health Organization (PAHO) Member approved the *Strategy and Plan of Action for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis* by Resolution CD50.R12 (*1*). The resolution calls on Member States to give priority to the elimination of mother-to-child transmission of HIV and congenital syphilis and to develop and execute national plans towards this goal, focusing on the needs of the most vulnerable populations. The resolution requests the PAHO Director to promote and support implementation of the Strategy and Plan of Action, promote partnerships and technical cooperation among countries, and report periodically to the Governing Bodies on progress toward the initiative's goals.

The PAHO HIV/STI Project, the Centre for Perinatology and Maternal Health (CLAP), and United Nations Children's Fund (UNICEF) are providing joint support for implementation of the Strategy and Plan of Action in collaboration with the Joint United Nations Programme on HIV and AIDS (UNAIDS), United Nations Fund for Population Activities (UNFPA), Centers for Disease Control and Prevention (CDC), and other partners. PAHO also established a reporting system to facilitate periodic reporting on a core set of indicators and, in 2013, coordinated a mid-term evaluation covering the first three years of implementation (2010–2012). The mid-term evaluation indicates that the Region has made significant progress but that accelerated scaling up of service coverage is needed to achieve the elimination targets by the year 2015.

This field guide was developed at the mid-point of the 2010–2015 implementation period as a resource for health authorities, program managers, and service providers, including private-sector organizations, NGOs, and civil society organizations, to develop or update national implementation strategies and plans, protocols, and operating practices with the aim of accelerating scale up of services. The document builds on and incorporates the most recent technical and programmatic guidance issued by the World Health Organization (WHO) and the Inter-Agency Task Team (IATT) for Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and Children, as well as the regional resources already developed and lessons learned from the mid-term evaluation and program assessments conducted in several countries during recent years. Countries that believe they may have achieved the elimination targets can initiate the validation process described in this document.

The implementation strategy elaborated in this field guide is comprehensive and promotes an integrated approach that will contribute not only to achievement of the elimination targets, but also to strengthening of comprehensive maternal, neonatal, and child health services as well as improvements in sexual and reproductive health services, including primary prevention of HIV, syphilis, and other STIs, and progress towards the Millennium Development Goals (MDG) and other global commitments.

With renewed and targeted efforts, our Region has the potential to achieve the elimination targets and ensure that our children are born free of HIV and congenital syphilis.

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Introduction

Introduction

In 1995 the Region adopted the Plan of Action for the Elimination of Congenital Syphilis (Resolution CE116.R3) (*1*), and in 2009 the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis was launched by PAHO and UNICEF. In September 2010, the PAHO Member States approved the Strategy and Plan of Action for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis by the year 2015 by resolution CD50.R12 (*1*).

Through this resolution, the Region commits to the following targets by the year 2015 (*2*):

- Reduction of the rate of mother-to-child transmission of HIV to 2% or less.
- Reduction of the incidence of mother-to-child transmission of HIV to 0.3 cases or less per 1,000 live births.
- Reduction of the incidence of congenital syphilis to 0.5 cases or less (including stillbirths) per 1,000 live births.

The resolution urges Member States to design and execute national plans and promote the establishment of public policies guided by the Strategy and Plan of Action, focusing on the needs of the most at-risk and vulnerable populations; share experiences and tools; promote an integrated approach based on primary health care and intersectoral action; promote the collection and use of data disaggregated by age, sex, and ethnicity; increase the coverage of quality health services; promote capacity among policymakers, program directors, and health care providers; improve coordination in the health sector and with other partners; and promote community participation (*1*).

The regional strategy is fully aligned with the following global initiatives: Global Elimination of Congenital Syphilis: Rationale and Strategy for Action (*3*), launched in 2007, and Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping Their Mothers Alive, adopted in 2011 (*4*).

The resolution commits PAHO to promote implementation of the Strategy and Plan of Action, collaborate with Member States, mobilize resources, promote technical cooperation among countries, and report periodically to the Governing Bodies on progress in reaching the goals of the Strategy and Plan of Action (*1*).

The PAHO HIV/STI Project, the Centre for Perinatology and Maternal Health (CLAP), and UNICEF are providing joint support for implementation of the Strategy and Plan of Action in collaboration with UNAIDS, UNFPA, CDC, and other partners. PAHO also established a reporting system to facilitate periodic reporting on a core set of indicators and, in 2013, coordinated a mid-term evaluation covering the first three years of implementation (2010–2012) (*5, 6*).

The mid-term evaluation indicates that the Region has made significant progress but that significant gaps remain and accelerated scaling up of service coverage is needed to achieve the elimination targets by the year 2015.

By the end of 2012, 33 countries and territories had developed strategic and/or operational plans, 30 had updated or developed integrated clinical guidelines, and 25 had developed monitoring and evaluation (M&E) strategies (*6*). The estimated regional HIV testing coverage among pregnant women increased from 53% in 2008 to 66% in 2011, and coverage of antenatal syphilis testing ranged from 35% to over 95% in the 24 countries that reported in 2011. The estimated coverage of antiretroviral therapy for pregnant women with HIV increased from 57% in 2008 to 70% in 2011 (*5*). Among the 22 countries reporting to PAHO on this indicator in 2011, the median coverage of syphilis testing among pregnant women was 85%. Coverage of syphilis treatment for pregnant women ranged from 24% to more than 95% in the 19 countries that reported to PAHO on this indicator in 2011 (*5*). Based on a modeling tool developed by UNAIDS, the HIV mother-to-child transmission rate in Latin America and the Caribbean for 2011 was estimated at 14.2% (95% CI: 5.8%– 18.5%), down from 18.6% (5%–22.9%) in 2010. If the breastfeeding component of transmission were excluded, the regional transmission rate would drop to 9.2% (*5*).

The available data indicates that as of 2012, at least five countries, including the United States of America and Canada, may have achieved the elimination target rate for HIV vertical transmission of 2% or less, and an additional 10 countries may be close to reaching the target, with estimated transmission rates between 2% and 7%. Fourteen countries may have achieved the elimination target for congenital syphilis (*5, 6*).

On the other hand, the mid-term evaluation also indicated that at least 6 countries have very low antenatal HIV or syphilis testing coverage (below 50%), and at least 10 have low to moderate coverage (between 50% and 70%) (*5, 6*).

Key implementation issues and challenges mentioned by the countries during the mid-term evaluation included 1) the need to strengthen health systems, health information and data collection systems, and develop service delivery models that integrate antenatal care (ANC), sexual and reproductive health (SRH) and HIV/STI services; 2) the need for the promotion of early initiation of antenatal care and improve the quality of ANC; and 3) the need to strengthen strategies to effectively reach adolescents and other vulnerable groups with primary prevention and maternal, neonatal and child health (MNCH) services (*6*).

This field guide aims to:

- **Summarize the lessons learned during the first three years of implementation of the Strategy and Plan of Action for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis.**
- **Summarize relevant technical guidance from the World Health Organization (WHO), PAHO, and other technical agencies.**
- **Provide health authorities, program managers, and other health personnel with practical guidance on updating or developing plans for accelerated implementation of the Regional Strategy and Plan of Action.**

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Targets and lines of action for elimination of mother-to-child transmission of HIV and congenital syphilis in the Americas

II Targets and lines of action for elimination of mother-to-child transmission of HIV and congenital syphilis in the Americas

II.1. Goals, objectives, and lines of action

The goal of the regional strategy is to eliminate mother-to-child transmission of HIV and congenital syphilis as public health problems in the Americas by the year 2015 through (2):

1. Reduction of the rate of mother-to-child transmission of HIV to 2% or less.
2. Reduction of the incidence of mother-to-child transmission of HIV to 0.3 cases or less per 1,000 live births.
3. Reduction of the incidence of congenital syphilis (including stillbirths) to 0.5 cases or less per 1,000 live births.

In order to achieve and sustain these targets, the following programmatic objectives must be met and maintained (2):

1. Increase to 95% or more the coverage of antenatal care and skilled attendance at birth.
2. Increase to 95% or more the coverage of HIV and syphilis screening of pregnant women.
3. Increase to 95% or more the coverage of adequate HIV[1] and syphilis[2] treatment in pregnant women and prophylactic management of HIV and syphilis in children.
4. Increase to more than 95% the number of first-level health care centers that provide services for prevention and diagnosis of HIV/STIs in an integrated manner with other services (antenatal care, sexual and reproductive health care, services for adolescents, prevention of and treatment for gender-based violence, etc.).
5. Increase to more than 95% the number of countries that have information systems for monitoring and evaluation of progress towards the elimination of mother-to-child transmission (EMTCT) of HIV and CS.

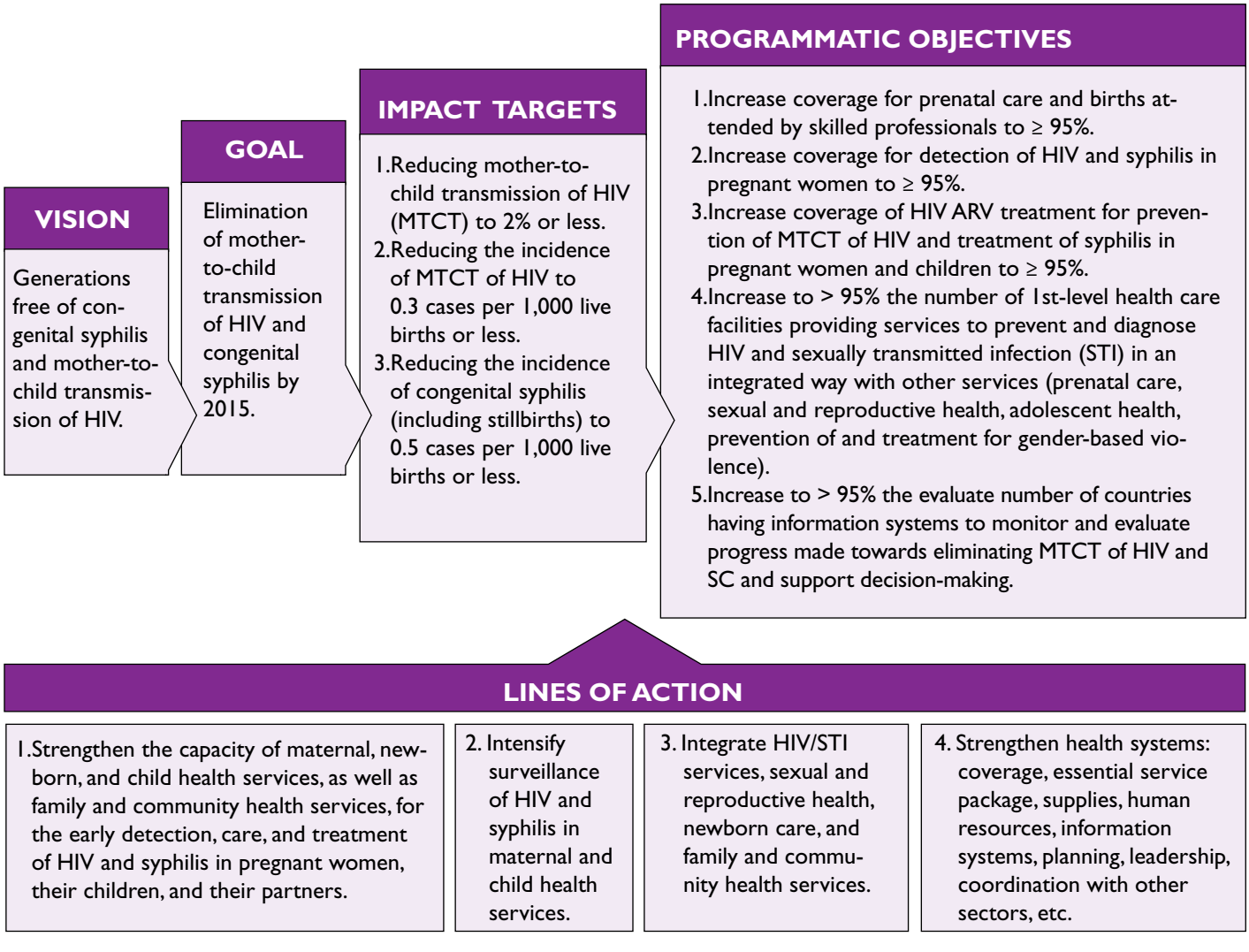
The regional strategy proposes four lines of action (Figure II.1) that are mutually complementary and jointly provide a comprehensive set of interventions needed to prevent new HIV and syphilis infections in persons of reproductive age and pregnant women, promote sexual and reproductive health and prevent unintended pregnancies among women living with HIV, promote early identification and appropriate treatment of pregnant women with HIV or syphilis infection and their male partners, and promote appropriate treatment and follow-up of infants exposed to HIV or syphilis (2).

1. Triple antiretroviral therapy.
2. At least a single dose of long-acting intramuscular penicillin.

The lines of action in the regional conceptual framework are in line with the four-pronged implementation strategy of the WHO PMTCT Strategic Vision (*7*) and the Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping Their Mothers Alive (*4*). Figure II.2 presents the linkages between the global strategy and the regional lines of action.

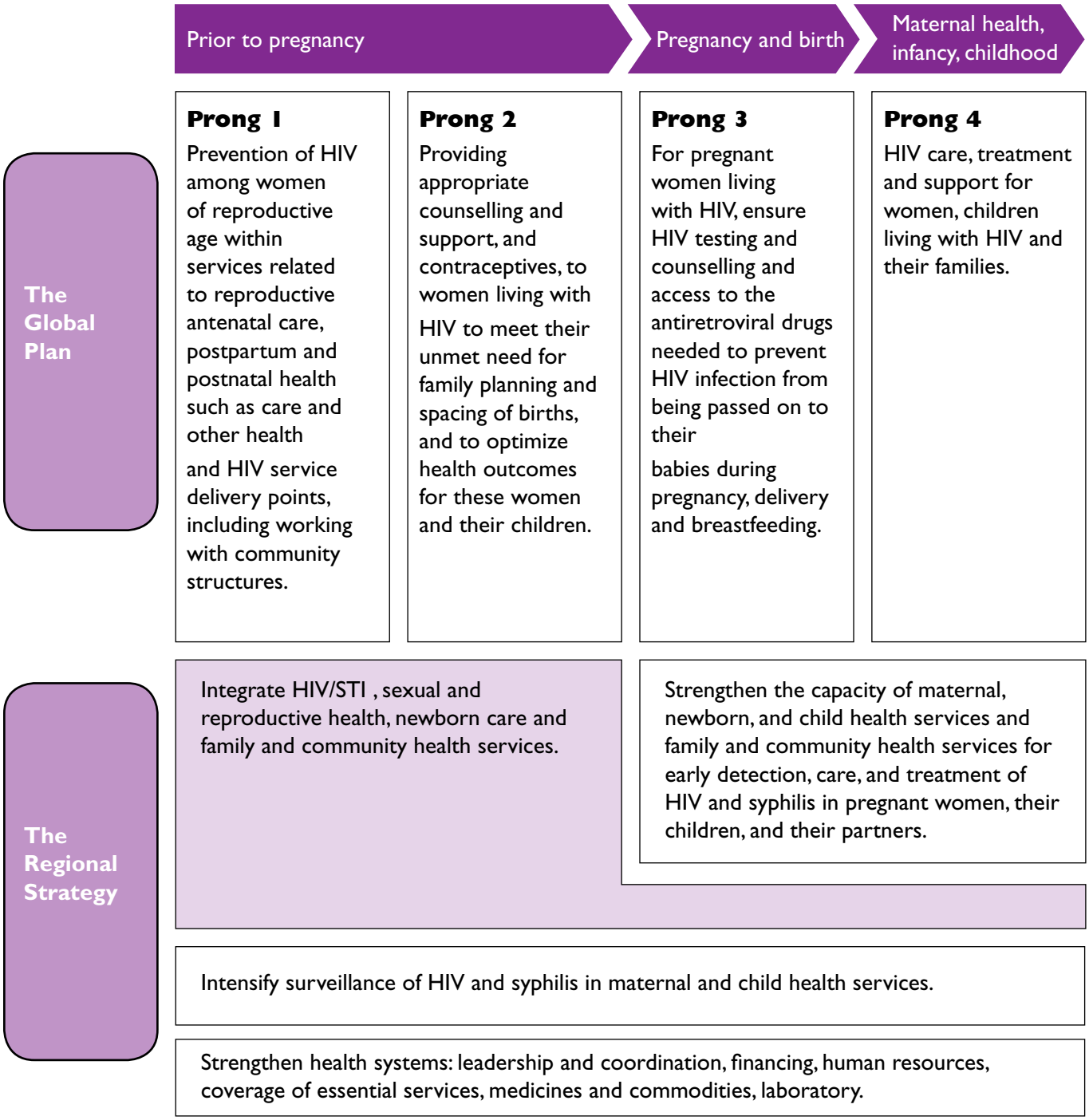
Schematic presentation of the Regional Strategy for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in the Americas

Figure II.1



Since the launch of the regional EMTCT strategy, PAHO and UNICEF, in collaboration with other partners, have developed various tools to assist countries with implementation, including a conceptual document (*2*), integrated guidelines (*8*), a monitoring and evaluation framework initially developed in 2010 and updated in 2013 (*9*), a costing tool (*10*), and technical recommendations for implementation of HIV and syphilis prevalence studies during labor or delivery (*11*). Annex 1 provides an overview of these resources.

Figure II.2 *Correlation of the lines of action of the regional strategy for the elimination of mother-to-child transmission of HIV and congenital syphilis with the implementation strategy of the global plan*



II.2. Linking the regional EMTCT strategy with other initiatives and programs

Implementation of the EMTCT strategy requires the following services: sexual and reproductive health, adolescent health, men's health, STI, maternal and child health, and HIV and syphilis treatment and care. Therefore, the EMTCT strategy should be implemented not as a vertical effort but, rather, as part of a comprehensive effort aligned with other programs aimed at strengthening health systems, preventing maternal mortality, and improving maternal and child health, HIV/STI prevention and treatment, and other related services and programs. The following paragraphs highlight some programmatic areas and initiatives directly related to the EMTCT strategy.

Treatment 2.0

Treatment 2.0 is a WHO/UNAIDS platform that aims to catalyze the next phase of HIV treatment scale up by promoting innovation and efficiency gains through focused work in five priority areas (*12*):

- Optimizing drug regimens through the development and use of simplified, less toxic drug regimens with high barriers to drug resistance, establishment of optimal dosages of ARV medicines, development of one-pill-a-day fixed-dose combinations, and expansion of access to effective, safer, and affordable first-, second-, and third-line drug regimens.
- Providing point-of-care (POC) and other simplified diagnostic and monitoring tools to expand HIV diagnostic testing and the virologic and immunologic tests used for management of ARV treatment.
- Reducing costs through pooled procurement of drugs and diagnostics, simplified manufacturing processes, potential dose reductions, and price negotiations.
- Adapting service delivery to more decentralized and integrated models, with increased community engagement in service delivery and improved retention in care.
- Mobilizing communities of people living with HIV and key populations involved in the demand creation, planning, delivery, and evaluation of quality-assured, rights-based HIV care and treatment programs.

With the introduction of the option of lifelong ARV treatment for HIV-positive women after delivery, also known as Option B+, (*13, 14*), full alignment of the Elimination Strategy with HIV treatment programs becomes imperative to ensure strong and sustainable treatment programs, application of the same principles to ARV treatment during pregnancy, and efficient post-delivery transition into the treatment program.

Millennium Development Goals (MDGs)

The following four MDGs are of particular relevance to the EMTCT strategy:

- **MDG 3: Promote gender equality and empower women**

  The regional EMTCT strategy directly contributes to MDG 3 by promoting the empowerment of women of all ages , in particular adolescent girls, through improving their access to SRH and HIV/STI prevention, treatment, and care services and strengthening their capacity to negotiate safer sexual practices and manage their own fertility (*15*).

- **MDG 4: Reduce child mortality**

  In 2011, an estimated 203,000 deaths of children under age 5 occurred in Latin America and the Caribbean, of which 53% (107,000) were neonatal deaths (*16*). The primary direct causes of neonatal mortality in LAC are infections and perinatal asphyxia, but many of the underlying causes are preventable and reflect social inequities such as limited access to education and health services, including antenatal care and skilled attendance at birth (*17*).

  Without proper treatment and follow-up, most children who contract HIV via their mother will die before their fifth birthday, and syphilis infection during pregnancy contributes to low birth weight, neonatal death, stillbirth, and congenital infection (*2*).

  Prevention of HIV and syphilis infection in pregnant women, expansion of the coverage of antenatal services and skilled attendance at birth, and early identification and proper treatment of pregnant women infected with HIV or syphilis are critical components of the elimination strategy that will contribute to the implementation of Resolution CD47.R19 (Neonatal Health in the Context of Maternal, Newborn, and Child Health), adopted by the PAHO Member States in 2006 (*17*), and Resolution CSP28.R20 (Strategy and Plan of Action for Integrated Child Health), adopted in September 2012 (*18*), aimed at reduction of under-5 mortality.

- **MDG 5: Improve maternal health**

  Between 1990 and 2010, the maternal mortality rate dropped by 43% in Latin America and by 30% in the Caribbean (*19*). While this constitutes significant progress, the trajectory of the decline is insufficient for the region to achieve MDG 5 by 2015 (*19*). In 2011, the 51st Directing Council approved a plan of action to accelerate reductions in maternal mortality and severe maternal morbidity (*20*). The plan of action proposes key interventions to promote unrestricted access to high-quality preconception care, including family planning, as well as antenatal, childbirth, and postpartum care provided by skilled personnel. Key interventions in the plan include the following:

  - Increase contraceptive coverage, including emergency contraceptive methods, and the availability of family planning counseling prior to conception and after an obstetric event.
  - Increase access to affordable, high-quality preconception, antenatal, childbirth, and postpartum care through consideration of a regionalized approach.
  - Increase the number of skilled personnel in health facilities who can provide preconception, antenatal, childbirth, and postpartum care.
  - Promote prevention and detection of intra-family violence during pregnancy.

- Strengthen information systems and maternal and perinatal health monitoring in the framework of integrated information and vital statistics systems.

There is a clear convergence between the key actions proposed in the plan of action for reductions in maternal mortality and the lines of action for elimination of vertical transmission of HIV and congenital syphilis. Optimal alignment and integration of these efforts would therefore contribute to a more comprehensive approach and acceleration in both areas.

Box II.1 Tuberculosis in pregnancy **Box II.1**

Tuberculosis contributes to maternal mortality and is among the leading causes of death among women aged 15-45 in high burden areas. Obstetric complications of TB include spontaneous abortion, small for date uterus, preterm labor, low birth weight, neonatal mortality, and in rare cases, congenital TB.

Early diagnosis of TB in pregnancy can be challenging because the non-specific symptoms of early TB such as weakness and excessive perspiration can erroneously be attributed to pregnancy, and the progressive weight loss can be masked or compensated by the pregnancy weight gain.

Awareness of the TB risk factors and symptoms, and active follow-up for early diagnosis is essential for all pregnant women.

Awareness and appropriate action are important for pregnant women living with HIV, to prevent obstetric complications in mother and infant related to TB infection, and transmission of TB to other mothers and infants in the maternity ward.

Sources: Loto, OM., Awowole, I. Tuberculosis in pregnancy: a review. J. Pregnancy. Vol. 2012, pp. 1-7 and Mathad, JS., Gupa A. Tuberculosis in pregnant and postpartum women: epidemiology, management, and research gaps. Clin Infect Dis. 2012 Dec;55(11): 1532-49.

- **MDG 6: Combating HIV/AIDS, malaria, and other diseases**

  In addition to HIV and syphilis, there are several other diseases that can be transmitted vertically. Interventions designed to reduce adverse outcomes overlap with the lines of action and priority activities in the EMTCT strategy, and countries can explore how optimal linkages can be established with malaria, TB, Hepatitis, Human Papilloma Virus (HPV) and other programs to maximize positive health outcomes (*21*). Annex 2 provides an overview of vertically transmitted diseases that can be incorporated in or linked with the Elimination strategy.

The Global Strategy for Women's and Children's Health

In 2010 the United Nations Secretary-General launched the Global Strategy for Women's and Children's Health, calling for all partners to unite and take real action through enhanced financing, strengthened policy and improved service delivery, to ensure that all women and children get the prevention, treatment and care they need. The global strategy, also referred to as *"Every Woman, every Child,"* highlights access to family planning, vaccines, proper nutrition, prevention and treatment for pneumonia, diarrhea, HIV/AIDS, malaria, tuberculosis (TB) and noncommunicable diseases (*22*).

A Promise Renewed

In June 2012 more than 80 governments and partners from civil society, faith-based organizations and private sector, were convened by UNICEF to launch a re-energized and sustained global effort to end preventable child deaths. This global movement is called "A Promise Renewed," and encompasses child, maternal and reproductive health. By the end of 2012, 172 governments, including 32 in Latin America and the Caribbean, had signed the pledge (*23*).

The Regional Plan of Action on Adolescent and Youth Health

The Regional Strategy for Improving Adolescent and Youth Health and the Plan of Action on Adolescent and Youth Health were approved by PAHO Member States in 2008 and 2009, respectively (*24*). Improving the sexual and reproductive health of adolescents is one of the priorities of these regional mandates.

Adolescents in the Region of the Americas continue to face challenges related to access to sexual and reproductive health information and services, while at the same time adolescents, in particular girls, bear a significant burden of sexual and reproductive health problems such as STIs, teen pregnancy, unsafe abortions, and sexual violence.

Expanding adolescents' access to comprehensive SRH services and addressing the underlying factors that contribute to their risk and vulnerability will contribute to reductions in HIV and syphilis infections in both current and future pregnancy cohorts, and timely diagnosis of such infections will facilitate the establishment of appropriate interventions for prevention of vertical transmission.

II.3. Summary of critical actions

- Utilize the tools developed by PAHO and UNICEF to strengthen national plans of action.
- Ensure optimal alignment of EMTCT services with HIV treatment services and efficient transition of women to adult treatment program following delivery.
- Seek optimal integration/alignment of the elimination plan of action with other related efforts, including programs and services designed to reduce maternal mortality and morbidity and infant mortality; improve sexual and reproductive health, maternal and child health, adolescent health; viral hepatitis, human papillomavirus (HPV), tuberculosis, and other infections.

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Integration of programs and services for sexual and reproductive health, HIV/STI prevention, maternal health, newborn and child health, and other family and community health services

III Integration of programs and services for sexual and reproductive health, HIV/STI prevention, maternal health, newborn and child health, and other family and community health services

This line of action relevant for all four prongs of the global plan (see Figure II.2) (*4*) promotes the development of comprehensive and integrated service delivery networks for primary prevention, early diagnosis, treatment, care, and follow-up.

Two programmatic components are highlighted in this chapter: (A) promotion of sexual and reproductive health and prevention of HIV and syphilis infection among women of reproductive age, and (B) promotion of sexual and reproductive health for women living with HIV, including providing appropriate counseling, support, and contraceptives and decreasing their unmet family planning needs.

III.1. Promotion of sexual and reproductive health and prevention of HIV and syphilis infection in women of reproductive age

The Inter-Agency Task Team (IATT) for Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and Children provides the following rationale for the importance of SRH and primary prevention in achieving the elimination targets:

- Modeling has demonstrated that the elimination targets will not be achieved without reducing the burden of HIV and syphilis infection in the annual cohort of pregnant women through prevention of HIV and syphilis infection among women of reproductive age (*25*).
- HIV-negative women are at increased risk of infection during pregnancy and breastfeeding due to physiological and behavioral risks (*25*).
- Acute maternal HIV infection during pregnancy and breastfeeding is associated with elevated rates of MTCT. Therefore, remaining HIV-negative, particularly during pregnancy, is essential in reducing vertical transmission (*25*).
- The motivation of parents to protect the well-being of their infant might contribute to greater uptake of safer sexual practices (*25*).

Key populations for primary prevention in this context are (a) all women of reproductive age and their sexual partners, in particular those preparing to have a child, (b) pregnant women and their sexual partners, and (c) breastfeeding women and their sexual partners.

Essential SRH services ***Box III.1***

- Promotion of sexual health, including fostering of a positive and respectful approach to sexuality and sexual relations.
- Promotion of safer sexual practices, including delay of sexual initiation, reduction of the number of sexual partners, and consistent condom use.
- Family planning and birth spacing services.
- Antenatal care, skilled attendance at delivery, and postnatal care.
- Management of obstetric and neonatal complications and emergencies.
- Prevention of abortion, promotion of safer abortion options, and management of complications resulting from unsafe abortions.
- Prevention, screening, and treatment of reproductive tract infections and sexually transmitted infections, including HIV, during the pre-pregnancy, pregnancy, and breastfeeding periods.
- Early diagnosis and treatment of breast and cervical cancer.
- Promotion of, education on, and support for exclusive breastfeeding.
- Counseling on infant feeding among HIV-positive women.
- Prevention and appropriate treatment of subfertility and infertility.
- Active discouragement of harmful practices such as female genital cutting as well as harmful gender norms, values, and stereotypes.
- Adolescent sexual and reproductive health.
- Prevention and management of gender-based violence.
- Promotion and awareness of sexual and reproductive health rights and their implications.

Adapted from: Population Council and UNFPA. Planning and Implementing an essential package of sexual and reproductive health services: guidance for integrating family planning and STI/RTI with other reproductive health and primary health services. Population Council, Washington, D.C., 2010; Pan American Health Organization. Linking sexual and reproductive health and gender programs and services with prevention of HIV/STI. PAHO, Washington, D.C., 2010.

The World Health Organization (WHO) recommends implementation of a package of preconception care to reduce maternal and childhood mortality and morbidity. Preconception care is defined as the provision of biomedical, behavioral and social interventions to women and couples before conception occurs, aimed at improving their health status and reducing behaviors and individual and environmental factors that contribute to poor maternal and child health outcomes (27).

The WHO identifies 13 areas to be addressed in a comprehensive preconception care package, including prevention, screening and treatment of STI, promotion of safer sexual practices, and

provision of HIV testing and counseling (*27*). Active promotion and provision of preconception care for women and couples planning to get pregnant, will contribute to primary prevention of HIV and syphilis infection, and appropriate pre-pregnancy treatment in case of infection.

The mid-term evaluation (*6*) and country assessments indicate that all the countries of the region have SRH services; however, the delivery of these services tends to be fragmented and offered by different providers, including public and private providers, family planning associations and other community-based organizations (CBOs). Linkages and formalized referral systems are limited. In addition, legal, policy, and societal limitations remain with respect to delivery of comprehensive SRH services to adolescents. A major persisting gap is the lack of a systematic response to prevent and address gender-based violence and its implications for SRH.

Global technical guidance recommends that planning, introduction, and expansion of an integrated package of SRH services be undertaken within the framework of the six WHO health system building blocks (described in more detail in Chapter V): leadership and governance, health financing, human resources, service delivery, health information, and medical products, vaccines, and technologies (*26, 28*).

Box III.2 *Planning and implementing a comprehensive package of SRH services*

Step 1: Preparation

- Define the essential SRH package in the local context.
- Generate political will and support.
- Mobilize and convene stakeholders: political and programmatic decision makers, service providers, NGOs, civil society, and community leaders and representatives.

Step 2: Analysis

- Conduct a baseline assessment of relevant SRH conditions, existing programs delivering component services, existing policies and strategies, budgets, applicable laws, policies, treaties, the capacities of partners at all levels, and societal norms and standards (e.g., gender dynamics, religious beliefs, cultural norms).
- Define potential gaps and required resources.

Step 3: Operationalization

- Negotiate and build a consensus on division of labor with respect to delivery, monitoring, and evaluation of the reconfigured package of services.
- Define targets and develop implementation plans with timelines and budgets.
- Develop or modify human resource profiles, flow charts, standard operating procedures, referral tools and guides, etc.
- Identify initial implementation sites.
- Build the capacity of service providers.
- Put in place necessary equipment and support services, including laboratory and pharmacy services.

Box III.2 (Continued)

Step 4: Implementation and evaluation

- Conduct a pilot implementation, starting in facilities that have the capacity to provide the services and monitor inputs and outputs and lessons learned.
- Community information and mobilization.
- Establish mechanisms for surveillance and monitoring of outcomes.
- Collect and analyze data.

Step 5: Monitoring and support

- Continually strengthen partnerships and the commitment of stakeholders and decision makers.
- Engage in stepwise scaling up that takes into account lessons learned from monitoring and evaluation.
- Establish routine quality assurance mechanisms.
- Ensure ongoing mentorship, supervision, on-the-job-training, and capacity building as needed.

Adapted from: Population Council and UNFPA. Planning and Implementing an essential package of sexual and reproductive health services: guidance for integrating family planning and STI/RTI with other reproductive health and primary health services. Population Council, Washington, D.C., 2010; World Health Organization. Asia-Pacific operational framework for linking HIV/STI services with reproductive, adolescent, maternal, newborn and child health services. WHO, Geneva, 2008.

Antenatal, HIV, SRH, STI, adolescent, and men's health services, as well as community-based programs and services, are suitable entry points for an integrated package of SRH services and should therefore be involved from the beginning (*26*). In addition, community-based stakeholders and organizations, including the media, schools, workplaces, faith-based organizations, and other NGOs and CBOs, and communities themselves should be actively involved in the design, delivery, and monitoring of these services (*26*).

III.2. Promotion of sexual and reproductive health and prevention of unintended pregnancies among women living with HIV

In spite of noted progress, the unmet need for family planning remains significant in the Region, including among women living with HIV. Each year there are 1.2 million unplanned pregnancies in the LAC region (*19*). The benefits of family planning, including birth spacing and prevention of unintended pregnancies, extend beyond prevention of vertical transmission and include potential reductions in maternal and infant mortality, healthier mothers and children, and better prospects for women in terms of education and employment (*25*).

Interventions in this area must take into account that all couples and individuals, including those living with HIV, have the right to decide freely and responsibly the number, spacing, and timing of their children and to have the information and means to do so. Therefore, interventions must be free of coercion or force and provide the full range of SRH services, with attention to specific issues related to HIV status (see Box III.3). SRH entry points for women living with HIV include HIV treatment and care services; maternal, newborn, and child health services; family planning services; HIV counseling and testing; and STI services (*25*).

Box III.3 *Family planning needs of women living with HIV*

- Address concerns regarding drug interactions between certain ARV medicines and hormonal contraceptives, which could lower contraceptive efficacy. Recommend dual protection (condoms in addition to hormonal contraceptive) as the standard.
- STI prevention, screening, and treatment: Persons living with HIV may be at greater risk for STIs, including HPV, syphilis, and genital herpes (HSV-2 or HSV-1), and these conditions may be more severe as well as prolonged or atypical in presentation.
- Provide information regarding the potential health risks to the woman's health if she becomes pregnant, especially if her CD4 count is low.
- Serodiscordance: Discuss the risk of HIV infection in serodiscordant partners and strategies to reduce this risk, in particular if a woman intends to become pregnant. When serodiscordant couples are identified and where additional HIV prevention choices for them are needed, daily oral pre-exposure prophylaxis may be considered as a possible additional intervention for the uninfected partner (14).
- Safer conception: Discuss options for safer conception methods in case of pregnancy wish.
- Prevention of vertical transmission: provide information regarding prevention of transmission of HIV during pregnancy, delivery and breastfeeding.

Adapted from: Interagency Task Team for Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and Children. Preventing HIV and unintended pregnancies: strategic framework 2011–2015. IATT, New York, 2012.

III.3. Summary of critical actions

- Ensure access to an integrated package of HIV/SRH services, including education, counseling, condoms, contraceptives, and HIV/STI screening, in preconception care, maternal health, men's health, adolescent health, and HIV programs and services.
- Expand access to contraceptives, particularly among adolescent girls and young women.
- Promote dual protection (condoms in addition to a hormonal contraceptive) as the gold standard, particularly among adolescent girls and young women, and women living with HIV.
- Provide education on and raise awareness regarding the risks of vertical transmission of HIV, syphilis, and other STIs during pregnancy and promote safer sexual practices, including condom use during pregnancy.
- Offer sexual and reproductive health services for women and couples living with HIV, taking into account the specific SRH needs of HIV-positive women.
- Provide and promote couples testing and promote initiation of treatment for infected partners in serodiscordant couples.
- Foster the involvement of male sexual partners in ANC and EMTCT services, including syphilis treatment of male partners of pregnant women who test positive for syphilis; and in decisions regarding safer sexual practices, condom use, ART, and infant testing; and in efforts to reduce intimate partner violence.
- Advocate for and support the implementation of programs that empower women, in particular adolescent girls, to break intergenerational cycles of poverty and inequity to reduce unwanted and unplanned pregnancies, gender-based violence, and vulnerability to HIV and STI infections.
- Routinely collect, analyze, and use relevant data disaggregated by age groups, ethnicity and other relevant variables, to identify barriers, challenges, and failures in the system and to inform targeted interventions designed to improve access, coverage and outcomes of services.
- Update training curricula for nurses, physicians, and other service providers to promote integrated health services (e.g., preconception, ANC, adolescent care services) and to incorporate training on SRH and primary prevention of HIV/STIs.
- Conduct routine periodic evaluations of the quality of integrated antenatal, adolescent health, and SRH services.

four

Early detection, treatment and care of HIV and syphilis in pregnant women, their partners, and their children

IV Early detection, treatment and care of HIV and syphilis in pregnant women, their partners, and their children

This line of action corresponds with Prongs 3 and 4 of the global plan (see Figure II.2), aimed at timely identification of HIV or syphilis infection in pregnant women followed by appropriate action to prevent vertical transmission, and to provide follow-up care for women living with HIV and their families.

Various technical guidelines and technical updates have been developed by WHO, PAHO, and technical partners such as CDC elaborating on HIV and syphilis diagnosis, treatment, and follow-up. This chapter summarizes the existing technical guidance and elaborates on implementation issues and lessons learned.

IV.1. HIV and syphilis testing

Most HIV and syphilis infections are entirely asymptomatic, and thus mother to child transmission (MTCT) of HIV and syphilis occurs among women who may not be aware that they are infected. Timely and efficient diagnosis during pregnancy is essential to reduce the risk of vertical transmission.

Early HIV diagnosis during pregnancy is essential to allow for timely initiation of prophylactic antiretroviral treatment and to plan for safe delivery and subsequent feeding options that minimize the risk of transmission from mother to infant.

Early detection and treatment are particularly important in the case of syphilis infection because of the very high risk of transmission. Approximately 50% of pregnant women with untreated syphilis will transmit the infection to their unborn child (*15*, *29*). Maternal syphilis infection can lead to adverse consequences, including fetal loss and stillbirth, as early as the second trimester. Although the risk for mortality is greater with recent infections, serious adverse pregnancy outcomes related to syphilis transmission from mother to child also occur in the case of untreated, latent infections longer than two years in duration (*30*).

Antenatal HIV and syphilis screening are well established in the Region (*6*). Most countries have been providing routine antenatal syphilis testing for many years in at least some urban centers in which there is sufficient laboratory capacity and have added antenatal HIV screening in the past 5–10 years. Country assessments (*6*) also indicate that antenatal HIV and syphilis screening are well accepted by pregnant women and that refusals are rare. However, coverage and monitoring of antenatal HIV and syphilis screening remain a challenge, and only a few countries have achieved the required 95% coverage level (*5*). HIV and syphilis testing must be available for all pregnant women accessing public as well as private health services.

Point-of-care (POC) HIV and syphilis testing

Implementation of simple, low-cost HIV and syphilis testing technologies and strategies will support accelerated expansion of coverage, facilitate efficient diagnosis and prompt treatment, and improve links to care and prevention (*31*).

There is a growing market of POC rapid HIV and syphilis tests. Most of these tests can use whole-blood samples from a finger prick and provide same-day results. The tests can be performed by well-trained and supervised nonlaboratory staff and can be used in all settings, including low-resource settings with limited infrastructure. It is recommended that countries review and consider appropriate inclusion of POC tests in their national algorithms and strategies. Chapter VII elaborates on considerations related to POC testing, including quality control.

Key issues and challenges associated with the scaling up of antenatal HIV and syphilis screening include the following:

- Pregnant women who attend antenatal care in late stages of pregnancy or not at all: As noted, adverse outcomes due to syphilis infection, including fetal loss and stillbirth, can occur as early as the second trimester of pregnancy. Therefore, gestational syphilis should be diagnosed and treated as early as possible in the pregnancy. WHO and PAHO recommend early initiation of antenatal care and initiation of syphilis and HIV testing at the first antenatal visit (*14*, *29*). Delays can result in women not being tested, as they may not return for further antenatal care. Regional and global guidelines (*14*) recommend initiation of ARV treatment as soon as a pregnant woman is diagnosed with HIV infection, independent of clinical stage or CD4 count. Women with reactive syphilis tests, as well as their male sexual partners, should promptly receive treatment.

- Limited syphilis testing capacity in antenatal clinics: Syphilis diagnosis has mostly relied upon nontreponemal screening tests (i.e., RPR or VDRL), with treponemal confirmatory testing (e.g., TPHA, TPPA, EIA). Although the RPR and VDRL tests are relatively simple and inexpensive, each requires basic laboratory capacity, including trained laboratory technicians, a rotator, and electricity. Since this capacity is usually not widely available, pregnant women are typically referred for syphilis testing, or blood specimens are taken at the health center and sent out for testing, sometimes with significant delays in return of test results. The availability of rapid syphilis tests provides the opportunity to screen for syphilis and provide immediate results at the antenatal clinic visit, as is the case with rapid HIV tests (*14*, *32*). Availability of syphilis test results at the clinic visit facilitates prompt (same-visit) treatment (intramuscular penicillin injection), thereby minimizing the chance of delayed or no treatment. Regardless of the methodology used, efficient testing and prompt availability of test results are essential to reduce loss to follow-up.

- Lack of routine inclusion of men in antenatal care: WHO recommends that male partners of pregnant women who are diagnosed with syphilis also be treated to prevent reinfection of the pregnant woman (*3*). Routine HIV screening of the male partner should be encouraged as well to allow infected men to be referred for life-saving treatment and to reduce the risk of HIV acquisition among uninfected men (*33*). Couples testing and counseling has multiple benefits, including appropriate action to prevent transmission to the uninfected partner, support for mutual disclosure, and involvement of the male partner in treatment, adherence, and care for the infant (*33*). Country assessments indicate that so far few countries in the Region have established mechanisms to include male partners in antenatal care and that few routinely offer couples testing and counseling.

- Loss to follow-up due to delays in testing or delivery of test results: Country assessments indicate that pregnant women face multiple barriers to accessing the full range of services they need, including difficulties with referrals to other sites for HIV and syphilis testing, co-pays and out-of-pocket expenses, and delays in delivery of test results. These barriers contribute to delays in initiation of treatment. Test procedures should be as simple as possible and low in cost, and test results should be available as soon as possible (*14*). Same-day results can greatly contribute to increased uptake of HIV and syphilis testing. Such rapid tests should be used in the context of adequate quality assurance, including national-level reference laboratories that provide external quality assurance as well as strategies that ensure proper use of the tests (e.g., proficiency testing strategies) (*14*).
- Stock-outs and interruptions in the availability of test supplies: Some countries have noted stock-outs of HIV or syphilis testing supplies, or interruptions in local availability, due to supply management factors. Maintenance of high screening coverage requires guaranteed availability of testing supplies, which can be accomplished only through an organized, quality-assured distribution process. Ensuring adequate and uninterrupted availability of diagnostics as well as essential medicines and other health products is critical and countries should build capacity for effective planning, procurement, distribution and rational use of these health products (*14*).
- Failure to diagnose seroconversion and reinfection during pregnancy: Effective prevention of vertical transmission of syphilis and HIV depends on the timely identification and treatment of infection during pregnancy. Global HIV testing and counseling guidelines recommend re-testing in the third trimester in low-level and concentrated epidemics if the pregnant woman is in a high-risk group (*32*). These groups include pregnant women with a partner whose status is unknown but who engages in high-risk behaviors, those with a known HIV-positive partner, sex workers, drug users, and those who have been exposed to HIV in the past three months (*32*). In the case of syphilis, screening and treatment of sex partners are important to prevent reinfection (*3*). Because sexual risk behaviors are common to a variety of sexually transmitted infections, pregnant women diagnosed with HIV or syphilis might also be screened for other potentially asymptomatic infections such as hepatitis, chlamydia, gonorrhea, and HTLV-1, and HPV (*14*, *21*). Countries should review their testing strategies and determine the optimal strategy for antenatal HIV and syphilis screening as well as screening for other infections.

IV.2. Treatment and follow-up of pregnant women with syphilis or HIV

Because women may initiate ANC late or not return after an initial visit, the most efficient and effective means of treating syphilis or HIV is to start at the first antenatal visit immediately following a positive test result, with appropriate follow-up care and support.

Table IV.1 and IV.2 summarize guidance for treatment and follow-up of pregnant women with syphilis and HIV, respectively. The recommendations for pregnant women living with HIV are drawn from the most current WHO guidance (*14, 34, 35*), while the syphilis recommendations draw from various sources, including the PAHO integrated guidelines for elimination of mother-to-child transmission of HIV and congenital syphilis, published in 2010 (*8*) and CDC recommendations (*36*). It is important to note that the PAHO guidelines were not been developed through the same GRADE systematic review process as is applied to the development of the WHO guidelines, but were developed based on literature review, expert opinion and peer review .

For further details, the reader is referred to the referenced source documents.

Treatment of maternal syphilis

Table IV.1

1	• Treatment should start immediately after a positive result, preferably at the antenatal clinic, unless the woman's status requires more complex care (*8*, *36*).
2	• Treatment of primary, secondary, and early latent syphilis consists of 2.4 million units of intramuscular (IM) benzathine penicillin provided in a single dose (*8*, *36*). • For mothers with latent infections of more than 1 year in duration or infections of unknown duration, treatment consists of 3 weekly doses of 2.4 million units of IM penicillin (*8*, *36*). • Although oral medications can be effective in treating syphilis in adults, intramuscular penicillin is the only agent known to safely and effectively treat the fetus (*36*). • Patients with penicillin allergy can be desensitized; this requires a facility able to provide respiratory support and cardiac monitoring if required. The PAHO clinical guidelines (*8*) and CDC STI guidelines (*36*) elaborate on desensitization therapy and on treatment options in cases in which penicillin cannot be used.
3	• All of the woman's sexual contacts should be tested and if positive treated for syphilis in accordance with national guidelines (*8*, *36*).
4	• Treated women should be evaluated with quantitative nontreponemal tests (VDRL or RPR) at 1–3-month intervals (*8*, *36*).
5	• A fourfold or higher increase in titers may indicate treatment failure, reinfection, or the presence of neurosyphilis. Treatment should be repeated, and close follow-up is needed (*8*, *36*).
6	• Treatment of maternal syphilis must be registered on the patient's chart. In cases of positive diagnosis in the mother and no documentation of treatment in the chart, the live or stillborn infant should be noted as having a congenital syphilis diagnosis (*36*).

Follow-up of HIV-positive pregnant women

Table IV.2

1	• WHO recommends that all pregnant and breastfeeding women with HIV should initiate triple ARVs (ART) which should be maintained at least for the duration of mother-to-child transmission risk. HIV testing of the male partner should be encouraged (*13*, *14*).
2	• The currently recommended first-line regimen for adults, including pregnant women, is TDF + 3TC (or FTC) + EFV (*13*, *14*), available as single-pill fixed-dose combination. • The appropriate ARV prophylaxis for an HIV-positive pregnant woman depends on various factors, including whether she is already on treatment for her own health, prior short-term exposure to ARV treatment in the context of a previous pregnancy, and the timing of initiation of treatment (during pregnancy, shortly before delivery, or during delivery). Global guidelines elaborate on options for the different scenarios (*14*, *34*).

Table IV.2 (Continued)

3	• WHO recommends lifelong continuation of ART initiated during pregnancy, also referred to as Option B+ as an option (*14*). Advantages of Option B+ include further simplification of the treatment regimen, elimination of CD4 count as a prerequisite, simplification of service delivery and harmonization with ART programs, protection for future pregnancies, and a potential prevention benefit of reduction of sexual transmission to sexual partners (*14*).
4	• The risk of HIV transmission during labour and delivery can be minimized by following several key principles and practices, including facility-based delivery by trained skilled birth attendants; avoiding unnecessary instrumentation and premature rupture of membranes; and non-invasive suction of nasogastric secretions and washing away blood in the newborn. (*14*).
5	• Although Caesarean section has been shown to protect against HIV transmission, especially in the absence of ARV drugs or in the case of high viral load, WHO does not recommend it in resource-limited settings specifically for HIV infection; rather it is recommended for obstetric and other medical indications (*14*).

The use of efavirenz (EFV) for pregnant women was previously not recommended due to concerns about the safety of use in early pregnancy. The current WHO guidelines state that systematic analysis of available evidence showed no increased risk of birth defects with EFV compared with other ARV drugs used during the first trimester of pregnancy. The evidence also suggests that a once-daily combination of TDF + 3TC (or FTC) + EFV is less frequently associated with severe adverse events and has a better virological and treatment response compared with other one- or twice-daily regimens (*14*).

The TDF + 3TC (or FTC) + EFV regimen is available as a single-pill fixed-dose combination. Use of the same regimen for EMTCT and for first-line adult treatment can contribute to simplified drug forecasting, procurement, distribution and monitoring (*14*).

The mid-term evaluation of the implementation of the elimination strategy indicated that several countries in the Region have already introduced lifelong ARV treatment following pregnancy (Option B+), and others are preparing to introduce this option (*6*). Box IV.1 summarizes considerations involved in the implementation of Option B+ (*39*).

Considerations in the introduction of Option B+ **Box IV.1**

- Alignment of national structures responsible for coordination of PMTCT, ART, and other relevant programs (i.e., MNCH, family planning).
- Assessment of the acceptability of Option B+ for women living with HIV.
- Development of policies and procedures necessary to adopt Option B+.
- Assessment of the cost, cost-effectiveness, and feasibility of providing ART for all women to prevent MTCT.
- Assessment of optimal modalities for ART service delivery during and after pregnancy, and preparation of the health system to provide these services, including laboratory and supply chain management.
- Assurance of a prompt and effective transition from PMTCT to ART programs, with routine quality assessment of referral systems.
- Assurance of appropriate adherence support, patient education, family planning, and other services.

Adapted from: Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and Children. Expanding and simplifying treatment for pregnant women living with HIV: managing the transition to Option B and B+. IATT, New York, 2013.

The estimated 2011 coverage of antiretroviral treatment among pregnant women in the R egion was 61% (79% in the Caribbean and 56% in Latin America) (*5*). As noted earlier, suboptimal coverage of HIV screening influences timely identification and treatment of pregnant women living with HIV. However, the available data (*5*) indicate that there are also women who are diagnosed but not treated, pointing to gaps and challenges related to effective follow-up of women with positive HIV serology. It is important for countries to analyze and address these gaps and challenges to reduce missed opportunities.

IV.3. Treatment and follow-up of infants exposed to HIV or syphilis

Table IV.3 and IV.4 summarize guidance for treatment and follow-up of infants exposed to HIV and syphilis, respectively. The recommendations for HIV-exposed infants are drawn from the most current WHO guidance (*14, 34, 35*), while the syphilis recommendations draw from various sources, including the PAHO integrated guidelines (*8*) and CDC recommendations (*36*). As previously mentioned, the PAHO guidelines were not been developed through the same GRADE systematic review process as is applied to the development of the WHO guidelines, but were developed based on literature review, expert opinion and peer review.

Table IV.3 *Treatment and follow-up of infants exposed to HIV*

Element	Details
1	All infants born to HIV-positive mothers should receive prophylactic treatment to reduce their risk of HIV infection. Breastfed Infants should receive 6 weeks of infant prophylaxis with once-daily NVP (*14*). Infants receiving replacement feeding should receive 4-6 weeks of infant prophylaxis with once-daily NVP or twice-daily AZT (*14*).
2	Most countries in the LAC region provide replacement feeding for exposed infants. If replacement feeding is not acceptable, feasible, affordable, sustainable, and safe, exclusive breastfeeding for 6 months is recommended, with continued maternal ARV use (*14*). The combination of breastfeeding and replacement feeding should be avoided, as this option carries the highest risk of transmission (*14*).
3	Follow-up care for HIV-exposed infants includes ART adherence counseling and support, cotrimoxazole prophylaxis, monitoring of potential ART side effects, general care and growth monitoring, diagnosis of HIV infection, monitoring and treatment of tuberculosis (TB) and other opportunistic infection, and possibly a modified immunization schedule if the child is HIV-positive (*14*). The WHO does not recommend Bacille Calmette-Guerin (BCG) vaccine for children with HIV infection. Detailed guidance and vaccination schedules can be found in referenced WHO document (*40*). Annexes 3 and 4 provide additional information regarding management of TB/HIV coinfection during pregnancy.
4	WHO guidelines recommend early virological HIV testing at 4-6 weeks. For infants with an initial positive virological test result, it is strongly recommended that ART be started without delay and, at the same time, a second specimen be collected to confirm the initial positive virological test result. (*14*). Infants with signs or symptoms suggestive of HIV infection should undergo HIV serological testing and, if positive, virological testing (14). WHO further recommends that well, HIV-exposed infants undergo HIV serological testing at around nine months of age or at the time of the last immunization visit, followed by virological testing in case of a reactive serological test.

Table IV.4 *Follow-up of infants exposed to syphilis*

Element	Details
1	In the case of women who were diagnosed with syphilis during pregnancy and whose nontreponemal test did not return to negative (or the results are unknown), the mother-infant pair should undergo quantitative, nontreponemal testing after delivery (preferably the same test at the same time, conducted by the same laboratory). Infant tests should be done on infant serum and not cord blood. All infants should be clinically evaluated (*8, 36*). Mothers delivering stillborn infants should undergo nontreponemal screening. Any stillborn infant whose mother had a syphilis diagnosis, did not receive appropriate treatment more than 4 weeks prior to delivery, or had a seroreactive nontreponemal test at delivery should be considered as having a congenital syphilis diagnosis. While this does not require an additional pathologic work-up of the infant, such a work-up would be ideal (*41*).

Table IV.4 (Continued)

Element	Details
2	If children (a) have clinical or radiological evidence of congenital syphilis, (b) were born to a mother who did not receive adequate treatment for maternal syphilis at least 4 weeks before delivery, (c) are asymptomatic and have an (infant) RPR or VDRL titer fourfold higher than the mother's titer (regardless of maternal treatment), or (d) are asymptomatic and their mother was adequately treated but there are no quantified titers for comparison, they must receive the following therapy (*8, 36*): • Aqueous crystalline penicillin G: 100,000–150,000 units/kg/day, administered as 50,000 units/kg/dose IV every 12 hours the first 7 days of life and every 8 hours thereafter for a total of 10 days OR: • Procaine penicillin G: 50,000 units/kg/dose IM in a single daily dose for 10 days
3	The following children should receive 50,000 units/kg/dose IM of benzathine penicillin G in a single dose: those who have a normal physical examination and a serum quantitative nontreponemal serologic titer that is the same as or less than fourfold higher than the mother's titer and those whose mothers were treated more than 4 weeks before delivery, had treatment appropriate for their stage of infection, and had no evidence of reinfection or relapse. No further evaluation is required (*8, 36*).
4	All children with positive syphilis serology at birth must receive postnatal monitoring with clinical examinations and nontreponemal serological tests every two to three months until the test becomes negative or until the titer has been reduced in four dilutions (*8, 36*). Antibody titers should decrease at 3 months and turn negative at 6 months if the child was not infected. If the titers remain stable or increase after 6–12 months, the child should be reevaluated *(8, 36*).

Follow-up care for exposed infants poses major challenges to countries, as evidenced by the limited availability of data in this area (*5*). In 2010 and 2011, 20 countries did not report data on the number of HIV-exposed infants treated and the number lost to follow-up. In the countries that did report in 2011, the percentage of exposed infants lost to follow-up ranged from 0% to 70%, totaling more than 1,500 such infants. Similarly, in 2010 and 2011, more than 10 countries did not report on cases of congenital syphilis (*5*).

Studies on loss to follow-up of infants exposed to HIV, conducted mostly in Africa, have shown that factors associated with increased risk of loss to follow-up include health systems without quality-assured follow-up systems, delays in testing, lack of social support, lack of knowledge, poverty, and younger maternal age (*42,43,44*). Interventions and factors that contributed to reductions in the number of infants lost to follow-up in these studies included a special postnatal clinic for HIV-positive mothers and their infants; reductions in the time needed to make a diagnosis; active follow-up of mother-infant pairs after delivery by patient advocates, peer educators, or specially assigned health workers; and integration of follow-up in regular infant and child health programs (*43, 44*). A critical component of national strategies must be to strengthen the capacity for early diagnosis of infants exposed to HIV or syphilis.

IV.4. Summary of critical actions

- Promote early enrollment in antenatal care, in the first trimester of pregnancy.
- Review and update HIV and syphilis testing practices for adults and infants, along with guidelines, standard operating procedures (SOPs), and algorithms, in line with current global guidance, aiming for simplification and decentralization, and quality assured test results.
- Introduce same-visit HIV and syphilis testing where feasible, with same-day provision of results and prompt initiation of treatment.
- Where same-visit HIV and syphilis tests using laboratory services are not feasible, introduce point-of-care rapid HIV and syphilis testing, with results and treatment provided at the clinic visit.
- Promote partner testing for HIV and syphilis and provide couples counseling and testing services, ensuring treatment for sexual partners of women who test positive for syphilis.
- Provide periodic refresher courses for health care providers on quality integrated antenatal services, including routine HIV and syphilis testing coupled with prompt prophylaxis or treatment.
- Conduct periodic program evaluations of ANC services to identify program implementation gaps and challenges.
- Introduce the recommended first line regimen TDF + 3TC (or FCT) + EFV for HIV-positive pregnant women, provided in a single pill, fixed-dose combination where feasible.
- Introduce lifelong ARV treatment for HIV-positive pregnant women (Option B+).
- Ensure full alignment of EMTCT services with ARV treatment programs and services, along with efficient transition of HIV-infected women and infants to treatment programs.
- Implement strategies such as active follow-up (e.g., home visits), tracking of mother-infant pairs, and early diagnosis of infants to reduce the number of HIV- and syphilis- exposed infants lost to follow-up.

five

Strengthening health systems and expanding coverage of essential services

V Strengthening health systems and expanding coverage of essential services

This line of action cuts across the programmatic areas and is included in the regional framework in recognition of the critical importance of a health system that is able to deliver the needed services to all, in particular those in greatest need, in a comprehensive way and on an adequate scale to achieve and maintain the elimination targets.

V.1. Strengthening health systems

WHO defines six functional aspects or "building blocks" that make up a health system (*28*):

- Effective leadership and governance ensure that strategic policy frameworks exist and are combined with capable oversight, coalition-building, regulation, and accountability.
- A good health financing system raises adequate funds for health in ways that ensure access to services and protection from financial catastrophe or impoverishment caused by medical expenses. It provides incentives for providers and users to be efficient.
- A well-performing health workforce is one that is competent and works in ways that are responsive, fair, and efficient to achieve the best health outcomes possible given available resources and circumstances.
- Good health services deliver effective, safe, high-quality health interventions to those who need them, with minimum waste of resources.
- A well-functioning health information system ensures the production, analysis, dissemination, and use of reliable and timely information on health determinants, health system performance, and health status.
- A well-functioning health system ensures equitable access to essential medical products, vaccines, and technologies of assured quality, safety, efficacy, and cost-effectiveness and their scientifically sound and cost-effective use.

WHO defines health system strengthening as improving these six building blocks and managing their interactions in ways that achieve more equitable and sustained improvements across health services and health outcomes (*28*, *45*). Efforts to strengthen health systems require bolstering each of the building blocks as well as the way the building blocks work together to create a functional health system. Table V.1 summarizes key aspects of each building block.

Health system building block priorities **Table V.1**

Building block	Priorities
Leadership and governance	Health sector policies, harmonization and alignment, oversight and regulation
Health financing	Health financing policies, health expenditure tools and data, costing
Health workforce	Workforce policies and investment plans, advocacy, norms, standards, data
Service delivery	Packages, delivery models, infrastructure, management, safety and quality, demand for care
Health information	Facility- and population-based information and surveillance systems, standards, and tools
Medical products, vaccines, and technologies	Norms, standards, policies, reliable procurement, equitable access, quality

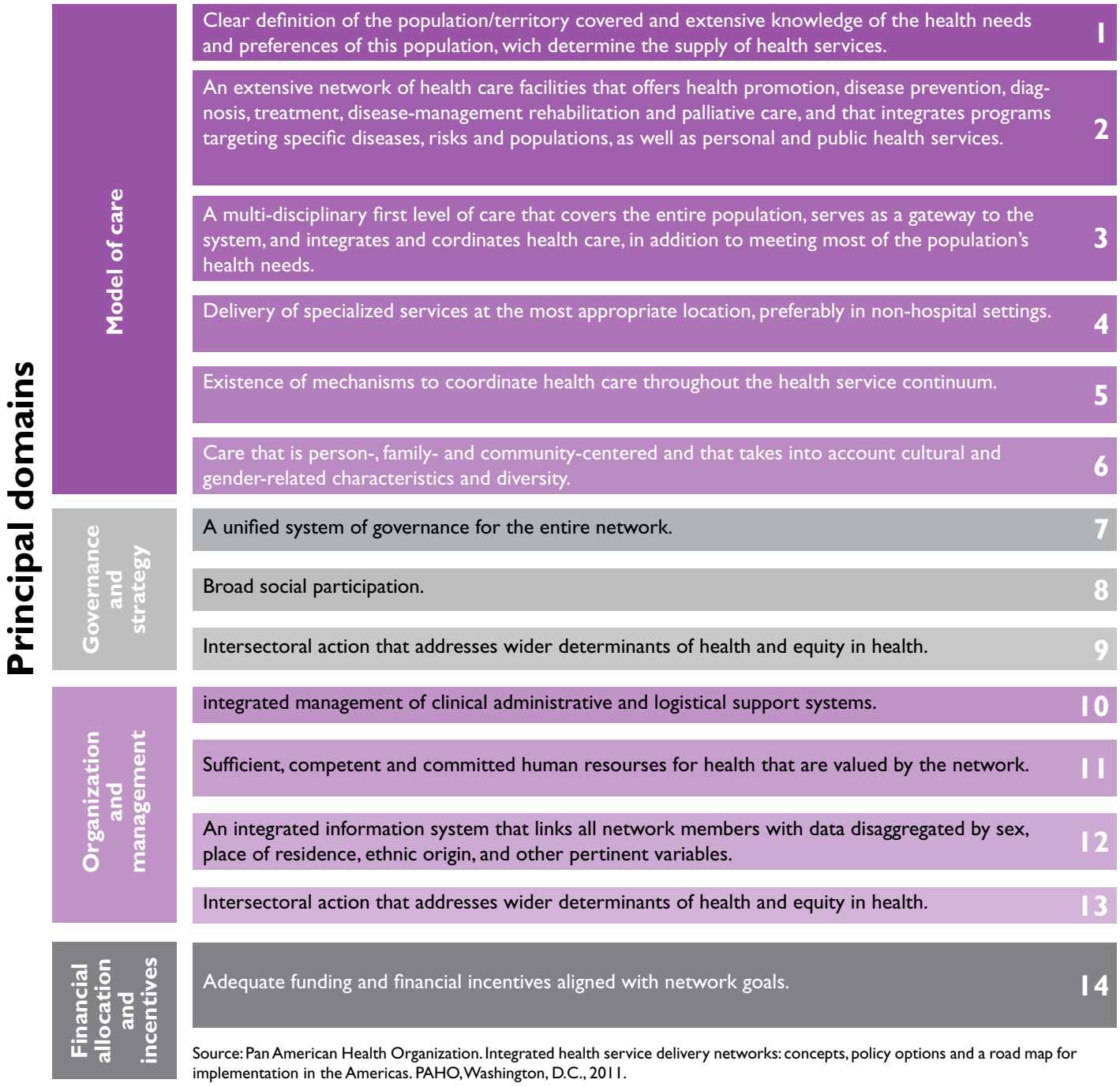
Source: World Health Organization (WHO). Everybody's business: strengthening health systems to improve health outcomes. WHO's framework for action. WHO, Geneva, 2007.

Health systems in the Americas tend to be highly fragmented, leading to difficulties in access to services, delivery of services of poor quality, inefficient use of resources, and low user satisfaction (*43*). Consequently, health system strengthening is a cross-cutting priority in the Health Agenda for the Americas 2008–2017 (*47*).

In response to the need for health system strengthening, PAHO created an initiative on integrated health service delivery networks (IHSDNs) that culminated in the adoption of Resolution CD49.R22 by PAHO Member States in 2009 and a proposal to establish a road map for implementing such networks (*47*). The purpose of the IHSDN initiative is to contribute to the development of primary health care–based health systems through operationalizing essential elements such as universal coverage and access; comprehensive, integrated, continuous, and appropriate care; optimal organization and management; a family and community orientation; and intersectoral action (*47*).

Implementation of the PAHO IHSDN initiative showed that the wide range of health systems makes it difficult to issue specific regional recommendations for health system strengthening and creation of delivery networks, as every country or local context should formulate its own strategy according to its political circumstances, economic resources, administrative capacity, and lessons learned. However, in general each process should include the following steps: (1) identification of the main problems related to health service fragmentation, (2) development of national plans, (3) implementation of plans, and (4) ongoing evaluation (*47*).

Figure V.1 *Essential attributes of IHSDNs*



Source: Pan American Health Organization. Integrated health service delivery networks: concepts, policy options and a road map for implementation in the Americas. PAHO, Washington, D.C., 2011.

V.2. Strengthening programs for elimination of mother-to-child transmission of HIV and congenital syphilis

The strategy for elimination of vertical transmission of HIV and syphilis calls for and provides an opportunity for strengthening of health systems in the region through application of a "diagonal" approach in national plans of action. WHO defines a diagonal approach as (*46*):

- Taking desired health outcomes as the starting point for identifying health system constraints that inhibit effective scaling up of services.
- Addressing health system bottlenecks in such a way that specific health outcomes are met while system-wide effects are achieved and other programs also benefit.
- Addressing health system policies and capacity issues.
- Encouraging the development of national health sector strategies and plans and reducing investments in isolated plans for specific aspects of health systems.
- Establishing robust monitoring and evaluation frameworks.

Along these lines, PAHO has developed an assessment methodology that incorporates the health system building blocks as well as the main programmatic areas related to the elimination targets (*45*). Figure V.2 presents the analytical framework for such an assessment.

Analytical framework for assessment of the national strategy for elimination of mother-to-child transmission of HIV and congenital syphilis

Figure V.2

Health system building block	Programmatic area							
	Primary prevention of HIV and syphilis	SRH services for HIV-positive women and their partners	Antenatal care (coverage and quality)	HIV and syphilis screening of pregnant women and their partners	HIV and syphilis treatment for infected pregnant women, their partners and infants	Follow-up and diagnosis of exposed infants	Nutritional support for infants exposed to HIV	Care and support for women and children living with HIV, and their families
Leadership and governance								
Financing								
Health workforce								
Service delivery								
Medical products and technology								
Health information system								
Cross-cutting issues: gender, human rights, ethnicity, stigma and discrimination, etc.								

Adapted from: Organización Panamericana de la Salud. Evaluación para el fortalecimiento de la respuesta del sistema de salud al VIH/sida: lineamientos para la región de las Américas. OPS, Washington, D.C., 2010.

The methodology facilitates assessment of the performance of the health system building blocks and the programmatic areas at the national and local levels and in various service delivery contexts (*48*). The methodology has been applied in several countries in the region, and these experiences indicate that the tool is useful in supporting identification of challenges and bottlenecks and informing strategic planning to strengthen national programs and accelerate progress towards the elimination targets (*6*).

Effective implementation of this line of action will require close collaboration between the managers and stakeholders representing the programmatic areas, as well as the health planners and stakeholders representing the health system building blocks, to ensure appropriate input and optimal benefit.

V.3. Summary of critical actions

- Promote and apply a health systems perspective in the planning, implementation, and monitoring of plans of action.
- Ensure the involvement and input of health planners and stakeholders representing the areas incorporated in the health system building blocks in the planning, implementation, and monitoring of plans of action.
- Conduct assessment of the national strategy, incorporating a comprehensive health systems and programmatic perspective in the methodology.
- Incorporate health system strengthening in implementation strategies and plans of action to ensure sustainability of progress.

six

Surveillance and monitoring of HIV and syphilis in maternal and child health services

VI Surveillance and monitoring of HIV and syphilis in maternal and child health services

This line of action is also cross-cutting, aiming to strengthen monitoring and evaluation (M&E) and surveillance systems across programmatic areas, including primary prevention, antenatal care, HIV and syphilis diagnosis, treatment, care, and follow-up. The main purpose of this line of action is to support countries in generating information to monitor how the program is performing, whether targets are being reached, and to identify gaps and challenges.

In addition to the critical importance of reliable evidence to inform strategic planning for improvement of program performance, the availability of reliable national data is a condition for validation of achievement of the elimination targets (*48*). Countries eligible for validation must have a functional monitoring and surveillance system, one that:

- Can accurately assess intervention coverage and detect all cases (with a minimal acceptable error) of vertical transmission in a timely manner.
- Is able to capture service delivery and outcome data from both the public and private health sectors.
- Minimizes sources of systematic bias and follows data quality standards.

In collaboration with UNICEF, PAHO developed a regional monitoring strategy that proposes a core set of indicators to monitor progress towards the elimination targets (*9*). To minimize the burden on countries, these indicators are aligned with global indicators and reporting requirements. The use of a standardized set of indicators also facilitates regional monitoring of progress and reporting to the Governing Bodies by PAHO, as stipulated in Resolution CD50.R12 (*1*). The regional monitoring strategy (*9*) outlines the indicators proposed for each of the priority areas (see Tables VI.1, VI.2, and VI.3), defines the numerators and denominators for each indicator, and includes information on data sources.

To complement and elaborate on the information outlined in the monitoring strategy, the sections to follow summarize essential elements of a national system required for effective monitoring of the elimination strategy and validation of achievement of the elimination targets.

VI.1. Impact indicators

Table VI.1 presents the impact indicators for monitoring of elimination of congenital syphilis and mother-to-child transmission of HIV as public health problems.

Table VI.1 *Impact indicators*

Element	Details
1	Annual rate of reported cases of congenital syphilis per 1,000 live births.
2	Reported rate of mother-to-child transmission of HIV: percentage of infants born to HIV-positive mothers, who tested positive for HIV.
3	Annual rate of reported cases of mother-to-child transmission of HIV per 1,000 live births.

As specified in the regional monitoring strategy, countries should aim to monitor the impact indicators using actual data. However, estimates of the denominators for Indicators 1.1. and 1.3 (estimated numbers of live births) can draw from UN population estimates of numbers of live births or from the US Census Bureau international database (*9*).

In most countries in the region, congenital syphilis continues to be subject to compulsory notification. However, major challenges remain with respect to national case definitions of congenital syphilis, accurate diagnosis of cases, and inclusion of stillbirths attributable to syphilis (*6*). Therefore, the M&E framework recommends routine evaluation of the quality of CS surveillance and case reporting systems (*9*).

With regard to HIV, particular challenges have been noted related to following up mother-baby pairs (*5, 6*). Because there is a high percentage (>10%) of exposed infants with undetermined diagnoses, it is difficult to accurately assess the impact of the program. Therefore, countries should strengthen their mechanisms for follow-up of mother-baby pairs and conduct early infant diagnosis as part of the M&E strategy.

VI.2. Primary prevention and sexual and reproductive health indicators

Below Table VI.2 summarizes the indicators proposed to monitor progress made towards providing universal access to family planning and towards primary prevention of HIV and syphilis.

Treatment of maternal syphilis **Table VI.2**

Indicator	Description
2.1	Unmet family planning need.
2.2	Percentage of adolescents (ages 15–19) who are mothers or who are or have been pregnant.
2.3	Percentage of young women and men ages 15–24 who both correctly identify ways to prevent sexual transmission of HIV and who reject major misconceptions about HIV transmission.
2.4	Percentage of young women and men ages 15–24 who have had sexual intercourse before the age of 15.
2.5	Percentage of women and men ages 15–49 who had more than one sexual partner in the past 12 months who used a condom during their last sexual intercourse.
2.6	Percentage of pregnant women attended by skilled health personnel during the prenatal period.
2.7	Percentage of pregnant women whose first prenatal care visit occurs before 20 weeks gestational age.
2.8	Prevalence of HIV in pregnant women, total and disaggregated by age group: • 15–24 years • >24 years
2.9	Prevalence of syphilis in pregnant women, total and disaggregated by age group: • 15–24 years • >24 years

Indicators 2.1–2.5 are measured through population-based surveys such as demographic and health surveys, multiple indicator cluster surveys, behavior surveillance surveys, and contraceptive prevalence surveys. Such studies generally require significant investment and are therefore not conducted frequently. Identification of additional assessment opportunities, in the form of other population-based studies that can be expanded or modified at minor cost to include the questions needed to measure these indicators, can contribute to more cost-effective monitoring of indicators. A critical aspect is consistency in sampling and data collection methodologies to ensure comparability of results across studies.

Indicators 2.6 and 2.7 monitor the quality of antenatal care, and 2.8 and 2.9 assess the impact of primary prevention efforts as measured by the prevalence of HIV and syphilis infection in the annual pregnancy cohort. Indicators 2.8 and 2.9 reflect the prevalence among women who opt for prenatal care and thus might not represent all pregnant women. However, analysis of these indicators over time can be useful, and high ANC and testing coverage will increase the validity of the results obtained. It is important to emphasize that calculation of Indicator 2.8—the prevalence of HIV in pregnant women—must be based on all HIV-positive pregnant women, not only those tested. Thus, the lower the ANC and HIV testing coverage, the less reliable this indicator will be. The two prevalence indicators also provide some understanding of the impact of primary prevention efforts, particularly when they are disaggregated by age group. Trends in HIV seropositivity among pregnant women aged 15–24 years are considered a proxy for HIV incidence.

VI.3. Diagnosis, treatment, and care indicators

The following Table VI.3 summarizes the indicators proposed to monitor progress towards early diagnosis of HIV and syphilis infection in pregnant women and their sexual partners, appropriate treatment and care of seropositive women, and follow-up of exposed infants.

Table VI.3 *Diagnosis, treatment, and care indicators*

Indicator	Description
3.1	Percentage of pregnant women who were tested for HIV and received their results during pregnancy, during labor and delivery, and during the postpartum period (< 72 hours), including those with previously known positive HIV status.
3.2	Percentage of pregnant women tested for syphilis during pregnancy, total and before 20 weeks.
3.3	Percentage of pregnant women tested for syphilis at the first prenatal care visit.
3.4	Percentage of syphilis-seropositive pregnant women whose sexual partners are appropriately treated.
3.5	Percentage of syphilis-seropositive pregnant women who are appropriately treated.(at least 2.4 million units of IM benzathine penicillin in a single dose).
3.6	Percentage of HIV-positive pregnant women who received antiretrovirals to reduce the risk of mother-to-child transmission of HIV (a single dose of nevirapine is not considered a valid regimen for prevention of mother-to-child transmission of HIV).

Table VI.3 (Continued)

Indicator	Description
3.7	Percentage of infants born to HIV-positive mothers receiving antiretrovirals for prevention of mother-to-child transmission of HIV.
3.8	Percentage of infants born to HIV-positive mothers who were tested to determine their HIV status.
3.9	Percentage of infants born to HIV-positive mothers without a final HIV status assessment.
3.10	Distribution of infants born to HIV-positive mothers by feeding practices at 3 months.
3.11	Percentage of children (ages 0–14 years) living with HIV who were eligible for antiretroviral therapy and are currently receiving it.
3.12	National policy in place with Option B+, for prevention of mother-to-child transmission of HIV.
3.13	Percentage of stillbirths attributable to maternal syphilis.

An additional indicator (Indicator 4.1) is the percentage of infants who were born to mothers with positive syphilis tests and who received adequate treatment. This was included as an optional indicator in line with the WHO global strategy for the elimination of congenital syphilis (*3*).

Core data set for monitoring antenatal care and HIV and syphilis diagnosis, treatment, and care **Table VI.4**

Category	Data
All pregnant women	• Name and unique identifier. • Demographic characteristics: sex, date of birth/age, race/ethnicity, town of residence, marital status. • Gestational age at first antenatal care visit. • Total number of prenatal care visits. • Risk factors (sex work, substance use, poverty, domestic violence, multiple sexual partners, homelessness, mental illness, etc.). • Dates of HIV, tests used, and test results. • HIV testing and counseling of male sexual partner(s). • Dates of syphilis tests, tests used, and test results. • Syphilis testing of male sexual partner(s). • Supplemental data on TB and other infections (e.g., HCV, HTLV).

Table VI.4 (Continued)

Category	Data
HIV-positive mother	• Date and gestational age at first HIV test. • Treatment start date. • Gestational age at start of treatment. • Treatment regimen. • First and subsequent CD-4 counts. • First and subsequent viral load counts. • Continued ARV treatment after delivery (yes/no).
HIV-exposed infants	• Name and unique identifier linked to that of the mother. • Treatment of mother (yes/no and type of treatment). • Treatment of infant (dates and types). • Dates and types of HIV tests. • Final infant diagnosis (result and age at diagnosis).
Syphilis-positive mother	• Date and gestational age at syphilis diagnosis. • Treatment start date. • Treatment details. • Dates of follow-up syphilis tests. • Sexual partner(s) treated (yes/no).
Syphilis-exposed infant	• Date of delivery. • Vital status (alive, born alive and diseased, stillborn, unknown). • Date of death. • Birth weight (in grams). • Estimated gestational age. • Dates, types, and results of syphilis tests. • Signs of congenital syphilis. • Dates and types of treatment.

Most countries in the Region have systems for routine collection of certain MNCH data elements, ranging from comprehensive electronic systems to paper-based periodic reports. The most cost-effective and sustainable option is for countries to integrate above mentioned variables in the routine MNCH health information system with linkages to other relevant databases, including the HIV patient monitoring system and surveillance system.

With respect to HIV, PAHO recommends case-based or longitudinal surveillance that facilitates longitudinal tracking of infected individuals. Among women diagnosed during pregnancy, the antenatal clinic becomes the starting point for case reporting and surveillance. Similarly, for women diagnosed during delivery, the delivery site becomes the starting point for case reporting. Longitudinal or case-based surveillance facilitates access to information regarding diagnosis and treatment prior to the current pregnancy.

CDC definition of syphilitic stillbirth **Box VI. I**

A fetal death that occurs after 20 weeks of gestation or in which the fetus weighs more than 500 g and the mother had untreated or inadequately treated syphilis at delivery.

Source: Centers for Disease Control and Prevention (CDC). STD surveillance case definitions. Available at: http://www.cdc.gov/std/stats08/app-casedef.htm

One of the data management tools available to countries is the Perinatal Electronic System (SIP), developed by CLAP/PAHO. It consists of the Perinatal Clinical Record, the Perinatal Card, and web-based software designed to process the information. In a single page, the system puts together a comprehensive set of data on pregnancy, delivery, and birth, summarizing the information required for adequate care of the pregnant woman and her newborn. The SIP can be managed electronically, with a module for easy generation of reports. The system is available free of charge and can be accessed through the following link: http://www.clap.ops-oms.org/sistemas/.

An estimated 25% of pregnancies affected by active syphilis result in early fetal loss and stillbirth. A proportion of 2% or less of stillbirths attributable to maternal syphilis has been identified as a global indicator of congenital syphilis elimination (*9*).

Generating data for Indicator 3.13 (percentage of stillbirths attributable to maternal syphilis) requires a system for monitoring of fetal deaths. Since many adverse events due to syphilis occur in the second trimester, the period proposed for this indicator extends beyond the WHO stillbirth definition as a third-trimester fetal death (more than 28 weeks of gestation or a fetal weight of 1,000 grams or more) (*49*).

For this indicator, a stillborn infant is defined as a fetus delivered without vital signs (absence of breathing, heartbeat, umbilical pulse, or voluntary muscular movement) at 20 or more gestational weeks. In the event that gestational age is unknown, a fetal weight of 500 grams or above is used as a criterion (*9*).

To monitor this indicator, all mothers of stillborn infants should have serologic testing for syphilis. While other options are available to diagnose congenital syphilis in stillborn infants (e.g., autopsy, immunofluorescent antigen testing), a lower-cost public health approach is to establish the syphilis status of the mothers, since in the absence of other causes of fetal death a positive syphilis test of the mother in the absence of appropriate treatment would be a strong indication of congenital syphilis.

In addition to monitoring purposes, syphilis testing and treatment where appropriate of mothers of stillborn infants protect women from the complications of progressive infection and protect their future infants from congenital syphilis.

Challenges with surveillance and monitoring

The mid-term evaluation (*6*) identified several challenges related to diagnosis, treatment, and care monitoring, as follows.

- Limited or weak strategic information systems for maternal and child health services and missing data elements: For example, several of the countries assessed did not routinely collect antenatal syphilis screening data, even though routine ANC syphilis screening is well established.
- Challenges with completeness and accuracy of reporting due to various reasons, including lack of designated staff for collection and collation of the data at the various levels, lack of clear definitions of data elements, and breakdowns in reporting between the service delivery and program levels.
- Fragmented subsystems that operate independently from each other, making it difficult to link records and care provided across subsystems, particularly in the absence of a unique identifier.
- Lack of uniformity in case definitions of key events: For example, in some countries there are differences in the definition of stillbirth used by the vital registry and the definition used by the public health authority.
- Reporting of aggregated data at the local level: Some reporting systems are based on tallying and periodic completion of aggregated numbers (number of new ANC clients booked, number of clients tested for HIV during the reporting period, number of positive tests, etc.). This level of data collection is insufficiently rigorous for elimination purposes, as the process is prone to errors and double counting and does not allow for tracking of individuals across the cascade, in particular in the absence of a unique client identifier.
- Data are collected on the basis of procedures instead of persons: For example, in some countries reporting systems generate numbers of HIV and syphilis tests done. These numbers include multiple screening and confirmation tests, making it difficult to translate the numbers into coverage and outcome percentages. Data must be based on and related to clients.
- Data are limited to the public sector: Most countries face challenges with respect to engaging private providers in routine data collection mechanisms. Efficient engagement of the private sector involves a legal dimension that includes establishment of a clear legal framework for private-sector reporting and an operational dimension that includes establishment of functional data collection systems that respond to the information needs of the central government and are acceptable to private providers. Very few countries have been able to establish functional routine systems in this area, and countries typically rely on ad hoc data collection to generate needed information. Ongoing dialogue with the private sector is necessary to determine the levels of regulation and incentives needed for sustained engagement of the private sector in data collection and reporting.
- Limited analysis and use of data for decision making: Country assessments indicate that available data tend to be used to comply with international reporting requirements and are often not fully analyzed or reported back to local stakeholders to inform planning and modification of services and programs.
- Lack of qualified human resources to adequately support the health information system: several countries reported lack of epidemiologists and mid-level staff trained in data management.

Public-private partnerships in the Expanded Program for Immunization (EPI) **Box VI.2**

In the Region the EPI program can be used as a model for public-private partnerships, with the government providing the vaccines and the private providers reporting on immunizations provided.

VI.4. Case investigation and case finding

As noted earlier, the existence of a functional monitoring and surveillance system is a requirement for validation of achievement of the elimination targets. In addition to ongoing data collection based on the indicators mentioned, two additional measures—case finding and case investigation—can contribute to establishing the rigor required in the context of elimination efforts.

Case finding

Case finding can be defined as the act or strategy of locating individuals with the specific disease or condition under investigation. Cases can be symptomatic or asymptomatic.

In the context of syphilis and HIV, case finding is of particular relevance, as infected infants can go undetected without careful scrutiny. Essential conditions for systematic case finding include (a) a clear definition of a suspected case and (b) a clear definition of where and how probable cases will be identified.

Congenital syphilis

Any infant or stillbirth with unknown status and any of the characteristics in the PAHO congenital syphilis case definition (*Annex 6*) should undergo further assessment for case finding.

Other strategies countries can consider for active case finding of congenital syphilis include:

- Asking all women who are treated for syphilis whether they have been pregnant during the last 12 months and asking about the outcomes of the pregnancy.
- Reviewing fetal death records and determining whether they include the syphilis status of the mother.
- Collaborating with private and public hospitals, pediatricians, child health care centers, and emergency care sites to identify suspected cases for further investigation.
- Identifying and monitoring women not tested during ANC.
- Integrating congenital syphilis cases into active hospital surveillance conducted for diseases such as congenital rubella syndrome and acute flaccid paralysis.

HIV

The HIV status of all infants born to HIV-positive mothers should be assessed. HIV status should also be ascertained for infants born to a mother:

- who was not screened for HIV during pregnancy.
- who was not screened according to protocol.
- whose screening status is unknown.

In addition, all children who present with any of the following symptoms should be tested for HIV:

- Failure to thrive or wasting.
- Recurrent bacterial infection.
- Persistent diarrhea.
- Oral thrush.
- Unexplained hepatosplenomegaly and/or generalized lymphadenopathy.
- Developmental delays.

Other strategies countries can consider for active case finding of mother-to-child transmission of HIV include:

- Collaborating with private and public well-baby clinics, pediatricians, child health care centers, hospitals, and emergency care sites to identify suspected cases for further investigation.

Case investigation

The purpose of case investigation is to:

- Verify the validity of cases.
- Determine where there may have been failures in the program.
- Identify missing cases not detected earlier.

Several countries that conduct routine case investigation have established committees for periodic review of case investigation reports to obtain information on individual cases as well as to assess lessons learned from the specific trends or aspects observed (*6*).

The following information should be collected in the congenital syphilis case investigation form:

- Maternal information.
  - Name and/or unique identifier.
  - Date of birth.
  - Town of residence.

- Other relevant demographic information (e.g., nationality, ethnicity).
- Other relevant demographic information (e.g., nationality, ethnicity).
- Risk factors (e.g., sex work, substance use, homelessness, mental illness).
- Obstetric history (e.g., number of pregnancies, number of live births).
- Antenatal care (yes/no), trimester of first prenatal visit, total number of prenatal visits.
- Date of and gestational age at first syphilis test, type(s) of tests.
- Dates and types of treatment.
- Dates and types of additional syphilis tests.
- Other relevant maternal diagnoses (e.g., HIV).
- Treatment of male partner(s) (yes/no).

• Infant/fetus information

- Date of delivery.
- Vital status (alive, born alive and diseased, stillborn, unknown).
- Date of death.
- Birth weight (in grams).
- Estimated gestational age.
- Nontreponemal syphilis test (e.g., VDRL, RPR) (yes/no).
- Date of test and titer.
- Dates and types of additional tests (e.g., dark-field, direct fluorescent antibody, long bone X-ray, CSF VDRL).
- Signs of congenital syphilis.
- Dates and types of treatment .

Similarly, the following information should be collected in the HIV vertical transmission case investigation form:

• Maternal information

- Name and/or unique identifier.
- Date of birth.
- Marital status.
- Town of residence.
- Other relevant demographic information (e.g., nationality, ethnicity).
- Risk factors (e.g., sex work, injection drug/substance use, homelessness, mental illness).
- Obstetric history (e.g., number of pregnancies, number of live births).
- Antenatal care (yes/no), trimester of first prenatal visit, total number of prenatal visits.
- Dates, gestational age and results of first and subsequent HIV tests.
- ARV regimen and date of initiation.
- Treatment adherence status.
- CD4 tests and results.

  - Other relevant maternal diagnoses (e.g., syphilis, TB).
  - Other relevant maternal data (receipt of blood or blood component transfusion, tissue/organ transplant, etc.).
  - Type of delivery.

- Infant/fetus information
  - Name and/or unique identifier.
  - Facility and date of delivery.
  - Birth weight (in grams).
  - Estimated gestational age (full term, premature).
  - Types, dates and duration of treatment received either as prophylaxis or treatment (if HIV-infected).
  - Dates, types, and results of all HIV tests.
  - Types of nutrition (breast milk, replacement, mixed; in instances of breastfeeding, time periods should be specified).

Completion of the syphilis and HIV case investigation forms will require accessing various sources of information, including antenatal, labor, and postnatal data sources. Assignment of adequate human resources will be necessary.

VI.5. Summary of critical actions

- Review and update national surveillance and monitoring protocols and tools to ensure that all essential data elements are collected and that the system the necessary data.
- Actively explore opportunities to include monitoring of primary prevention indicators in existing population-based surveys.
- Introduce or strengthen national systems for monitoring of fetal death, ensuring that all deaths occurring at 20 or more weeks of gestation or at a fetal weight of 500 grams or more are included and that the syphilis status of the mother is noted.
- Ensure that adequate systems are in place for timely collection, collation, analysis, and dissemination of local-, regional-, and national-level information and that this information is used for strategic planning.
- Foster partnerships with private-sector organizations to facilitate data reporting.
- Review and harmonize surveillance case definitions for stillbirths and congenital syphilis and align them with international definitions.
- Develop mechanisms for case finding and case investigation.
- Plan method to collect data on new child HIV and syphilis infections.

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Laboratory support

VII Laboratory support

A national reference laboratory system that ensures high-quality services and provides support to lower-level laboratories is critical for implementation of the elimination strategy. In addition to routine antenatal laboratory services, essential laboratory elements include syphilis and HIV testing for adults and infants, CD4 and viral load testing, and testing for other infections that might be included in the elimination program, such as hepatitis B and C and HTLV-1. It is essential that tests are available at the most appropriate level of services and that high-quality testing—regardless of level—is assured. This can be accomplished through clearly defined national guidance outlining the roles and responsibilities of different levels of laboratories, as well as development of and adherence to standard operating procedures that are appropriate to the level of the laboratory. Additionally, laboratory personnel must be trained in carrying out appropriate testing and in adhering to standard operating procedures, including internal and external quality assurance and proficiency testing.

Effective methodologies for the detection of syphilis and HIV infection have been available for decades. In recent years, diagnostic technologies for both diseases have been expanded to include simple and POC technologies that can be applied by nonlaboratory personnel in environments other than traditional laboratory settings, thus making provision of same-day results possible (*31,50,51*). Critical to the reliable performance of these simpler tests, however, is the need to ensure that tests (and the testing process) are available without stock-outs, are subjected to rigorous quality control, and are conducted in an appropriate quality-assured environment under the direction of a well-functioning national reference laboratory.

VII.1. Syphilis diagnosis in adults and infants

Two main types of serological testing are used to diagnose syphilis: nontreponemal tests and treponemal tests. Nontreponemal tests, such as VDRL and RPR, detect antibodies directed against lipoid antigens released from damaged host cells and possibly from the treponemes themselves (*31,52,53*). These tests are low in cost and relatively easy to perform, but they must be conducted by trained laboratory personnel. Serum or plasma samples must be used in these tests rather than whole blood, and therefore laboratory equipment such as specialized reagents, a centrifuge to separate sera and a rotator for RPR (both requiring electricity), and a microscope for VDRL testing is necessary. Since nontreponemal tests may give false-positive biologic results in the presence of certain conditions or infections (*31*), it is recommended that positive nontreponemal results be confirmed using treponemal tests. Although RPR card tests are sometimes used by untrained or inexperienced personnel outside of basic laboratories, this practice should be discouraged as the quality of the test results is typically very poor (*52,53*).

Treponemal tests (e.g., TPHA, TPPA, ELISA, chemiluminescence and treponemal rapid tests, FTA-ABS) detect antibodies directed against Treponema pallidum proteins. These antibodies persist for life, even after provision of effective treatment (*54*), and thus a positive test could signal a past, treated infection or a current infection. As a result, establishment of a definitive diagnosis of active syphilis with only a treponemal diagnostic test is difficult in the absence of clinical signs or

a nontreponemal test. Used alone, treponemal tests can be useful in screening in certain settings with a low prevalence of syphilis and a high risk of poor outcomes if cases are missed (e.g., as quick antenatal tests for prevention of congenital syphilis). Even in these settings, a confirmatory nontreponemal test would be ideal to reduce the potential for over-treatment. However, treponemal tests are not useful in monitoring therapy efficacy or detecting relapses or reinfections. Treponemal tests detect IgG antibodies, which cross freely through the placenta. They also cannot be quantified. For these reasons, they cannot be used to diagnose newborns or infants.

Regular (nonrapid) treponemal tests are sometimes more costly and typically require more sophisticated equipment than nontreponemal tests, and, as is true with nontreponemal tests, they require trained laboratory personnel. These tests (with the exception of treponemal ELISA and chemiluminescence tests, which can be used as first-line automated diagnostic tests for screening large numbers of samples in settings where labor costs are high) are commonly used to confirm positive nontreponemal test results (*55*).

Since treponemal tests cannot be used to distinguish between active and past, treated infections, they are not typically used as the initial screening tool except in high-volume laboratories where treponemal testing has been automated or in point-of-care situations (e.g., antenatal screening, as described earlier). In such cases, reactive samples should ideally be confirmed using a nontreponemal test. In low-prevalence settings where the number of previously infected persons would be expected to be low, the presence of treponemal antibodies would be more predictive of current than past syphilis infections.

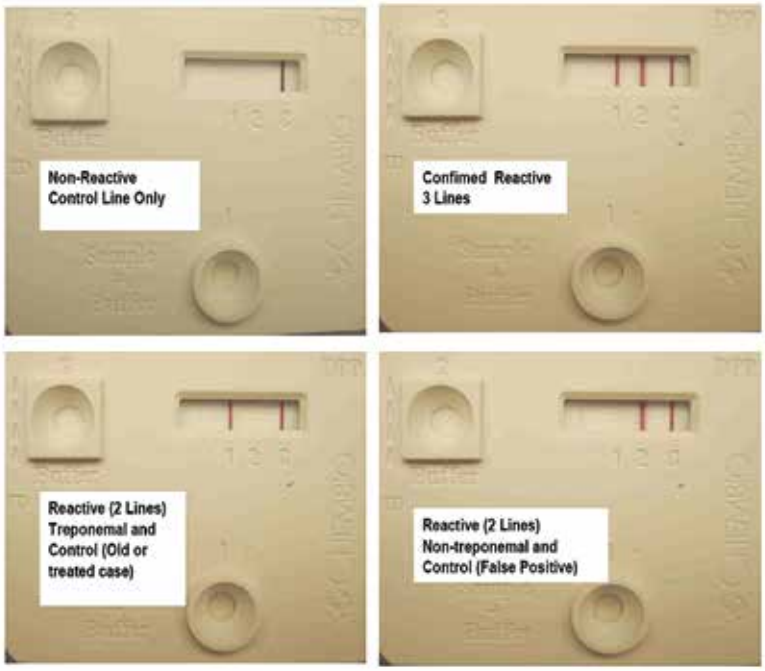
Rapid syphilis tests

Several rapid tests for syphilis diagnosis are now available. In addition to being less costly than other diagnostic tests, they are portable and user-friendly, can use whole blood, require no special equipment or storage conditions, and have relatively high sensitivities (85%–98%) and specificities (92%–98%) relative to laboratory-based treponemal tests (*31,51*). Importantly, these rapid tests can allow providers who do not have specialized technical expertise to do testing, obtain results, and provide treatment directly at the clinic visit.

Rapid treponemal tests can be considered for use as first-line screening tests in areas where infection rates are generally low and the frequency of antibody reactions due to past infections is low as well. A limitation of these tests is that they cannot differentiate between past and current infections, and hence positive treponemal tests (whether rapid or laboratory based) should ideally be confirmed with nontreponemal tests. Treatment of pregnant women with positive rapid treponemal test results can result in overtreatment; however, given the serious consequences of missed treatment during pregnancy and the low risk of adverse effects of syphilis treatment, the benefits of treatment outweigh the harm of overtreatment (*31*).

Another rapid syphilis test is the dual nontreponemal/treponemal single-platform test, which allows syphilis screening and confirmation with a single finger stick. There is evidence that the dual syphilis test is very effective in detecting infections in which RPR titers are 1:8 or above. The test is not yet widely available in the Americas but is anticipated to become available in more areas over time. This test would be very useful in antenatal care, particularly for women with a history of treated syphilis who have had more than one pregnancy.

Box VII. I *Dual nontreponemal/treponemal syphilis test*



More recent additions to the market are dual rapid test devices that combine HIV and treponemal tests, allowing screening for both infections with a single finger stick—again very useful in antenatal settings. Early evaluations of these tests indicate very high HIV sensitivity and less high, but adequate, syphilis sensitivity. When the tests are used according to the manufacturers' directions, their sensitivity ranges from 85%–98% and their specificity from 93%–98%. Rapid syphilis tests can be purchased through the WHO bulk procurement program at between US$ 0.19 and US$ 1 (*31*).

As noted, these tests can be very useful in antenatal settings, especially those in which women are not currently being screened or, if they have been screened and have positive results, are not receiving prompt treatment. The tests can be provided at the point of care, can use whole-blood samples from a finger prick, and provide results and allow for treatment at a single visit. They can be used in all health care settings, even those with limited electricity, refrigeration, or skilled laboratory staff (*15, 31*).

Direct identification tests

In addition to the diagnostic options mentioned, there are direct tests such as dark-field microscopy, immunofluorescence, and immunocytochemistry. These tests are not elaborated on in this field guide, as they require high levels of technical expertise and are not particularly relevant for antenatal settings.

Diagnosis of congenital syphilis

As noted earlier, mother-to-child transmission of syphilis in utero causes adverse pregnancy outcomes in more than 50% of untreated maternal infections (*29,56,57*), with the likelihood and severity of adverse outcomes increasing if infections are more recent. The complications of untreated maternal syphilis include second-trimester fetal loss, stillbirth, neonatal death, low birth weight, prematurity, intrauterine growth retardation, and congenital syphilis in live-born infants. Observational studies of infants born with congenital syphilis suggest that these infants have a high risk for morbidity and that up to 10% may die within the first year of life. Many health workers are unaware that congenital syphilis in infants, with its well-recognized stigmata and symptoms (Annex 6), represents only a fraction (about 25%) of the serious pregnancy outcomes associated with syphilis in pregnancy. Maternal infection can result in stillbirth or fetal death after 20 weeks of gestation, and these cases might not be recognized as attributable to syphilis.

A confirmed diagnosis of congenital syphilis requires laboratory demonstration of T. pallidum. However, at present few institutions are able to conduct such tests. Even if done, a negative diagnostic test (e.g., dark-field microscopy) does not rule out congenital syphilis. In practice, congenital syphilis is generally diagnosed on the basis of evidence of maternal infection determined through serologic testing. While information on risk and the clinical presentation of the infant can be helpful, infected infants may not demonstrate typical signs of infection. Treatment decisions should be based on maternal infection, serologic tests, or risk, and not only on the infant's clinical examination or laboratory test results. Serological diagnosis of congenital syphilis in infants presents some difficulty owing to the persistence of maternal treponemal and nontreponemal IgG antibodies in the infant's blood for up to 15 months after delivery. Infants born to seropositive women who did not previously receive appropriate treatment should be treated according to agreed-upon national clinical protocols (*8*).

Antepartum diagnosis and stillbirths

- Syphilis screening is recommended for all pregnant women, ideally early in pregnancy.
- In cases in which a mother who has not previously been tested delivers a stillborn infant, maternal testing can confirm syphilis infection and facilitate treatment of the mother.
- Stillbirth or fetal loss at 20 weeks or more of gestation or at a weight above 500 grams in a syphilis-seropositive mother who has not undergone adequate treatment should be considered a case of congenital syphilis.

Diagnosis in live-born infants

- Infants born to mothers presumed to have syphilis infection should be thoroughly examined at birth. If congenital syphilis is suspected, specialized laboratory or radiological tests can help support the diagnosis; however, a negative test or radiograph cannot rule out infection. Many of these tests are not available in all settings.
- Direct detection tests such as dark-field microscopy may be used to detect treponemes in lesions, tissues, or secretions (*8, 36*).
- Radiological changes in long bones can be relatively specific, although lack of X-ray findings does not rule out infection in an infant or child (*36*).
- Ideally, serological testing should include a quantitative VDRL (as opposed to RPR) test performed on a CSF sample, along with a CSF cell count and measurement of protein level. These more complex tests must be conducted in hospital settings with suitably equipped and staffed laboratories. CSF test results obtained during the neonatal period can be difficult to interpret, as values differ by gestational age. While a positive CSF test is consistent with congenital syphilis, a negative CSF VDRL does not rule out infection (*36*).
- Infants who are born to seropositive mothers and whose titers are at least fourfold higher than those of the mother when the maternal and infant samples are tested simultaneously are considered as having a congenital syphilis diagnosis (e.g., if the mother's titer is 1:8, the infant's titer is 1:32 or greater) (*8, 36*). Infants whose titers are less than fourfold those of their mother should be presumed to have CS and should receive appropriate treatment and follow-up testing.

VII.2. HIV diagnosis in adults and infants

A variety of HIV diagnostics, including conventional laboratory-based diagnostic tests (e.g., ELISA, Western Blot) and rapid diagnostic tests (RDTs), are available to support HIV diagnoses in adults and children. WHO recommends the use of RDTs to improve service delivery quality and the acceptability and uptake of HIV testing and counseling, as these tests allow quicker provision of test results, do not require venipuncture specimen collection, and can be performed by nonlaboratory personnel with appropriate training and supervision (*14, 32*). In settings where there are significant numbers of tests being carried out and patients are retained (e.g., inpatient and some ANC settings), testing according to laboratory-based methods may be more cost-effective and appropriate.

Each country should choose a national strategy and testing algorithms appropriate to its national context. The national selection process should be guided by considerations such as the following (*32*):

- The risk profile and prevalence of infection in the populations to be tested
- Test performance (sensitivity, specificity) and cost
- Ease of use (number of processing steps, technical expertise and equipment required)
- Testing objectives (screening, confirmation, clinical monitoring, etc.)
- Conditions of use (humid, dry, cold, hot)
- Storage conditions (e.g., temperature)
- Shelf life (a longer shelf life reduces pressure on the supply chain)

Box VII.2 *Serial and parallel testing algorithms*

- In a sequential testing strategy, samples are initially tested with one highly sensitive assay. Reactive samples are then retested using a second highly specific assay. A third test may be performed depending on the result of the second assay and the objective of the testing. Both the selection of and the order in which the assays are used (i.e., the algorithm) are of the utmost importance for the final outcome. If test combinations are not carefully selected, individuals may be incorrectly diagnosed. WHO recommends sequential testing in most settings because it is more economical, as the second test is required only when the initial test result is positive.
- In a parallel testing strategy, samples are tested using two different assays simultaneously. As with sequential testing, a third test may be performed depending on the results of the assays and the objective of the test. In low-prevalence settings, the parallel testing strategy is recommended only when it can add value in situations requiring a rapid decision (e.g., a pregnant woman who arrives at the clinic or hospital for delivery without having been previously tested). In these cases, two rapid parallel tests using whole-blood finger-stick specimens will provide results in just 10–15 minutes.

Source: World Health Organization. Service delivery approaches to HIV testing and counseling (HTC): a strategic HTC programme framework. WHO, Geneva, 2012.

Testing algorithms can apply only RDTs or combinations of RDTs and ELISAs or other EIAs. WHO recommends that the Western Blot and other confirmatory assays be used only to resolve inconclusive test results (*32*). HIV rapid tests that meet minimum WHO prequalification standards can be procured through the UN bulk procurement scheme (*32*).

Based on the assumption that all HIV assays used have sensitivities of at least 99% and specificities of at least 98%, resulting in an overall positive predictive value of 99%, WHO recommends the following sequential testing strategy for diagnosis in low-prevalence settings (HIV prevalence below 5% in the population to be tested) (*32*):

- A first test with one assay; this can be any assay (rapid or nonrapid).
- Specimens that are nonreactive are considered negative and reported as such.
- Specimens that are reactive on the first assay should be retested using a second assay different from the first.
- In the case of specimens that are reactive on both the first and the second assays, a third assay should be used to confirm the results.
- If the third assay is nonreactive, the result is considered inconclusive, and the person should be retested in 14 days.
- Specimen tests that are reactive on the first assay and nonreactive on the second assay should be repeated using the same specimen with the same two assays if the tests are done with serum/plasma, or with a new specimen when using finger-stick whole blood.
- Specimens reactive on the first assay but nonreactive on the second assay are considered HIV-negative and will be reported as such.
- If the first test is an antigen/antibody-detection assay and the second test an antibody-detection-only assay, the result will be noted as inconclusive, and retesting should be performed with another specimen taken after 14 days.

Diagnosing HIV infection in infants

High mortality among untreated infants infected with HIV in the first year of life makes early HIV diagnosis and rapid initiation of treatment of infected infants essential. The laboratory serology tests typically used to diagnose HIV infection detect the presence of antibodies against viral proteins. These techniques are not useful in newborns and infants younger than 18 months because of the presence of HIV antibodies transferred by the mother.

The virological tests used to diagnose HIV infection in children are DNA polymerase chain reaction (PCR), HIV RNA PCR (viral load), and p24 (*14, 35*). All infants born to HIV-positive women, regardless of treatment history, should be tested. WHO recommends virological HIV testing at 4-6 weeks of birth or at the earliest opportunity thereafter, so that infants with HIV infection can start ART. For infants with an initial positive virological test result, a second specimen should be collected to confirm the initial positive test result (*14*). Repeat testing is recommended for breastfed infants, six weeks or more after breastfeeding cessation (14).

HIV DNA PCR

- This test detects HIV viral DNA in blood cells.

- The relatively complex DNA PCR technology must be used in conventional laboratory environments.
- The timing for virological testing dovetails well with the start of the normal immunization schedule, and linking of the two can improve follow-up of infants.
- Modalities are available to ensure access of DNA PCR testing, particularly in resource-limited settings. For example, the use of dried blood spots for sample collection, packaging, shipment, and testing has been standardized and is being implemented worldwide.

HIV RNA PCR (HIV viral load testing)

- Viral load testing, or detection of viral RNA in plasma, provides a quantitative measure of the presence of HIV virus in the blood.
- Viral load testing is utilized primarily to monitor response to ART. It may also be used for infant diagnosis, but the test should be performed only after 6 weeks of age, when the infant discontinues the use of prophylactic antiretrovirals to reduce mother-to-child transmission (*35*).

Ultrasensitive HIV p24 antigen testing

- This test detects viral protein in the blood.
- Only the ultrasensitive version of the test should be used in diagnosing infants (*35*).

WHO guidelines (*14, 35*) further elaborate on infant HIV diagnosis.

VII.3. Monitoring treatment response

Laboratory tests used to monitor the response to ART are CD4 cell count and HIV viral load. WHO recommends viral load as the preferred monitoring approach to diagnose and confirm ARV treatment failure. If viral load is not routinely available, CD4 count and clinical monitoring should be used to diagnose treatment failure (*14*).

Viral load testing, or detection of viral RNA in plasma, provides a quantitative measure of the presence of HIV virus in the blood. This test can be used to monitor the treatment and care of HIV-infected pregnant women and their partners. Viral load test results are reported as the number of HIV copies in a milliliter of blood.

VII.4. Quality control, quality assurance, and quality management of HIV and syphilis testing

All HIV and syphilis tests conducted in POC and laboratory settings must be conducted in a tightly quality-controlled and quality-assured environment to ensure test accuracy and reproducibility (*58*). All levels of the service delivery network (laboratories and testing sites) have responsibilities related to development and maintenance of a quality environment.

Simplification of HIV proficiency testing **Box VII.3**

Proficiency testing is an important part of external quality assurance strategies. Traditional proficiency testing panels use serum or plasma specimens, requiring stringent conditions for storage and transportation, including a cold chain.

CDC supports the development of dried tube specimens that are cold-chain independent and stable for at least one month.

Field testing indicates that dried tube specimens can simplify external quality assurance programs and enable expansion of rapid HIV testing to remote sites.

Source: Parekh BS, Anyanwu J, Patel H, et al. Dried tube specimens: a simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings. J Virol Methods 2009;163(2):295–300.

Responsibilities of central-level sites (preferably central public health laboratories)

- Development of national policies and SOPs for HIV and syphilis testing, including guidelines on appropriate selection and use of tests
- Appointment of a national quality focal point (entity or quality manager)
- Establishment of a system to ensure that all tests and testing algorithms are evaluated and validated prior to implementation
- Establishment of a system for licensing and accreditation of testing sites
- Creation of a mechanism to ensure that effective training programs are developed and that all testing personnel, including nonlaboratory staff, are trained and certified and undergo periodic competency checks
- Oversight of the development, implementation, and monitoring of quality plans by laboratories and implementation of safety requirements
- Maintenance of efficient and cost-effective procurement systems to ensure consistent availability of reagents and supplies
- Establishment of efficient and effective equipment maintenance arrangements to ensure consistent and optimum functioning of equipment
- Assessments of stock to be distributed by the national program, with each lot tested against known samples to assess quality
- Oversight of proficiency testing strategies at local laboratories

Responsibilities of local testing sites (health centers and laboratories)

- Designation of a competent quality officer with the responsibility for on-site quality operations and the authority to make and implement relevant decisions and consult with key decision makers in a timely manner

- Assurance that appropriately trained and certified staff are in place and that there are appropriate systems for periodic competency checks, with thorough, competency based training to ensure trainees' ability to practice effectively
- Assurance that testing staff are familiar with and consistently use SOPs to guide testing on a day-to-day basis
- Compliance with validation, quality control, quality assurance, confidentiality, safety, and record-keeping requirements as outlined in the relevant SOPs
- Ongoing and effective supervision of new staff with documented checks and balances
- Evaluation of on-site supervisory personnel against a structured monitoring checklist and timely compliance with agreed-upon corrective actions, including retraining interventions if needed
- Efficient inventory control management to ensure a consistent supply of reagents and other consumables and the limiting of reagent shortages or wastage of expired reagents
- Use of only nationally licensed or approved HIV and syphilis kits and tests
- Compliance with stated facility and equipment maintenance requirements to ensure safe practices, continued and optimum functioning of equipment, and the limiting of equipment downtime
- Compliance with process control activities, including use of only evaluated/validated tests and/or algorithms, strict adherence to written SOPs for all aspects of testing, continuous use of internal quality control materials, participation in proficiency testing and/or external quality assurance programs, documentation of quality control and test information, and maintenance of records as required
- Implementation of periodic customer satisfaction surveys and provision of timely responses to customer concerns

VII.5. Summary of critical actions

- Review and optimize testing practices to minimize the time needed for HIV and syphilis diagnoses for pregnant women and introduce point-of-care testing where feasible and appropriate.
- Review syphilis testing practices to ensure adequate nontreponemal/treponemal screening algorithms.
- Update infant diagnosis practices to ensure early and efficient diagnosis, with PCR testing, by 6 months of age.
- Strengthen procurement systems to ensure uninterrupted availability of testing supplies.
- Ensure accuracy of test results through establishment of effective oversight measures, including appointment of quality officers, oversight, proficiency testing, and other quality control measures, at all levels of the laboratory network and at the point of care (nonlaboratory settings).

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Cross-cutting issues

VIII Cross-cutting issues

VIII.1. Integrating gender, human rights, and other social determinants

Gender refers to societal norms, values, and expectations regarding the roles, duties, rights, responsibilities, and status of women and men (*59*). Gender dynamics are of particular relevance in the context of the Elimination Initiative as they influence the ability of women and men to adopt safer sexual practices and make decisions about reproductive issues. Studies suggest that male partners influence women's uptake of antenatal care and HIV testing and their adherence to ART (*25*). The male partner also has a critical role in the protection of the health of the unborn child. Integration of gender issues implies careful consideration of how prevailing gender norms, values, and expectations influence each phase of the program, including primary prevention, family planning, antenatal care, HIV and syphilis testing and treatment, and follow-up of exposed infants and their mothers (*60*).

Efforts to mobilize male involvement must accommodate the various modalities and dimensions of female-male relationships in the community, including civil and common-law unions, concurrent and sequential multiple partnerships, and other common relationship forms. Identification and treatment of male sexual partners are particularly important in cases of syphilis infection to prevent reinfection of pregnant women.

Human rights are universal legal guarantees that protect individuals and groups against actions that interfere with fundamental freedoms and human dignity. They include the right to life, the right to personal integrity, the right to privacy, and the right to the highest attainable standard of health (*61*). The right to health incorporates four essential elements: (a) ensuring the **availability** of sufficient health facilities, services, and health products; (b) ensuring physical, financial, and cultural **accessibility** of services for all; (c) ensuring the **acceptability** of services and programs, particularly in relation to cultural norms and beliefs; and (d) ensuring adequate **quality** of services (*62*).

Integration of human rights also implies that health authorities, program managers, and service providers will guarantee freedom of choice and protection of autonomy, confidentiality, and informed consent equally—and to all—at all times.

An important gender and human rights dimension regards addressing intimate partner violence in the context of elimination efforts. Intimate partner violence profoundly affects people's physical, sexual, reproductive, emotional, mental, and social well-being and increases the risk of negative health consequences, including unwanted pregnancies, HIV/STIs, and mental health problems.

Addressing intimate partner violence in health care settings **Box VIII. I**

Primary prevention:
- Promote zero tolerance for violence in the community.
- Maintain confidentiality.
- Incorporate danger assessments in service delivery.
- Referral to additional services.

Secondary prevention:
- Routinely ask clients about violence.
- Support development of safety plans.
- Provide counseling and psychological services.
- Provide emergency contraception, post-exposure prophylaxis, and STI prophylaxis.
- Referral to additional services.

Tertiary prevention:
- Referral to specialized services for long-term care.

Source: Pan American Health Organization. Integration of gender and human rights in HIV and sexual and reproductive health services: training for health care providers. PAHO, Washington, D.C., 2013.

Following Table VIII.1 provides an overview of actions that can be taken to integrate gender and human rights in the elimination strategy.

Integrating gender and human rights in the strategy for elimination of mother-to-child transmission of HIV and congenital syphilis **Table VIII. I**

Area of action	Examples
Fostering a supportive environment	• Train health workers in gender and human rights. • Ensure health workers' and professional societies' commitment and capacity in consistently applying human rights principles, including confidentiality, informed consent, autonomy, and appropriate disclosure. • Take action to reduce HIV-related stigma and discrimination in health care settings. • Ensure the inclusion of updated guidance on gender-responsive HIV and syphilis screening and treatment in antenatal care in standardized ANC curricula for nurses, physicians, and other health care providers.

Table VIII. I (Continued)

Area of action	Examples
Male involvement	• Emphasize the role of the male sexual partner in protecting the health of the unborn child in community mobilization campaigns. • Involve the male partner in risk reduction counseling in ANC settings. • Engage men as partners in the establishment of a zero-tolerance environment for intimate partner violence. • Actively promote HIV and syphilis testing for male partners and provide linkages with services to respond to men's health concerns. • Provide syphilis treatment for male sexual partners of pregnant women.
Primary prevention and promotion of sexual and reproductive health	• Ensure that prevention messages are gender-transformative, portraying men as positive role models who engage in responsible sexual behaviors and have respect for women and portraying women as equal participants in sexual and reproductive health decisions. • Implement and promote programs that empower young girls. • Provide women living with HIV, HIV-positive couples, and HIV-discordant couples with appropriate sexual and reproductive health services to facilitate informed decision making regarding sexual health, safer sexual practices, and childbearing.
Antenatal care and HIV and syphilis screening, treatment, and follow-up	• Offer couples counseling with respect to HIV testing, disclosure of HIV status, and family planning. • Include screening for intimate partner violence in ANC care, assist with safety planning, and provide referral to more specialized services for women who experience intimate partner violence. • Assess the gender-based barriers women might face related to disclosure of HIV status and other factors that might influence access to services and adherence to treatment. • Involve male partners in discussions and decision making on follow-up care for exposed infants.

Other social determinants of health

In addition to gender, other social determinants such as ethnicity, educational level, employment, and poverty also influence vulnerability to HIV/STI infection, access to and uptake of sexual and reproductive health services, and access to HIV/STI treatment and care services. Programs must ensure that the most vulnerable groups are reached with services and that these social determinants are addressed in program design.

This includes ensuring that health care systems are built on principles of equity, health promotion and disease prevention, and fulfillment of the stewardship role of the health care system to promote and ensure that policies and actions in other sectors improve health equity. Actions that can be taken in this context include:

- Collection and analysis of coverage and outcome data disaggregated by sex, age group, ethnicity, and geographic location, to facilitate identification of inequities in access to, utilization of, and outcomes of services and programs
- Promotion and development of social protection policies, including those related to access to health care among the most vulnerable groups
- Advocating for programs that increase educational opportunities and empower key groups, including young women and ethnic minorities

The *Obstetricaux Gratuits* project in Haiti **Box VIII.2**

Haiti's numbers of maternal and newborn deaths are among the highest in the Americas. In a 2007 study, 76% of women in Haiti's South Department indicated that they would opt for birth at home rather than in a health facility due to lack of money. The Free Obstetric Care (*Soins Obstetricaux Gratuits*) project was designed to increase utilization of obstetric services through a set of interventions that included payment to health facilities for pregnancy, birth, and postpartum services; refunds to pregnant women for transportation costs; and payment to traditional birth attendants who accompany pregnant women to health institutions for delivery. The project also supported the rehabilitation of health institutions, training of health care providers, and the provision of medical supplies and essential drugs.

Areas where the program was implemented saw 3- to 6-fold increases in antenatal visits. Institutional birth coverage increased by 26.5% in Haiti, and health complications fell significantly in areas where the program was implemented.

Source: World Health Organization. Free obstetric care in Haiti: making pregnancy safer for mothers and newborns. WHO,

VIII.2. Communication, social mobilization, and media

While countries have made significant progress in the establishment or scaling up of services, strategic and sustained actions will be needed to achieve elimination targets. This will require the commitment and involvement of various stakeholders, including policymakers, program managers, service providers, pregnant women and their partners, and the community. It should also be noted that as countries expand coverage of essential services, targeted and intensified efforts will be needed to reach and engage vulnerable groups such as adolescents, migrants, substance users, and homeless women. This will necessitate well-defined and strategic mobilization and communication efforts that take full advantage of the media, grassroots partners, and other potential intermediaries.

A variety of health communication strategies are available to engage and support individuals, communities, and health professions. Three such strategies are advocacy, social mobilization, and behavior change communication.

1. **Advocacy** seeks to inform and motivate stakeholders in leadership and decision-making positions (e.g., political, community, and private-sector leaders) to support a specific issue. In this context, the goals of advocacy efforts are to provide these stakeholders with information on:

   - Areas in which critical changes are needed to achieve elimination targets (e.g., finances, legislation, policy, organizational).
   - How they can help make these changes.
   - How they can publicly support or champion the Elimination Initiative.

2. **Social mobilization** aims to enlist the participation of institutions, community networks, and social, faith-based, and other grassroots organizations to mobilize their memberships and resources to strengthen participation at the grassroots level. Social mobilization activities can include holding community fairs, placing the topic on the agenda of meetings organized by or for professional groups and associations, organizing community meetings or mobilization meetings with specific groups, and utilizing the media to disseminate updates, status reports, achievements, challenges, and other relevant messages.

3. **Behavior change communication** aims to educate, motivate, and support changes in the behavior of individuals and groups to achieve the elimination targets. Specific behavioral objectives are pursued through a combination of mass media, group, and interpersonal communication. During development of this component, the following elements must be considered:

   - Which behaviors need to be changed in order to generate the intended health outcomes (e.g., early antenatal care attendance, HIV and syphilis treatment of partners of pregnant women, adherence to ARV medicines among pregnant women, condom use among persons of reproductive age).
   - The underlying factors (enabling, reinforcing, predisposing) influencing these behaviors.
   - How to foster a supportive environment to achieve and maintain sexual and reproductive health and wellness, including safer sexual practices before and during pregnancy, prevention of unintended pregnancies, early antenatal attendance, and uptake of treatment and care services in cases of HIV or STI infection before and during pregnancy.

National plans of action should include social mobilization and communication strategies and resources to implement these strategies. Strategies and messages should be based on the local context, the relevance of the elimination targets for each stakeholder group, and each group's anticipated or required actions. Table VIII.2 provides an overview of key stakeholder groups and suggested actions related to each group. It is recommended that countries conduct a stakeholder analysis to inform advocacy efforts and communication strategies.

Summary of recommended communication and social mobilization actions ***Table VIII.2***

Stakeholder group	Actions needed to accelerate progress
Policymakers and national leaders (including members of parliament, first ladies, etc.)	• Foster a supportive and enabling environment for effective implementation of the elimination strategy. • Ensure sufficient financial support for rapid and sustainable scaling up of essential prevention, treatment, and care programs and services. • Provide national- and community-level leadership and public support for elimination efforts.
Program managers	• Prioritize the elimination strategy. • Reorganize services to facilitate optimal availability of, access to, and quality of the integrated package of services. • Introduce standard operating procedures consistent with global and regional guidance and provide oversight for implementation. • Provide training and support for service providers to implement quality services. • Ensure effective integration and alignment of programs and services. • Ensure effective distribution of supplies.
Health care providers	• Demonstrate a commitment to achieving the elimination targets. • Provide supportive, nonjudgmental services that encourage women to return for follow-up. • Implement quality standard operating procedures. • Participate in available training opportunities.
Professional groups and associations of physicians, midwives, nurses, and lay health workers	• Mobilize the support and involvement of members and professional groups. • Develop or update curricula and competency profiles in line with current technical and programmatic guidance and requirements.
Pregnant women	• Adopt safer sexual practices for prevention of HIV and syphilis infection during pregnancy. • Enroll early in antenatal care. • Accept HIV and syphilis testing and testing of male sexual partners during pregnancy. • Adhere to treatment and care if HIV or syphilis tests are positive.
Male sexual partners of pregnant women	• Accept HIV testing and syphilis treatment if partner has positive syphilis serology. • Adopt safer sexual practices to prevent HIV and syphilis infection of partner and her unborn child.
Persons of reproductive age	• Prevent HIV and syphilis infection in the context of preconception health. • Seek preconception HIV and syphilis testing. • Seek and utilize family planning services.
Women living with HIV	• Seek and utilize family planning services to prevent unwanted and unintended pregnancies. • Adhere to treatment to improve health status and protect the unborn child.
NGOs and CBOs (women's groups, men's groups, persons living with HIV, faith-based organizations, service clubs, youth groups, etc.)	• Mobilize the community around safe motherhood and prevention of mother-to-child transmission of HIV and congenital syphilis. • Endorse healthy and supportive community attitudes and norms and counter harmful norms related to HIV/STIs, gender, childbearing, and health care.

Table VIII.2 (Continued)

Stakeholder group	Actions needed to accelerate progress
Media	• Provide free press for the Elimination Initiative. • Contribute to community education on primary HIV/STI prevention among persons of reproductive age, timely initiation of antenatal care, and the importance of HIV and syphilis treatment and care during and after pregnancy. • Mobilize the community to engage in elimination efforts.

VIII.3. Coordination and implementation

Resolution CD50.R12 (*1*) urges countries to give priority to eliminating mother-to-child transmission of HIV and congenital syphilis, designing and executing national plans, promoting the collection and use of data, and improving coordination in the health sector and with partners from other sectors.

Country focal point

It is recommended that to operationalize the coordination function, countries appoint a national focal point, preferably a coordination team (committee, working group) that brings together representatives of the critical programmatic areas highlighted in the strategic framework and in this field guide, including maternal and child health, HIV/STI prevention, treatment and care, adolescent health, and surveillance and monitoring. The main functions of such a team would be facilitation of the development, periodic review, and updating of the national plan; provision of oversight for its implementation; and coordination of internal and external reporting.

Box VIII.3 *Core elements of national implementation strategies and plans*

- Baselines and targets (end and progressive intermediate targets).
- Coordination and oversight structures and mechanisms.
- Key activities for each line of action, with core responsible entities.
- Laboratory support.
- Communication strategy.
- Monitoring and surveillance plan (including indicators, data sources, data collection strategies, responsible entities, reporting calendar, etc.).
- Budget.

Plan of action

As mentioned, the mid-term evaluation and this field guide provide an opportunity for countries to develop or update their plans of action, and key components of a national plan have been described above.

The plans of countries that believe they may have achieved the elimination targets should focus on measures to sustain their achievements and prepare for validation, including ensuring that the key components of the validation process are in place:

- A functional national M&E and surveillance system.
- National- and subnational-level data on core indicators, compiled for at least two years, that are accessible for validation by an external team.
- Clearly defined programs and services, implemented in a manner consistent with basic human rights and equity considerations.
- Evidence of the sustainability of programs and services.

VIII.4. Summary of critical actions

- Train service providers in gender and human rights.
- Foster a zero-tolerance environment for gender-based violence.
- Actively engage male partners in prevention, diagnosis, treatment and care services to protect the health of the unborn child.
- Establish mechanisms for oversight and monitoring of adherence to human rights principles, including autonomy, confidentiality, and informed consent.
- Collect and analyze data disaggregated by sex, age group, ethnicity, and geographic location to identify and address inequities.
- Advocate for and support programs beyond the health sector that empower adolescent girls and other vulnerable groups and decrease their vulnerability.
- Conduct stakeholder analyses and develop a communication and social mobilization strategy.
- Establish or update national coordination mechanisms and plans of action in line with current global and regional guidance and lessons learned from the mid-term evaluation.

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Validation of achievement of the elimination targets

IX Validation of achievement of the elimination targets

IX.1. The validation process

Validation of achievement of elimination targets will take place on a country-by-country basis. Countries will initiate the process of validation through submission of a country report and a formal request to PAHO, which will serve as the regional secretariat for validation together with UNICEF. Validation assessments will be done by teams of experts. Final verification and confirmation of elimination will be completed through global mechanisms facilitated by the World Health Organization.

Candidate countries for validation of elimination must meet the following conditions:

1. Evidence of achievement of a) the elimination targets for at least two years, b) achieved these targets in at least one of the lowest-performing sub-national administrative units, c) met the programmatic objectives for at least two years.

2. Existence of a functional monitoring and surveillance system that has a national scope (involving both the public and private sectors), is sufficiently sensitive to detect all cases of mother-to-child transmission of HIV and syphilis, and includes:

   - Antenatal care surveillance.
   - Active surveillance of pregnant women with positive serology for HIV or syphilis.
   - Active follow-up of all infants exposed to HIV or syphilis until a definitive diagnosis can be made.
   - Active case finding and case investigation of HIV infection and congenital syphilis among children younger than 3 years of age.

3. Existence of an adequate national laboratory network that has mechanisms in place to ensure reliable test results and includes:

   - HIV diagnosis (adults, children, and infants).
   - Syphilis diagnosis (adults and children).
   - CD4 count.
   - Viral load.

4. Evidence of the essential health systems and programmatic capacity to sustain elimination targets.

A regional validation committee (RVC) will coordinate and provide oversight for the validation of countries, and PAHO and UNICEF will provide secretariat support for the validation process.

Validation assessments will be conducted by teams of external experts under supervision of the RVC. The RVC will establish a roster of recognized regional and global experts whose members can be assigned to Validation Teams (VTs).

The validation process will include the following phases:

1. **Validation request:** The country's ministry of health initiates the validation process through submission of a formal request and a country report presenting data on the set of regionally agreed-upon impact, output, and outcome indicators, covering a minimum of three consecutive years and describing the structure and functions of the national program, including the surveillance system. Annex 7 provides an outline for the country report. It is recommended that countries establish a National Validation Committee (NVC) to coordinate the development of the country report and serve as a counterpart for the external validation team.

2. **Pre-validation phase:** Upon submission of the country report, the pre-validation phase will be initiated, consisting of the following:

   A. Review of country report: The RVC will review the country report and request clarification or additional information as needed, and establish a VT.

   B. Pre-validation country visit: If needed, an initial mission to the country will be conducted for further clarification and determination of the readiness of the country for the formal validation assessment. The RVC will determine whether such a visit is necessary.

   C. Recommendation: Based on the findings of the pre-validation phase, the RVC will decide on a full validation assessment. If the RVC recommends postponement of the validation assessment, this must be supported by a clear rationale and recommendations to the national authorities regarding areas and issues to address prior to validation.

3. **Validation assessment:** The validation assessment incorporates four core elements: assessment of the surveillance system, assessment of the laboratory network, verification of achievement of the elimination targets and objectives, and assessment of the health systems and programmatic capacity necessary to sustain the elimination targets.

   A. Verification of achievement of the elimination targets: assessment of the reliability of the denominators and the numerators used to calculate the elimination targets. Verification of the completeness and reliability of data sources for the denominators, triangulation of reported data with other sources, and verification of case definitions and diagnostic algorithms will be required to arrive at a conclusion regarding the reliability of the reported numbers.

   B. Assessment of the surveillance system: evaluation of the design of the system and the completeness, quality, and representativeness of the data.

   C. Assessment of the laboratory network: determination of whether an adequate laboratory network exists to support essential services. The network should have sufficient funding and trained staff, reliable algorithms and quality assurance mechanisms, reasonable turnaround times for confirmed test results, laboratory supply mechanisms, and a functional laboratory information management system.

   D. Assessment of the health systems and programmatic capacity necessary to sustain the elimination targets:

      - Review of the programmatic components relevant to the Elimination Initiative, in-

cluding primary prevention of HIV and syphilis, antenatal care services, HIV and syphilis testing, and treatment and care for infected pregnant women, their infants, and their male partners from a health system perspective.

- Review of the overall health system environment, based on the WHO building blocks (leadership and governance, health system financing, service delivery, health workforce, medical products and technology, and health information systems) and their interaction with the programmatic components.
- Review of service coverage for key populations at higher risk, including migrants, mobile populations, indigenous people, and youth.
- Review of cross-cutting issues including gender, human rights, ethnic/cultural diversity, and other social determinants of health relevant to the achievement and sustainability of the elimination targets.

The estimated time needed for a full validation process after a country's submission of its report is 6–12 months, depending on the size of the country and the scope of the assessment.

The validation methodology was implemented on a pilot basis in St. Lucia and Chile, and the experience indicated that the methodology is sufficiently comprehensive and sensitive to provide a sound understanding of the status of the elimination targets. Several additional countries have applied the methodology to conduct assessments of the status of their programs as a means of informing strategic planning and preparing for validation.

IX.2. Summary of critical actions

- Countries that believe they may have achieved the elimination targets should prepare a country report and submit a request for validation.
- Countries can utilize the validation assessment methodology to assess the status of their programs and inform strategic planning.

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Annexes

Regional resources

Annex 1

Resource	Content	Reference and link
Concept document (Spanish and English)	This document provides a rationale for the goal of elimination of mother-to-child transmission of HIV and congenital syphilis, as well as feasibility and cost-benefit information. The document also introduces the vision, targets, guiding principles, and proposed lines of action for implementation of the Elimination Initiative.	Organización Panamericana de la Salud. Iniciativa regional para la eliminaciones de la transmisión maternoinfantil del VIH y de la sífilis congénita en América Latina y el Caribe. Documento conceptual. CLAP/SMR, Montevideo, 2009. *http://new.paho.org/hq/dmdocuments/2009/Documento%20Conceptual%20-%20Eliminaci%C3%B3n%20de%20la%20transmisi%C3%B3n%20maternoinfantil%20del%20VIH%20y%20de%20la%20s%C3%ADfilis%20cong%C3%A9nita.pdf* Pan American Health Organization. Regional Initiative for Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean. Concept document for the Caribbean. PAHO, Washington, D.C., 2010. *http://www2.paho.org/hq/dmdocuments/2010/Regional%20Initiative%20for%20Elimination%20Concept%20Document%20for%20the%20Caribbean.pdf*
Integrated guidelines (Spanish, French, and English)	The focus of this document is on priority interventions for an integrated approach towards HIV and syphilis diagnosis, clinical management of pregnant women infected with HIV or syphilis, and follow-up of exposed infants.	Organización Panamericana de la Salud. Guía clínica para la eliminación de la transmisión maternoinfantil del VIH y de la sífilis congénita en América Latina y el Caribe. CLAP/SMR, Montevideo, 2009. Pan American Health Organization. Clinical guidelines for the elimination of mother-to-child transmission of HIV and congenital syphilis. CLAP/SMR, Montevideo, 2009. *http://www.unicef.org/lac/Guia_Clinica_Eliminacion_de_Transmision_del_VIH_y_SC_eng(2).pdf*
Monitoring strategy (Spanish and English)	The monitoring strategy proposes a comprehensive set of indicators for monitoring of progress. PAHO is using these indicators to monitor progress at the regional level and recommends that countries use them for country-level monitoring. The monitoring strategy was updated in 2012. Links refer to the updated version.	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. 2nd ed. PAHO, Washington, D.C., 2013. *http://new.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=20135&Itemid=270&lang=en*

Annex 1 (Continued)

Resource	Content	Reference and link
Technical recommendations for national surveillance studies during labor or the puerperium (Spanish)	This document provides guidance for the development of protocols for implementation of national sentinel surveillance studies during labor or the puerperium.	Organización Panamericana de la Salud. Recomendaciones técnicas para la elaboración de protocolos para estudios de prevalencia de sífilis y VIH en parturientas y/o puérperas. OPS, Montevideo, 2011. *http://new.paho.org/clap/index.php?option=com_docman&task=doc_download&gid=209&Itemid=*
Costing tool (Spanish, French, and English)	This tool was developed to assist countries in estimating the financial resources needed at the national or local level to achieve the elimination targets and to inform planning.	Elimination Initiative costing tool and user manual (2011) *http://new.paho.org/hq/index.php?option=com_content&view=article&id=5874%3Aherramienta-de-costeo-para-la-iniciativa-de-eliminaciun&catid=1098%3Afchhiv-information%2C-news%2C-events%2C-etc&lang=en*
Validation guidelines (drafts in Spanish and English)	This document provides regional guidelines for the validation of elimination of mother-to-child transmission of HIV and congenital syphilis through a standardized and credible process. The document is primarily intended for use by external validation teams, but the methodology can also be used by program managers to assess country status.	Pan American Health Organization. Regional guidance for validation of elimination of mother-to-child transmission of HIV and congenital syphilis. PAHO, Washington, D.C., 2013. Draft document, available at PAHO Secretariat.

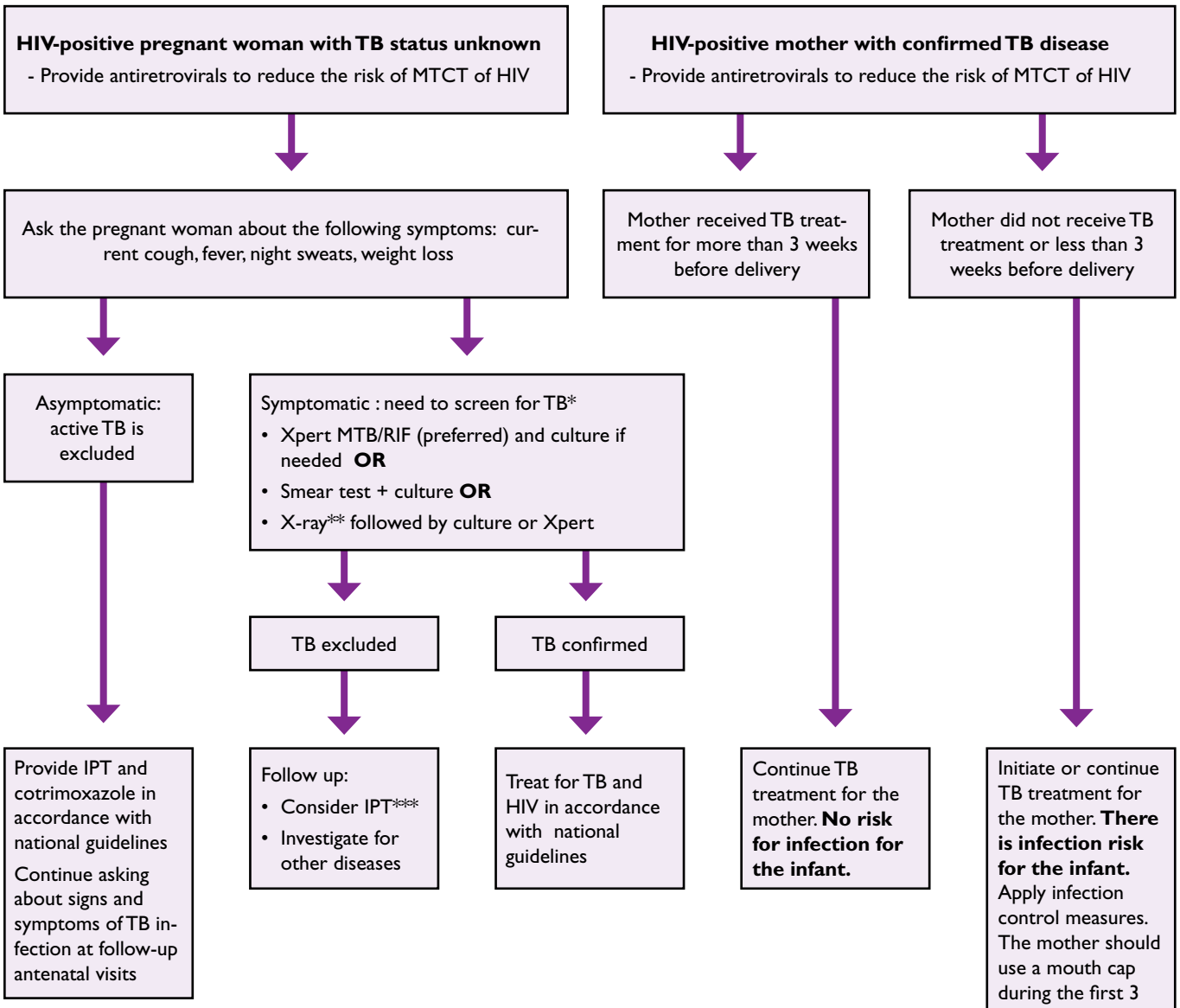
Summary overview of selected vertically transmitted infections

Annex 2

Pathogen/disease				Interventions to prevent or reduce adverse outcomes
	Intrauterine	Perinatal	Postnatal	
Hepatitis B virus	+	++	+/−	Preconception immunization and hepatitis B vaccine for the newborn within 12 hours of birth.
Hepatitis C virus	+/−	++ (H)	. . .	Recommend avoidance of intravenous drug use.
Human T-lymphotropic virus type I (HTLV-I)	+	+	++	Safe sex, condom use, maternal screening. CDC recommends to avoid breastfeeding in case of positive test.
Chlamydia trachomatis	+	++ (G)	. . .	Safe sex, condom use, pregnancy screening, erythromycin/azithromicin treatment, neonatal eye prophylaxis.
Neisseria gonorrhea	+	++ (G)	. . .	Safe sex, condom use, pregnancy screening, cefixime and ceftriaxzone treatment, neonatal eye prophylaxis.
Listeria monocytogenes	++	+ (G, H)	. . .	Recommend avoidance of cold cuts/soft cheeses, penicillin.
Group B streptococci	+/−	++ (G, H)	+/−	Intravenous penicillin or ampicillin treatment more than 4 hours before birth.
Rubella virus	++	. . .	+	Preconception immunization.
Plasmodium falciparum (malaria)	++	. . .	. . .	Sleeping under bednets treated with insecticide.
Varicella zoster virus (chickenpox)	+/−	++ (H)	. . .	Preconception immunization.
Herpes simplex virus	+	++ (G, H)	. . .	Safe sex, condoms. For mothers without known genital herpes, avoid unprotected third-trimester intercourse with partners known or suspected to have genital herpes. For mothers without oralabial lesions (cold sores), avoid third-trimester oral sex with partners with a history of oralabial lesions. For mothers who acquired a new infection or developed recurrent genital herpetic lesions late in pregnancy, consider oral or intravenous acyclovir and/or cesarean section.
Toxoplasma gondii	++	. . .	. . .	Avoid cat litter soil.

Note: ++ = main route of transmission; + = recognized but less common route; +/− = possible but uncommon route; (G) = genital; (H) = hematogenous.
Source: Pan American Health Organization. Perinatal infections transmitted by the mother to her infant: educational material for health personnel. CLAP Scientific Publication 1567.02.

Annex 3 *Identification and management of TB/HIV coinfection during pregnancy and post-delivery*



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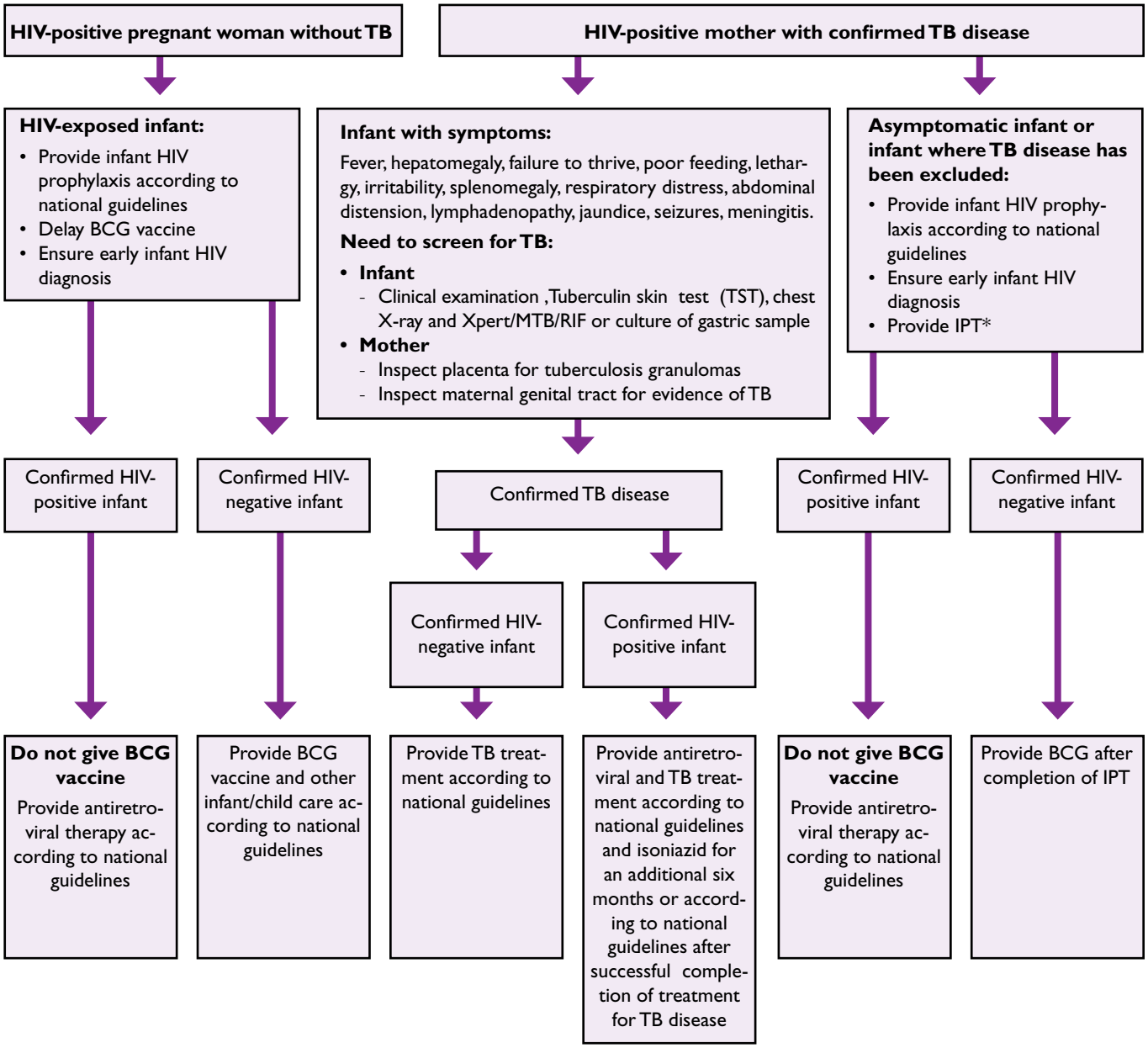
Mathad, J, and Gupta, A. Tuberculosis in pregnant and postpartum women: epidemiology, management, and research gaps. Clin Infect Dis 2012. DOI:10.1093/cid/cis732

Loto O, and Awowole I. Tuberculosis in pregnancy: a review. J Pregnancy 2012. DOI:10.1155/2012/379271.

* Depending on national guidelines and availability.
** Caution in use of X-ray in early pregnancy needs to be considered.
*** Contraindications for IPT include: active hepatitis (acute or chronic), regular and heavy alcohol consumption and symptoms of peripheral neuropathy.

TB-related management of infants born from HIV-positive mothers

Annex 4



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*If the child is HIV-negative: provide 3 months isoniazid, then perform a Tuberculin Skin Test (TST). If the test is negative, isoniazid should be stopped and BCG vaccination given. If the test is positive, isoniazid should be continued for another 3 months, after which it should be stopped and BCG given.

Annex 5 — *Common HIV and syphilis laboratory and surveillance terminology*

Term	Definition
Antibody (ab)	An antibody is a protein produced by the body's immune system, and found in blood or other body fluids, that helps to fight foreign substances (antigens) such as bacteria or viruses that enter the body.
Antigen (ag)	An antigen is any substance recognized as foreign and capable of inducing a specific immune response in the body and of reacting with the products of that response (e.g., an antibody).
Human immunodeficiency virus (HIV)	HIV is a retrovirus that causes AIDS by primarily infecting helper T cells (CD4+ T-lymphocytes), resulting in impairment of the body's immune response.
HIV viral antigen	The HIV virus comprises a number of antigens associated with the viral envelope, core, and enzymes that stimulate the production of antibodies in the infected human host.
HIV antibody tests	HIV antibody tests detect antibodies to HIV 1 and 2.
HIV virological tests	HIV virological tests detect HIV nucleic acids (DNA or RNA) or HIV viral antigen (e.g., p24 ag).
HIV rapid tests	A rapid test is a qualitative or semiquantitative single-use, easy-to-perform HIV test that provides a quick result and allows for same-day patient management decisions.
Enzyme-linked immunosorbent assay (ELISA/EIA)	ELISA is a quantitative test that utilizes an enzymatic reaction as an indicator of the presence of HIV antibody or antigen in blood or body fluids, usually through the production of a color that can be read visually or using automated equipment. ELISA tests may be highly sensitive and specific.
Western Blot test (WB)	The Western Blot is a technique that separates the HIV viral antigens into bands on a cellulose strip that attract their corresponding antibodies. It is used to detect the presence of HIV antibodies.
HIV nucleic acids	Nucleic acids are found in all living cells and carry genetic material. The two major nucleic acids are deoxyribonucleic acid (DNA) and ribonucleic acid (RNA).
HIV nucleic acid test (NAT) or nucleic acid amplification test (NAAT)	Nucleic acid tests amplify HIV genetic material in blood samples to a measurable level.
HIV DNA PCR (polymerase chain reaction)	The polymerase chain reaction (PCR) test is a highly sensitive nucleic acid test that can amplify the amount of DNA from a tiny amount to a measurable amount within just a few hours and thus can be used to detect very small amounts of HIV virus in blood or other body fluids. Theoretically, PCR can take one molecule and produce measurable amounts of identical DNA in a short period of time.
CD4	T lymphocytes carrying antigen cluster differentiation 4 on their surface.
HIV viral load or HIV RNA PCR	HIV viral load is a test that measures the quantity of active HIV virus or viral RNA. It can be measured in plasma and other bodily fluids (semen, breast milk, etc.). Most commonly it refers to plasma, and results are expressed as the number of copies per milliliter of blood plasma. Viral load tests along with CD4 counts are used to determine when to initiate and/or change HIV medication regimens.
Window period	The time lag between HIV infection and the ability of a test to detect infection (e.g., through the detection of HIV antibodies, antigens, or viral nucleic acid).

Annex 5 (Continued)

Term	Definition
Sensitivity	Sensitivity is a statistical measure of the performance of a test and refers to the proportion of true positives or infected persons correctly identified by the test. It is calculated as the number of true positives divided by the number of true positives and false negatives. The higher the sensitivity of a test, the lower the rate of false negatives.
Specificity	Specificity is a statistical measure of the performance of a test and refers to the proportion of true negatives or uninfected persons correctly identified by the test. It is calculated as the number of true negatives divided by the number of true negatives and false positives. The higher the specificity of a test, the lower the rate of false positives.
Negative predictive value (NPV)	The negative predictive value of a test is the probability that a person is not infected when a test result is negative. This measure of accuracy should be used only if prevalence is available from the data.
Positive predictive value	The positive predictive value of a test is the probability that a person is infected when a test result is positive. In practice, predictive values should be calculated only from cohort studies or studies that legitimately reflect the number of people in that population who are infected with the disease of interest at that time. This is because predictive values are inherently dependent upon the prevalence of infection.
Laboratory quality assurance (QA)	Laboratory quality assurance refers to the systematic monitoring and evaluation of the various aspects of laboratory operations to ensure that standards of quality are being met. A QA program incorporates standards against which internal or external assessments/audits are undertaken. A mixture of appropriate policies, procedures, processes, and tools is used.
Nontreponemal tests	These syphilis tests detect antibodies directed against lipoid antigens released from damaged host cells or the treponemes themselves. Since nontreponemal tests may give false-positive results in the presence of certain conditions or infections, it is recommended to confirm positive results using treponemal tests.
Treponemal tests	These tests detect antibodies directed against Treponema pallidum proteins. These antibodies persist for life, even after provision of effective treatment. Therefore a positive test could signal a past, treated or current infection. Reactive samples should be confirmed using a nontreponemal test.

Annex 6 — *Clinical manifestations suggestive of congenital syphilis*

Clinical manifestations suggestive of early congenital syphilis (CS)

- Prematurity.
- Intrauterine growth retardation (IUGR).
- Congenital pulmonary syphilis (pneumonia alba).
- Hepatosplenomegaly.
- Generalized lymphadenopathy.
- Hematological manifestations: anemia, leukopenia, leukocytosis, thrombocytopenia.
- Mucocutaneous manifestations: purpura, palmoplantar pemphigus, maculopapular rash, flat condyloma, cracks, petechiae.
- Bone lesions, osteochondritis, periostitis.
- Renal manifestations: nephrotic syndrome.
- Manifestations of the central nervous system: aseptic meningitis, Parrot's pseudoparalysis.
- Ocular manifestations: corioretinitis, retinitis.
- Other findings: fever, syphilitic rhinitis, pancreatitis, jaundice, inflammation of the gastrointestinal tract, hypopituitarism, myocarditis.
- Hydrops fetalis (fetal hydrops).

Clinical manifestations suggestive of late congenital syphilis

- Hutchinson's teeth.
- Interstitial keratitis.
- Saddle-nose nasal deformity, frontal bossing.
- Rhagades, cutaneous gumma.
- Injuries to the central nervous system: mental retardation, hydrocephalus, seizures, deafness, blindness.
- Osteoarticular injuries: Clutton's joint, saber tibia, diaphyseal periosteal new bone formation due to gumma destruction, winged or scaphoid scapula.
- High arched palate, perforated hard palate, maxillary deformities, micrognathism (micrognathia, mandibular hypoplasia, or small jaw), mulberry molars.

Source: 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. 2nd ed. PAHO, Washington, D.C., 2013.

Outline country report to be submitted as part of the validation application **Annex 7**

I. Country context

- Political-administrative organization.
- Geography.
- Demography.
- Socio-economic context (macro-economic indicators, poverty, etc.).
- Basic health indicators (life expectancy, morbidity and mortality, etc.).

II. Description of the health system and the programmatic components of the Elimination strategy

- Health regions or districts.
- Governance and leadership (MNCH, HIV, syphilis).
- Health financing (MNCH, HIV, syphilis).
- Human resources (MNCH, HIV, syphilis).
- Service delivery (MNCH, HIV, syphilis; public and private).
- Laboratory services (MNCH, HIV, syphilis; public and private).
  - Laboratory network (public and private).
  - Algorithms for HIV and syphilis diagnoses in adults and infants.
  - Quality assurance mechanisms.
- Primary prevention programs and services for HIV and syphilis.
- Antenatal care and delivery.
- HIV and syphilis screening during pregnancy, including screening of male partners.
- HIV and syphilis treatment, care, and support.
- Follow-up of exposed infants.

III. Epidemiological profile of HIV and syphilis in the country

- HIV and syphilis prevalence trends in the general population by age group and sex.
- HIV and syphilis prevalence trends in the antenatal population by age group and sex.
- HIV and syphilis prevalence trends in specific populations (men who have sex with men, sex workers, ethnic/cultural minorities) by age group and sex.
- HIV and syphilis prevalence by geographical region.
- HIV modes of transmission.
- HIV-related morbidity and mortality by age group and sex.
- Other information:
  - Teen pregnancy trends and rates.
  - Stillbirth trends and contributing factors.

Annex 7 (Continued)

IV. Description of the surveillance system overall and related to the Elimination strategy, including:

- Description of data flow.
- Data sources and formats.
- Protocols and mechanisms for data processing, analysis, and dissemination.
- Data quality issues.

V. Data on national and regional indicators for at least 2 years

- National.
- By health region.

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of HIV and Congenital Syphilis
in the Americas

Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas