# Prevention of Mother-to-Child Transmission of HIV

## FHI 360's Strategic Approach

fhi360
THE SCIENCE OF IMPROVING LIVES

SEPTEMBER 2012

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FHI 360'S STRATEGIC APPROACH

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## ACRONYMS

| | |
|---|---|
| **AIDS** | Acquired immune deficiency syndrome |
| **ART** | Antiretroviral treatment |
| **ARV** | Antiretroviral |
| **CPT** | Cotrimoxazole preventive therapy |
| **EID** | Early infant diagnosis of HIV |
| **FP** | Family planning |
| **HIV** | Human immunodeficiency virus |
| **HTC** | HIV testing and counseling |
| **IATT** | Interagency task team |
| **LTFU** | Loss to follow-up |
| **M&E** | Monitoring and evaluation |
| **MNCH** | Maternal, neonatal and child health |
| **MDG** | Millennium development goal |
| **MTCT** | Mother-to-child transmission of HIV |
| **PDSA** | Plan-Do-Study-Act |
| **PEPFAR** | President's Emergency Plan for AIDS Relief |
| **PITC** | Provider-initiated testing and counseling of HIV |
| **PLHIV** | People living with HIV |
| **PMTCT** | Prevention of mother-to-child transmission of HIV |
| **QA** | Quality assurance |
| **QI** | Quality improvement |
| **sdNVP** | Single-dose nevirapine |
| **UN** | United Nations |
| **UNFPA** | United Nations Population Fund |
| **UNICEF** | United Nations Children's Fund |
| **WHO** | World Health Organization |

# Introduction

Mother-to-child transmission of HIV (MTCT) is the most prevalent source of pediatric HIV infection. Although pediatric HIV is almost entirely preventable, an estimated 390,000 children were infected with it in 2010, 90 percent of them in sub-Saharan Africa.[1] Without any interventions, between 20 and 45 percent of infants born to HIV-infected mothers will become infected, with an estimated risk of 5 to 10 percent during pregnancy, 10 to 20 percent during labor and delivery, and 5 to 20 percent through breastfeeding.

The risk of MTCT is associated with a variety of factors, which include decreased maternal CD4 lymphocyte counts, decreased maternal HIV p24 antibody levels, increased maternal HIV-1 titer and the presence of chorioamnionitis at delivery; but the only independent risk factor is high viral load.[2, 3] In the last 10 years, FHI 360 has supported efforts to increase both the coverage and quality of PMTCT in approximately 20 countries, 15 of which have the highest burden of MTCT.

By 2010, significant progress has been achieved globally in implementing PMTCT. Of the estimated 125 million pregnant women, 35 percent received an HIV test, increased from 26 percent in 2009, 21 percent in 2008 and 7 percent in 2005. In 2010, an estimated 59 percent of pregnant women living with HIV received antiretroviral (ARV) regimens to prevent MTCT. Among the estimated 1.49 million infants born to mothers living with HIV, 42 percent received antiretroviral treatment (ART) to prevent HIV transmission from their mothers, up from 32 percent in 2009.[4] Despite this progress, scientific advances in PMTCT have not yet been fully translated into implementation. For example, nearly 20 percent of the HIV-positive pregnant women who were given ARVs for PMTCT in 2010 received single-dose nevirapine (sdNVP), an ARV regimen that is no longer recommended by WHO. Also in 2010, only 28 percent of HIV-exposed children accessed early infant diagnosis (EID).[4] This lag is often attributable to fragile health systems in settings with limited resources. For this reason, FHI 360 focuses on strengthening health systems and integrating PMTCT into maternal, neonatal and child health (MNCH) programs.

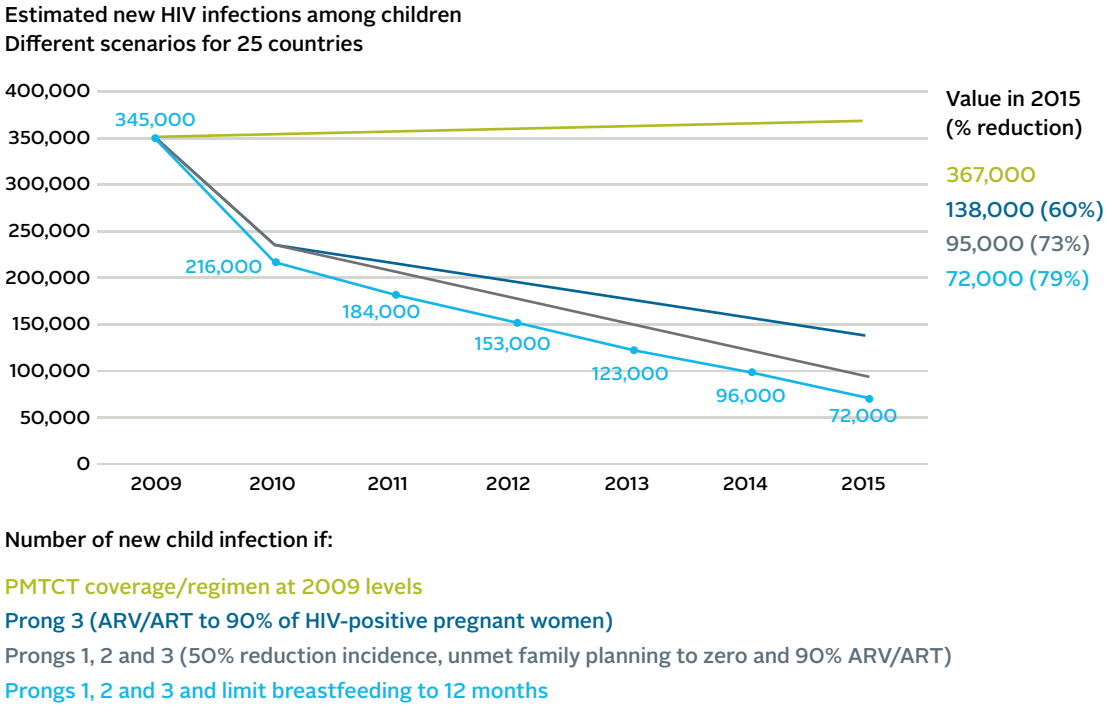
The international community, galvanized around the United Nations (UN), has expressed commitment to support programs on the prevention of mother-to-child transmission of

HIV (PMTCT). In line with the Millennium Development Goals (MDGs), the World Health Organization (WHO) set a goal of eliminating new pediatric HIV infections by the year 2015. This goal will be considered met if either the number of new pediatric HIV infections is reduced by 90 percent or the MTCT rate measured at age 12 months is below or equal to 5 percent, with 2009 as the baseline.[5, 6] Our objective in this document is to highlight FHI 360's goals and approaches to PMTCT, which are consistent with WHO's current recommendations.

FHI 360 endorses and supports WHO's comprehensive 4-prong strategy for PMTCT. The four prongs include (1) the primary prevention of HIV among women of childbearing age; (2) the prevention of unintended pregnancies among women living with HIV; (3) the prevention of the transmission of HIV infection from HIV-positive pregnant women to their children; and (4) the provision of appropriate care, treatment and support for women living with HIV, as well as their children and families. According to WHO, the goal of eliminating MTCT will be reached only if the coverage of Prongs 1 through 3 is considerably improved. (See Figure 1.)[7]

In support of the global plan to eliminate new pediatric HIV infections, the Interagency Task Team (IATT) for Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and their Children has developed a strategic framework for prongs 1 and 2. Readers are encouraged to refer to this framework.[8]

**FIGURE 1:** Contribution of prongs 1–3 to the elimination of MTCT



# State of the Art Review

A critical review of recent literature across all four prongs of PMTCT is summarized below, which informed the content of this PMTCT Strategic Framework.

## 1 PRONG 1: PRIMARY PREVENTION OF HIV FOR PMTCT

For countries with high HIV prevalence, HIV/AIDS has become a leading cause of death during pregnancy and the postpartum period.[9, 10] Acute maternal HIV infection during pregnancy and breastfeeding is associated with very high rates of MTCT.[11-14] HIV-related morbidity and mortality in a mother living with HIV has a critical impact on her child's survival.[15] Keeping a woman HIV negative, before and throughout her pregnancy and during breastfeeding, protects her infants and children from becoming HIV-infected.

HIV-negative individuals living in stable HIV-discordant partnerships are twice as likely to get infected with HIV as those living in concordant HIV-negative relationships.[16] A group of experts at a global PMTCT meeting convened by the President's Emergency Plan for AIDS Relief (PEPFAR) in May 2010 reached the consensus that detecting discordant couples through couple testing and counseling during PMTCT interventions allows targeted HIV prevention to people that are very much in need of it. Recent data from the HPTN 052 study emphasized the significant benefit of treating members of sero-discordant couples regardless of CD4 count to prevent transmission.[17] As a collateral benefit, couple testing is associated with better uptake of PMTCT interventions.[18, 19]

Another way to support primary prevention in the context of PMTCT is re-testing pregnant women that test HIV-negative in their early stages of pregnancy. Re-testing increases the ability of the health system to identify pregnant women who seroconvert during pregnancy, around delivery or while breastfeeding. Women with recently acquired HIV infections have higher risks of MTCT than those with chronic HIV.[11, 20]

Effective HIV-prevention interventions combine behavioral and biomedical interventions. Key behavioral interventions include couple counseling, testing and disclosure; condom promotion; targeted prevention with intravenous drug users; and alcohol risk reduction. Biomedical interventions include providing ART to HIV-infected partners, medical male circumcision and treating sexually transmitted infections. Combination HIV-prevention approaches also include structural-level efforts to reduce gender inequalities and support income-generating activities for women, address HIV stigma and address social or gender norms through community-related interventions. Structural interventions also address regulatory barriers and potential distrust during the development and implementation of HIV-prevention packages for vulnerable populations such as men having sex with men or sex workers.[21, 22]

## 2 PRONG 2: PREVENTING UNINTENDED PREGNANCIES AMONG HIV+ WOMEN

A reduction in unintended pregnancies will lead to a reduction in the number of infants born to HIV-positive mothers, thereby reducing the number of HIV-exposed infants. Modeling has demonstrated that eliminating MTCT will not be possible without addressing unmet needs for family planning.[23, 24]

The unmet need for family planning is high, particularly in sub-Saharan Africa, where HIV prevalence is also high. In 2007, the unmet need for family planning was 11.2 percent worldwide and 24.8 percent in sub-Saharan Africa.[25]

Globally, an estimated 80 million (38 percent) of the 211 million pregnancies each year are unintended. Studies from generalized epidemic settings in sub-Saharan Africa suggest that the rates of unintended pregnancy among women living with HIV may be higher than in the general population. Studies from Côte d'Ivoire, South Africa and Uganda have reported rates of unintended pregnancy that range from 51 to more than 90 percent in various populations of women living with HIV.[4]

In December 2011, the United Nations Population Fund (UNFPA), WHO and the United Nations Children's Fund (UNICEF) proposed a strategy that addresses the unmet needs for family planning in the context of PMTCT. The strategy emphasizes five components: linking sexual and reproductive health with HIV interventions at the policy, systems and service-delivery levels; engaging communities; getting more men more involved; engaging organizations of people living with HIV; and ensuring the provision of nondiscriminatory services in stigma-free settings.[8]

3

## PRONG 3: PREVENTING HIV INFECTION FROM HIV-POSITIVE PREGNANT WOMEN TO THEIR CHILDREN

During the antenatal period, all pregnant women must have access to HIV testing and counseling (HTC). Women who test positive for HIV must have access to the following: (1) screening for eligibility for lifelong ARV treatment, (2) ARV drugs and (3) Cotrimoxazole Preventive Therapy (CPT). Key steps to preventing MTCT during labor and delivery are (1) safe obstetrical practices, (2) judicious use of Cesarean sections when feasible and (3) provision of intra- and immediate postpartum doses of ARVs to mothers and newborns.

During the postnatal period, it is critical to ensure (1) the follow-up of HIV-exposed infants with growth and development and appropriate immunization based on HIV status, (2) counseling and support for infant feeding, (3) the monitoring of opportunistic infections and provision of CPT, (4) providing appropriate ARV to prevent MTCT during the breastfeeding period, (5) EID of HIV infection and (6) providing ART for confirmed HIV-infected infants.

The regimen for mothers during the postpartum period involves the following steps: (1) continuing HIV care and treatment, including ARVs (lifelong ART or prophylaxis as needed); (2) preventing and treating opportunistic infections, including tuberculosis; and (3) providing comprehensive care and treatment, including family planning services.

### HIV TESTING AND COUNSELING

With the development of new, highly sensitive and specific antibody-based rapid HIV testing, same day results have become possible. HTC for pregnant women is no longer marked by delays, barriers and little promise of accessing ARV.[27-29] Provider Initiated Testing and Counseling (PITC), coupled with same day results, have made HTC more acceptable, including in labor and delivery settings as well as in mobile antenatal clinics.[27-29] Acceptance of HTC is now high (over 90 percent) in the context of PMTCT.

## ELIGIBILITY FOR LIFELONG ART

CD4 count and clinical staging are used to determine the eligibility of HIV-positive pregnant women for lifelong ART. CD4 count is more sensitive than clinical staging, which misses a significant proportion of those actually eligible for lifelong ART when it is used alone.[30-32] Using the CD4 count threshold of 350 cells/mm$^3$, approximately 50 percent of HIV-positive pregnant women are eligible for lifelong ART, and only a limited proportion of them would be identified using clinical staging alone. In a PMTCT program in resources-constrained settings, 94 percent of women who were eligible for lifelong ART had a CD4 count below 350 cells/mm$^3$, while only 23 percent were in the WHO clinical stage 3 or 4. Effective strategies are needed to increase access to CD4 count in maternal and child health settings as demonstrated in many observational studies.[33, 34] With the newly (April 2012) released PMTCT recommendations, a program that implements option B+ (lifelong triple ARV to all HIV-positive pregnant women) will no longer need CD4 count to determine ART eligibility. CD4 counts (like viral load) assays are still desirable, however, for determining a woman's baseline immunological status and monitoring her response to treatment.[35]

## USE OF ARV IN PMTCT CONTEXT

Findings from recent clinical trials have pushed the frontiers of PMTCT. As demonstrated in high-income countries, the overall risk of MTCT can be reduced to less than 2 percent through the use of combination ARV drugs in HIV-positive pregnant women.[26] Kesho Bora, a multicountry study, found that providing ARVs to HIV-positive mothers who breastfeed reduces the risk of HIV transmission to their children.[36] The PEPI study in Malawi demonstrated that a 14-week extended nevirapine prophylaxis significantly reduces postnatal transmission among perinatally exposed children compared to the standard of care of sdNVP + 1 week AZT.[37] Other studies have underscored the critical importance of initiating lifelong ART at CD4 count equal to or below 350 cells/mm$^3$, not only to decrease maternal morbidity and mortality but also to significantly decrease MTCT.[38, 39]

The current evidence from clinical trials and programmatic experience supports the following: (1) lifelong ART is safe and effective in preventing MTCT, (2) longer ARV regimens (starting before or in early pregnancy) are more effective than shorter ones (starting after or at 36 weeks of pregnancy) and (3) the use of nevirapine as a single dose in HIV-positive pregnant women or as extended prophylaxis in HIV-exposed infants is associated with the emergence of HIV-resistant strains that can jeopardize future ART.[40-44]

## OBSTETRICAL PRACTICES AND PMTCT

The benefit of elective cesarean section (before labor and before rupture of membranes) in preventing MTCT has been demonstrated in a number of trials.[45, 46] The evidence available came from studies conducted before the widespread use of ARV. In women with less advanced or well-controlled HIV disease (among whom the risk of MTCT can be as low as 2 percent), the benefit of elective cesarean sections is unclear. It is also important to remember that a cesarean section carries risks of postpartum morbidity. In developing countries, the risks and benefits associated with an elective cesarean section have not been thoroughly explored.

The rupture of fetal membranes over four hours before delivery was found to increase the risk of MTCT.[47] This finding suggested the use of vaginal lavage with chlorhexidine during labor to reduce MTCT, but there was no conclusive evidence of its effectiveness.[48] In the current context of expanding access to ARVs, the effect of prolonged ruptures of membranes or vaginal lavage on MTCT requires careful consideration.[49, 50]

## POSTPARTUM FOLLOW-UP OF MOTHER BABY PAIRS

Between the time of HIV testing and six months post-partum/natal, a substantial proportion of HIV-positive mothers and their HIV-exposed or infected babies are lost to follow-up (LTFU), which is common in low- and middle-income countries. In these settings, MNCH services lose contact with over 50 percent of pregnant women (mothers) and/or their babies after enrolment in a PMTCT program.[51-53]

Loss to follow up is caused by a variety of factors, some of which are related to mothers' illiteracy, poor understanding of the PMTCT interventions and failure to disclose HIV-status.[52, 54, 55] Other factors are related to the health system or communities. Poor HIV information and counseling, lack of privacy during counseling, long distances to reach health facilities, long waiting times, poor coordination between antenatal and postnatal clinics, poor quality of health management information systems, home deliveries as well as stigma and discrimination were found to be associated with LTFU in many observational studies.[51, 53, 55, 56] Countries with the lowest LTFU tend to have strong health management information systems.[57, 58] This is most likely because defaulters are identified early and actions are taken quickly to remind them of their appointments.

HIV-positive mothers who are LTFU miss opportunities to receive essential services like long-term care and treatment and family planning. HIV-exposed children who are LTFU miss essential services such as initiation on ARV

prophylaxis, cotrimoxazole preventive therapy, early diagnosis of HIV infection and (if infected) early live-saving ART.[15, 59-61] Another critical tool to assess the effectiveness of PMTCT programs is EID.[62, 63]

### FEEDING OPTIONS FOR HIV-EXPOSED CHILDREN

For many years, feeding options for HIV-exposed children in resource-constrained settings remained a dilemma. On one side, breastfeeding by an HIV-infected mother carries the risk of MTCT; on the other side, formula feeding increases the risk of morbidity and mortality from common childhood illnesses.[64]

Recent groundbreaking studies on ARV and PMTCT during breastfeeding demonstrated that maternal ART alone or provision of ARVs to infants being breastfed by an HIV-positive mother can significantly reduce the risk of MTCT.[36, 37, 65-69] Findings from these studies resulted in updated WHO recommendations on infant feeding and HIV infections.[70]

## 4 PRONG 4: CARE, TREATMENT, AND SUPPORT TO WOMEN LIVING WITH HIV, THEIR CHILDREN AND FAMILIES

Evidence from a wide range of resource settings — low, middle and high — demonstrates a consistent pattern of positive benefits from HIV clinical care and antiretroviral therapy. These benefits include (1) reduced morbidity and mortality, (2) improved overall health and quality of life for those living with HIV and (3) reduced transmission. Since its inception in high-resource countries, ART has been shown to profoundly alter HIV disease progression, including the incidence of opportunistic infections in both adults and children.[71-73] A growing number of studies are reporting on clinical outcomes associated with the more recent expansion of HIV care and ART in low-resource settings in Africa, Asia and Latin America, where 90 percent of people with HIV live. These studies reveal that clinical and immunologic outcomes are comparable to those observed in high-resource settings. The evidence also highlights the clinical and programmatic issues specific to these settings that need to be addressed to optimize benefits of care and treatment for those living with HIV.[74-77] Most recently, numerous studies have also demonstrated that starting ART at higher CD4 counts and suppressing HIV viral loads decreases transmission.[17]

# FHI 360's Goal, Objectives and Guiding Principles

## GOAL

FHI 360's goal in its support to the global PMTCT effort is to help eliminate new pediatric HIV and allow women, children and their families to live healthy lives. FHI 360 supports PMTCT programs not only to attain reduced MTCT risk but also to strive for HIV-free survival of children and optimal health for mothers and families.

## OBJECTIVES

The specific objectives of FHI 360's PMTCT strategy are to

- improve the quality and use of MNCH services
- improve and promote the availability and use of HTC services in MNCH settings and beyond
- improve and promote access to ARVs for both PMTCT and treatment of HIV/AIDS
- improve and promote safer obstetric practices
- support and promote national policies and guidelines on safe infant feeding
- improve access and referral to care and support services for mothers and their children and families
- support the integration of HIV and MNCH/family planning services
- support informed reproductive decision making by couples with HIV
- complement ongoing HIV prevention and care efforts with activities such as reducing stigma and discrimination

## GUIDING PRINCIPLES

1

### SUPPORT THE 4-PRONG COMPREHENSIVE APPROACH TO PMTCT

FHI 360's approach addresses a wide range of prevention, care, treatment and support services along a continuum of care that begins with women of reproductive age and extends to HIV-positive women or couples, including HIV-positive pregnant women through the postpartum period. FHI 360's operations include providing sexual and reproductive health services; family planning services; and other related services that are provided directly, through referral networks or in the community.

2

### SUPPORT INTERVENTIONS BACKED BY SCIENTIFIC EVIDENCE AND EXPERT OPINION, AND THAT ARE IN LINE WITH THE INTERNATIONAL COMMUNITY

FHI 360 supports only those interventions, laboratory tests or drugs in PMTCT programs that are based on evidence and/or endorsed by authorized international bodies such as WHO. Moreover, FHI 360 contributes to the development of scientific evidence related to PMTCT (clinical trials, operational research and publications in peer-reviewed journals). In addition, FHI 360 will participate in international discussions about the safety, efficacy and feasibility of specific interventions for PMTCT.

3

### SUPPORT COUNTRY OWNERSHIP AND NATIONAL PMTCT POLICIES

FHI 360 is fully committed to the principle that governments and key stakeholders, including civil society, the private sector and people living with HIV (PLHIV), own and drive the program. Their involvement includes defining the problem, developing action plans and implementing activities. FHI 360 believes that country ownership is critical to sustainability, and we ensure that all of our interventions are in agreement with the national PMTCT policies of the respective countries. FHI 360 supports countries' efforts to develop their national normative tools.

4

## BUILD ON STRONG AND COORDINATED PARTNERSHIPS

Both at the international and national levels, FHI 360 believes that partnerships are important to harmonize and sustain action toward common goals and targets. We also believe that a national response implemented by various partners, but coordinated by a national body, is a critical step toward sustainability.

5

## AIM FOR HIGHEST IMPACT POSSIBLE

Resources should be committed to situations and settings where the highest impact will be obtained — for example, strategically and intensively focusing PMTCT interventions in high-prevalence settings.

6

## AIM FOR THE HIGHEST DEGREE OF EQUITY AND FOR MALE INVOLVEMENT

FHI 360 promotes interventions that encourage and facilitate male involvement in PMTCT. Our programs ensure that beneficiaries of the programs — women, infants, children and families — have equitable access to services, regardless of their socioeconomic background, education level, religion, race or gender.

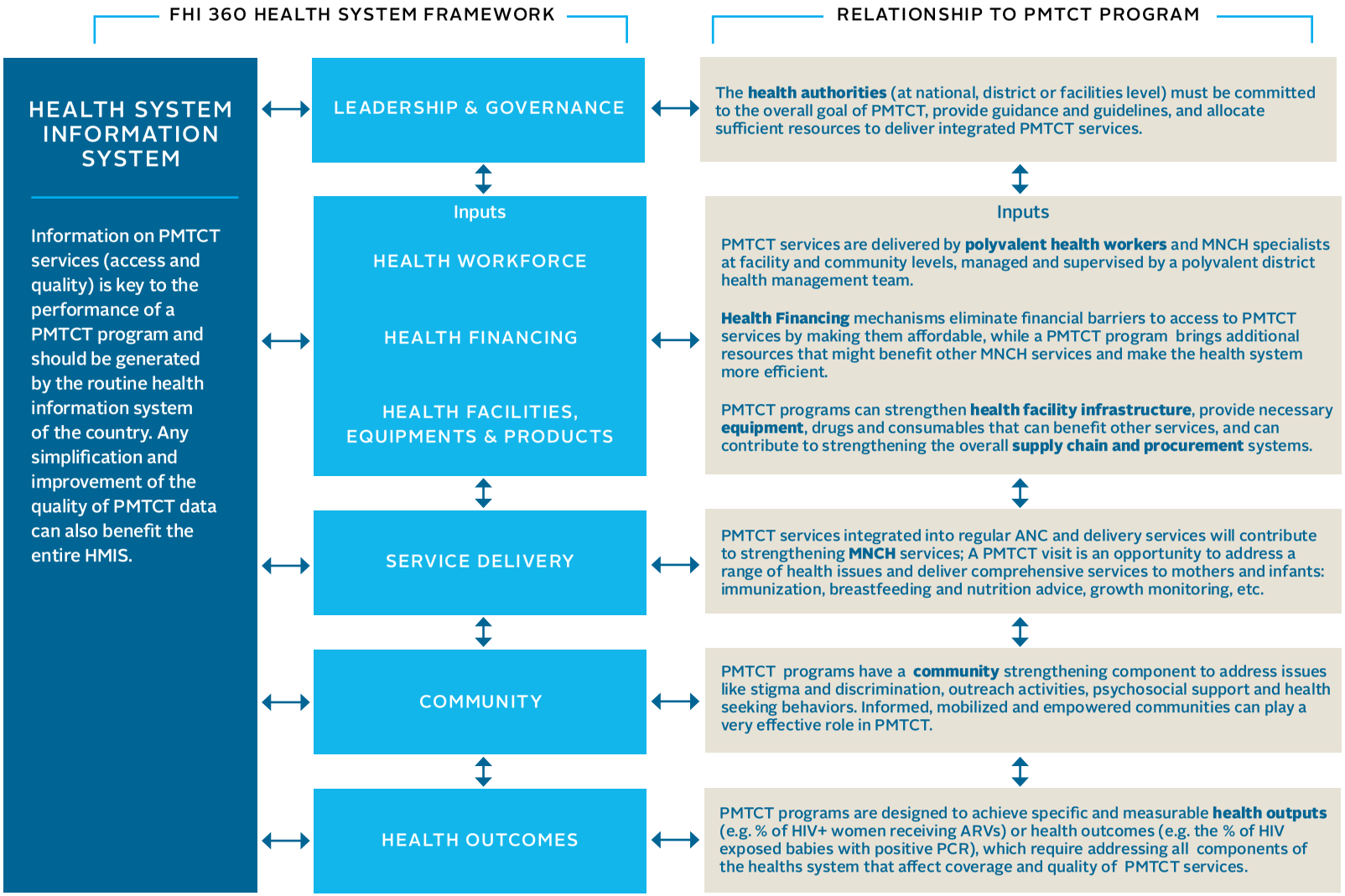
7

## STRENGTHEN HEALTH SYSTEMS AND INTEGRATE PMTCT INTO MNCH

PMTCT can only thrive in a strong health system. Although sponsors may perceive PMTCT as a vertical program, health authorities in a country regard PMTCT as additional interventions to the MNCH package and a service received by clients. Contributions of PMTCT programs to the entire health system are multi-faceted. FHI 360 has developed a Health System Strengthening framework.[78] Figure 2 illustrates how PMTCT contributes to and benefits from a health systems strengthening approach.

With the intensive scale-up of PMTCT care and treatment in resource-constrained settings, there might be concerns about overwhelming the fragile health system, which could result in declines in the delivery of other primary health care. FHI 360's experience in Rwanda and other evidence have shown instead that when programs such as PMTCT are integrated into MNCH and designed with the goal of achieving broad health benefits, they serve as a catalyst for strengthening health systems.[79, 80]

**FIGURE 2:** Relationship between a PMTCT program and the health system



# FHI 360's Technical and Programmatic Approaches

## TECHNICAL AND SCIENTIFIC LEADERSHIP

Through active collaboration with UN organizations, funding agencies and implementing partners, FHI 360 contributes to the PMTCT global agenda. FHI 360 is an active member of the IATT on PMTCT. We are in a unique position to share our field experience, influence global recommendations and be integrally involved in developing and guiding PMTCT policy.

FHI 360 supports intervention-linked research on current and future PMTCT efforts to discern new opportunities to advance service delivery, to determine the effectiveness and cost-effectiveness of different interventions and to inform providers and policymakers. We believe that questions for operational research can be generated from routine service data, but genuine quality assurance of data collected during service provision is required. Beyond generating questions, reliable service data can guide formal research projects, answer programmatic questions and improve the outcome of PMTCT interventions overall.

## CAPACITY BUILDING ACROSS LEVELS OF THE HEALTH SYSTEM

At the national level, FHI 360 supports policy, advocacy, and PMTCT planning. FHI 360 contributes to the development of PMTCT national policy, training curricula, as well as strategic and work plans. Beyond the national level, FHI 360 supports district health management teams to increase their awareness of PMTCT and to build their capacity to design and implement effective programs. This multifaceted support includes training, mentoring, developing standards and operating procedures, monitoring and evaluation (M&E), quality assurance (QA) or quality improvement (QI), improving infrastructure,

addressing diverse constraints through innovation (for example, using lay counselors where there is shortage of staff) and organizing referral networks for patients or for laboratory tests.

FHI 360 supports the *health district approach*, particularly in generalized HIV epidemics. To reach the largest number of pregnant women, PMTCT plans and activities should be population-based and aim for universal coverage within a given district. The selection of districts should be driven and owned by the respective countries, and the roll-out plans should be phased at a pace that takes into account the district's specific burden of HIV and availability of resources. In concentrated epidemics, PMTCT interventions target most-at-risk groups such as sex workers, women who inject drugs or partners of intravenous drug users.

FHI 360 has made noticeable contributions to many countries' PMTCT programs:

- In Nigeria, one-third of PMTCT services are offered in FHI 360-supported health facilities as of 2011.
- In Rwanda, 90 percent of pregnant women are tested with their partners in FHI 360 supported sites.
- In Tanzania, in 2011, FHI 360 has spearheaded the implementation of the "PMTCT one-stop shop," whereby pregnant women that test positive for HIV receive CD4 count assessment and lifelong ART or prophylaxis, as well as routine maternal and child health care — all at the same service point.

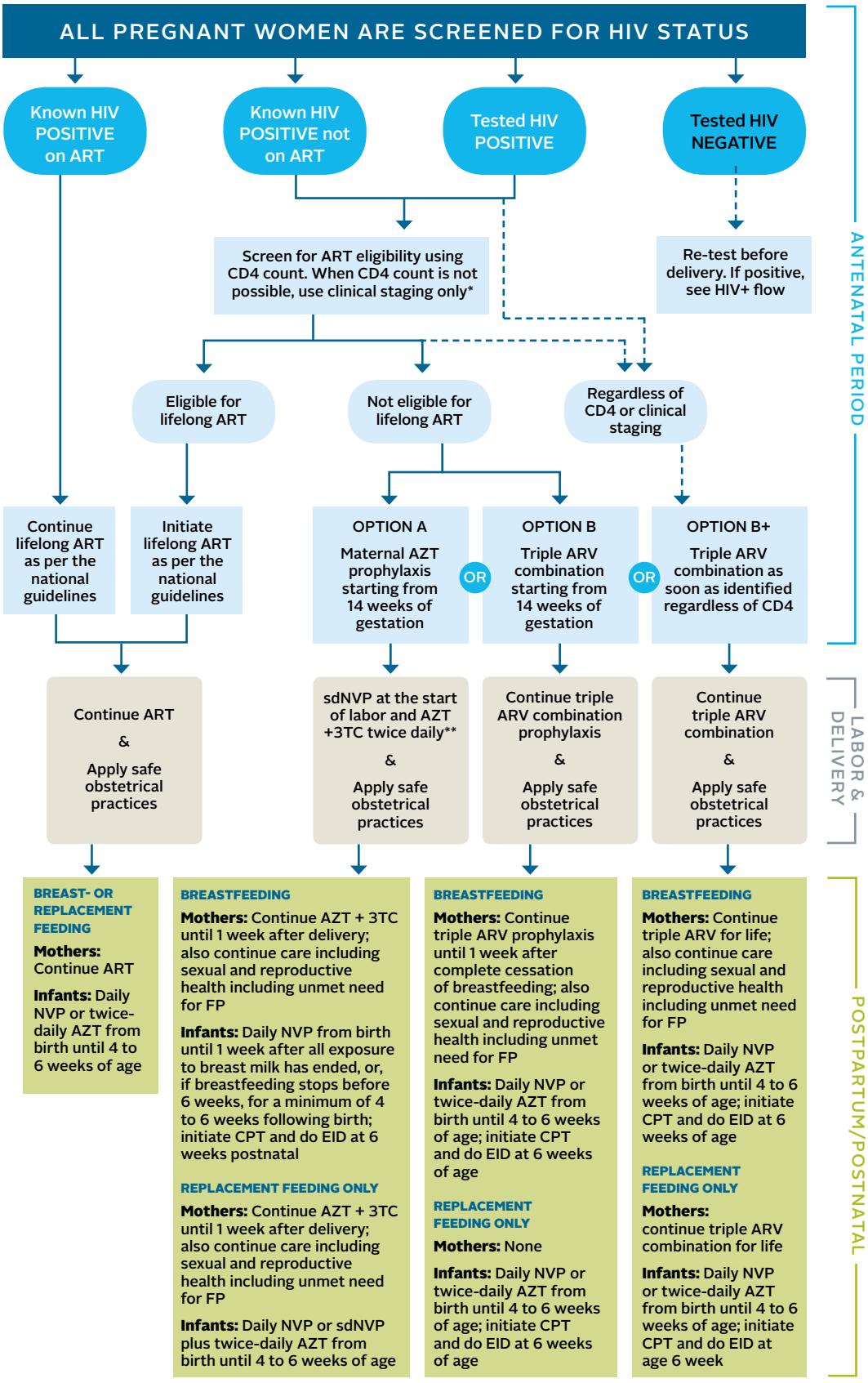
FHI 360 helps providers and managers to assess and determine the readiness of health facilities (including the referral points) to implement effective PMTCT programs.

Because FHI 360 recognizes the key role that the community plays in making a PMTCT program effective, we encourage community involvement in a number of ways, such as determining important elements to consider for greater male involvement or for the adoption of safe infant feeding practices. We promote and support activities in communities to improve health-seeking behaviors related to PMTCT, to tackle stigma and discrimination and to implement certain activities that do not necessarily fit best in health facilities, such as long-term counseling support through peer-group initiative. In Mozambique, for example, FHI 360 promotes mother-to-mother groups in which HIV-positive mothers receive psychosocial support from other HIV-positive mothers.

## SUPPORT PROVISION OF PMTCT SERVICES

To ensure sustainability, FHI 360 supports the integration of PMTCT services within general MNCH services, rather than creating parallel systems. PMTCT is logical flow of interventions that go from increasing the use of antenatal services, testing and counseling pregnant women for HIV and continue through EID. (See Figure 3.)

**FIGURE 3:** Sequence of PMTCT interventions




* *Start ARV prophylaxis while waiting to determine lifelong ART eligibility*
** *If AZT was taken for 4 weeks or more before delivery, omission of maternal sdNVP as well as the tail (AZT+3TC) can be considered*

## HIV TESTING AND COUNSELING

FHI 360 supports a PITC approach for HIV that targets pregnant women and their partners in MNCH. This approach includes facility-based and outreach ANC, as well as labor and delivery settings.

- FHI 360 recommends rapid HIV tests with same day results.
- FHI 360 ensures that consent (implicit or explicit) is sought, confidentiality is maintained and counseling is available for all models of HTC being implemented.
- FHI 360 encourages the re-testing of pregnant women that test HIV-negative in the early stage of pregnancy.

FHI 360's target is that at least 95 percent of pregnant women seen for antenatal care (and during labor), are screened for HIV and their HIV status is determined.

## ELIGIBILITY FOR LIFELONG ART

FHI 360 high recommends timely CD4 cell count investigation and clinical staging to determine eligibility for lifelong ART in pregnant women who tested HIV-positive. Where or when CD4 count is not feasible, eligibility should be based initially on clinical staging while efforts for access to CD4 count are being implemented. For the maximum impact, FHI 360 believes that assessment for lifelong ART eligibility and the offer of ARV medications should be implemented at the lowest level possible of the health system where the majority of pregnant women seek antenatal, labor and delivery care.

FHI 360's target is to offer CD4 count to at least 95 percent of HIV-positive pregnant women and make their results available at the point of service.

With the newly released PMTCT recommendations, a program that implements option B+, lifelong triple ARV, will no longer need CD4 count to determine ART eligibility. CD4 counts (like viral load) assays are still desirable, however, for determining baseline immunological status and monitoring response to treatment.[35]

## ARVS FOR HIV-POSITIVE PREGNANT WOMEN

FHI 360 supports the use of the most highly effective and feasible ARV regimens in the context of PMTCT. If determined eligible for lifelong ART, HIV-positive pregnant women should be offered combination ARV drugs as soon as possible. This approach provides the greatest MTCT risk reduction and maternal survival, which is integrally linked to child survival. Women who are not eligible for lifelong ART should be offered prophylactic ARV regimens early in pregnancy as outlined in the most recent WHO recommendations and endorsed by respective national PMTCT policies.

FHI 360's target is at least 95 percent coverage of HIV-positive pregnant women receiving ARVs as per the national policy.

## SAFE OBSTETRICAL PRACTICES

Good practices for HIV-positive pregnant women include (1) limited vaginal examination and (2) avoidance of episiotomy, forceps, vacuum extractor and artificial rupture of membranes unless absolutely indicated. If a spontaneous rupture of membranes occurs before or early during the course of labor, interventions to decrease the interval to delivery, such as administering oxytocin, may be considered in women without indications for cesarean delivery. FHI 360 promotes rigorous monitoring of labor through the use of partographs and timely action to prevent prolonged labor, especially when membranes are ruptured.

The use of elective cesarean deliveries for PMTCT should be judicious and decided on a case-by-case basis. For example, in a patient with low viral load, the benefit of a cesarean delivery solely for PMTCT is difficult to justify. FHI 360 does not promote routine, elective cesarean deliveries for PMTCT because of limited resources in developing countries, the risk of postpartum morbidity and the possible effect on future pregnancies.

Women of unknown HIV status should be offered HTC during labor and delivery or immediate postpartum and linked with appropriate services.

## INFANT ARV PROPHYLAXIS

This should be given according to the recommendations and the national policy of each country. If breastfeeding is the feeding mode chosen, it should be exclusive until the sixth month. It should be covered by either ARVs given to the mother or ARVs given to the breastfed child until at least one week after breastfeeding is completely stopped.

FHI 360's target is that at least 95 percent of infants born to HIV-positive mothers receive ARV according to the national policy.

## INFANT FEEDING CHOICES AND COUNSELING

FHI 360 supports national governments to identify the best and safest infant feeding options in their respective settings. The factors that are taken into account include (1) the sociocultural and economic context, (2) the availability and quality of health services, (3) the prevalence of HIV among pregnant women, (4) the causes of maternal and child undernutrition and (5) the causes of infant and child mortality. Health services will support HIV-positive mothers to either breastfeed and receive ARV interventions or avoid all breastfeeding. The objective is to maximize HIV-free survival among HIV-exposed infants and children. In light of the recent recommendations, during breastfeeding, ARV should be given to the lactating mother or to the breastfeeding child to minimize the risk of MTCT.[81, 82]

In resource-poor settings, the most common option is likely to be exclusive breastfeeding for the first six months of life, then introducing appropriate complementary foods thereafter and continuing breastfeeding for the first 12 months of life. At 12 months of age, breastfeeding should only stop once a nutritionally adequate and safe diet without breast milk can be provided. If infants or young children are known to be HIV-infected, mothers are encouraged to exclusively breastfeed for the first six months and continue breastfeeding as per the recommendations for the general population, that is, up to two years or beyond.[81]

Commercial infant formula milk for HIV-uninfected infants or for infants whose HIV status is unknown should be considered only when specific conditions are met: safe water and sanitation, the availability of sufficient formula milk, the ability to prepare formula milk hygienically, the capacity to provide formula milk exclusively for the first six months, family support of infant formula milk and the capacity to access MNCH services.[81]

## TREATMENT, CARE AND SUPPORT TO WOMEN LIVING WITH HIV AND THEIR CHILDREN AND FAMILIES

HIV-exposed infants and children should receive child survival interventions, such as immunization and malaria prevention in areas with malaria; growth monitoring; CPT; nutritional counseling and support; and tuberculosis screening, prevention and treatment if needed.

FHI 360's target is that at least 95 percent of infants and children born to HIV-positive mothers are initiated on CPT as early as six week of life.

EID must be made available for HIV-exposed infants/ children. Prospects for a healthy life are undermined when HIV-exposed infants are not screened for HIV-infection at an early age and provided with the treatment, care and support they need to thrive.[83]

FHI 360's target is that at least 95 percent of infants and children born to HIV-positive mothers are offered EID at sixth week of life.

All HIV-infected infants below two years of age and older children eligible based on CD4 and/or the WHO clinical stage should be provided with ART as part of the standard package of care. For older children not yet requiring ART, regular clinical staging and measurement of CD4 cell counts at least every six months is essential. Regular monitoring of clinical condition and CD4 cell count is important to ensure treatment effectiveness and detect failure for those receiving ART. All HIV-infected children require lifelong care and support including adherence and psychological and social support.[82]

For HIV-positive mothers, FHI 360 supports comprehensive care, treatment and psychosocial support, including family practice (where there is unmet need) and palliative care as a part of a continuum of care. The rest of household should have access to HTC and other support services. Family members testing HIV-positive should be offered care, treatment and support in the context of the family-centered model of care.[84]

FHI 360's target is that at least 95 percent of HIV-positive women with unmet need for family planning are offered a contraceptive method.

## FHI 360'S STANDARDS AND KEY INDICATORS FOR PMTCT

FHI 360 standards are built on scientific evidence and expert opinions backed by agreement among the international communities.[83] FHI 360 standards also take into account the national PMTCT policy. Our standards, which are coupled with PMTCT indicators, are summarized in an action table to help program and technical managers monitor PMTCT activities and take appropriate actions as needed (see Annex 1). These standards are:

- ✓ All pregnant women should have their **HIV status determined** or should be offered HTC during the antenatal period if a recent status is unknown.
- ✓ All pregnant women should be **screened** for HIV and/or offered HTC around the time of labor and delivery.
- ✓ All HIV-positive pregnant women should have **CD4 counts** done as soon as an HIV-positive status is established, and results should be made available as soon as possible or within one month before the expected delivery date. If a program is implementing the B+ option, CD4 count is still desirable, but not absolutely required.[35]
- ✓ All HIV-positive pregnant women should **receive ARV** according to national guidelines.
- ✓ All HIV-positive pregnant women with CD4 count ≤ 350 cells/mm$^3$ should initiate **lifelong ART** as soon as possible during pregnancy.
- ✓ All HIV-positive pregnant women with CD4 count ≤ 350 cells/mm$^3$ should **initiate CPT**.
- ✓ All infants born to HIV-positive mothers should **receive ARV** according to the national guidelines.
- ✓ All infants born to HIV-positive mothers should **initiate CPT** at the age of six weeks.
- ✓ All infants and children born to HIV-positive mothers should be offered **EID** as early as six-weeks postnatal or according to the national guidelines.
- ✓ All infants and children born to HIV-positive mothers and whose blood sample was collected for EID should receive their **test results** within four to eight weeks.
- ✓ When an HIV-infected mother **breastfeeds** her infant, either the mother or the infant should receive ARVs during the breastfeeding period or according to national guidelines.
- ✓ All HIV-positive postpartum women with an unmet need for **family planning** should be offered contraceptive methods and be provided with ongoing counseling.

As shown in Annex 1: PMTCT Standards, each standard is linked with a definition, guidance on how to measure the standard (by numerator and denominator), examples of possible data sources and a scale of how the measurement meets or does not meet FHI 360's target. Every program will define the actual data source available in their context. Additionally, targets may be modified in accordance with national targets set by the Ministry of Health.

After the standards have been measured, the results should be used to inform programmatic directions. For example, if the results indicate that the program is meeting the set targets, then documentation of lessons learned and/or a manuscript should be considered. If results show that the program is not meeting targets in one of more areas, then QI efforts should be introduced.

Moreover, a review of performance (or under-performance) based on the standards should involve all stakeholders. Results should be shared with ministries of health and may be used to advocate for revising national PMTCT guidelines, standard operating procedures, etc.

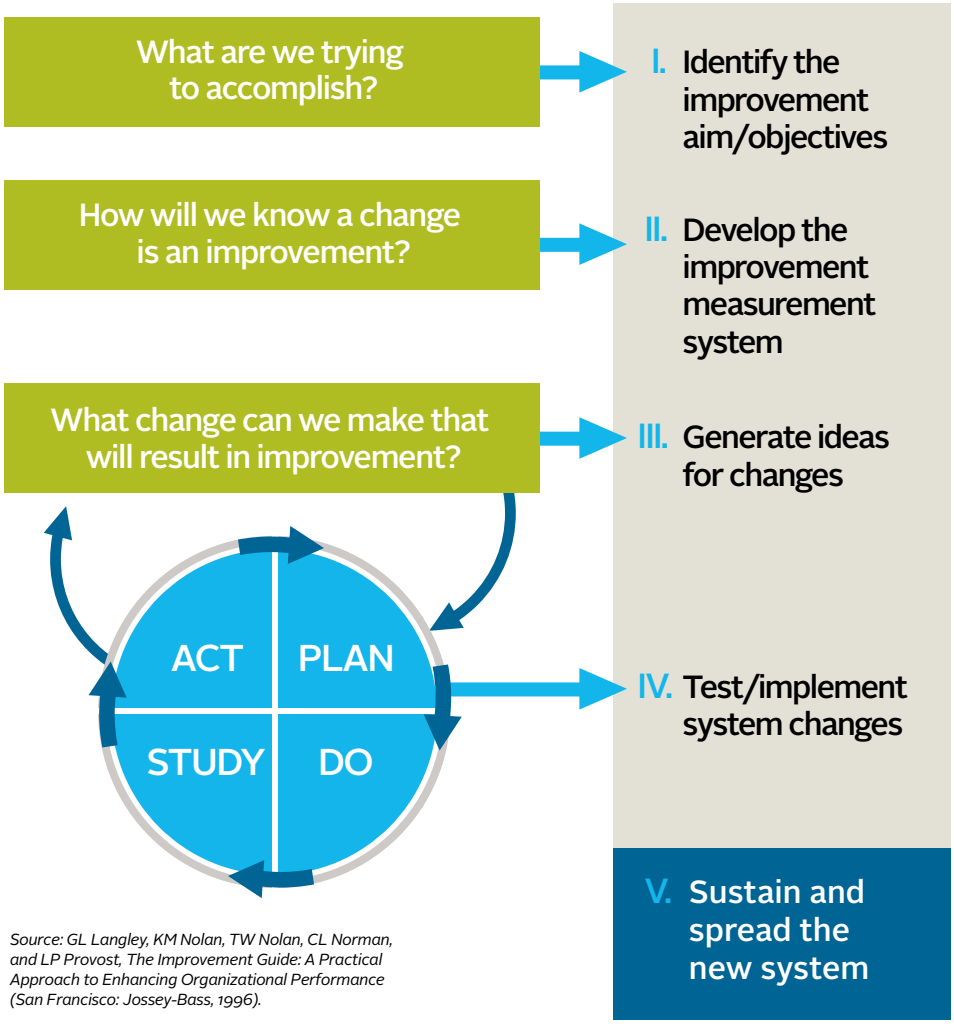
## QUALITY IMPROVEMENT FOR PMTCT

Quality Improvement offers an innovative approach to the rapid achievement of better health outcomes. FHI 360 applies this new science to improve the capacity of a health system to deliver PMTCT services that are known to be effective to the population in need, and to increase the sustainability of cost-effective services. Initially designed to improve the technical quality of services delivered to patients in a facility, the science has evolved to address any system issue that prevents the achievement of a specific health outcome. QI approaches empower health care providers and decision makers to examine their system, understand the issues and test changes for the benefit of clients and patients.

One of the methods of this innovative approach is the Collaborative Model for Improvement, designed by the Institute for Healthcare Improvement in the U.S. The Collaborative Model is used to manage a large-scale improvement effort that involves many service delivery sites that are interested in achieving the same health outcome (prevention of HIV transmission to infants) by testing many system changes concurrently and sharing the results during regular learning sessions. It is a time-limited strategy (usually 18 months) that brings a large number of teams together to work and learn how to achieve significant improvements rapidly with the intention of spreading these improvements to other sites. Each team collects a common set of indicators to measure whether the proposed changes are resulting in improvement. During learning sessions, teams plan the replication of best practices.

Each team participating in a Collaborative Model uses a generic (quality) improvement model. This model focuses on testing small-scale system changes, such as an increase in access to CD4 count among HIV-positive pregnant women or an increase in uptake of ARV drugs among HIV-exposed infants. If a specific change yields improvement, it is sustained and incorporated into the rest of the health system. If the change does not yield the expected improvement, it is abandoned and another change is tested.

**FIGURE 4:** FHI 360's Quality Improvement Model




*Source: GL Langley, KM Nolan, TW Nolan, CL Norman, and LP Provost, The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (San Francisco: Jossey-Bass, 1996).*

In the core of collaborative management is the QI model proposed by FHI 360 and represented in Figure 4. The model includes these five steps:

1 **IDENTIFY AN EXPLICIT IMPROVEMENT GOAL AND OBJECTIVES** that express in measurable terms a benefit for the beneficiaries receiving a specific service. The goal could be a small (for example, in a selected facility and by a defined date, improve access of HIV-positive pregnant women to CD4 count by a specified percentage) or relatively big (for example, in a selected health district and by a defined date, increase PMTCT services to pregnant women during the antenatal period.

2 **DEVELOP THE IMPROVEMENT MEASUREMENT SYSTEM** that would help track a possible improvement. This implies defining realistic key indicators (for example, the proportion of HIV-positive pregnant women accessing CD4 count or the proportion of pregnant women offered PMTCT services during the antenatal period), their source and how often they will be collected. Ideally, these indicators will be part of the existing data that is routinely collected. It should be easy to analyze and present on a run chart.

3 **GENERATE IDEAS FOR CHANGES.** This step involves brainstorming. For example, after a root cause analysis of why more women could not access CD4 count, generate adjustments or modifications. Generating ideas for changes involves the stakeholders of the system whose performance is being addressed. It also implies generating a list of changes to consider. This critical step will initiate a work plan that interfaces with the next phase, the PDSA (Plan-Do-Study-Act) cycle.

4 **TEST/IMPLEMENT SYSTEM CHANGES WITHIN THE PDSA CYCLE:** Through a structured process on a small scale, changes are introduced one by one or as a package of changes. They are assessed for their effect on the improvement goal and objectives by measuring indicators and analyzing data.

5 **SUSTAIN AND REPLICATE THE LESSON LEARNED.** In the PDSA cycle, lessons will have been learned from (1) the changes that produced success and that will be replicated and (2) mistakes that were made and should be avoided. Lessons learned would be spread through experience sharing, conferences and possibly peer-reviewed journals.

Using QI logic helps to plan a collaborative in a smart way, get results and scale up to a larger number of facilities. A Collaborative Model that provides a framework for the scale-up of best practices is one that has a good fit for PMTCT, has explicit evidence-based standards and requires application with joint PMTCT expert and QI-process guidance.

## REFERENCE LIST


1. UNAIDS. HIV Epidemic Update 2010. Geneva; 2011.
2. De Cock KM, Fowler MG, Mercier E, et al. Prevention of mother-to-child HIV transmission in resource-poor countries: translating research into policy and practice. JAMA. 2000 Mar 1;283(9):1175-82.
3. Mofenson LM, Lambert JS, Stiehm ER, et al. Risk factors for perinatal transmission of human immunodeficiency virus type 1 in women treated with zidovudine. Pediatric AIDS Clinical Trials Group Study 185 Team. N Engl J Med. 1999 Aug 5;341(6):385-93.
4. WHO, UNAIDS, UNICEF. Global HIV/AIDS Response, Progress Report 2011. Geneva; 2011.
5. UNAIDS. Count Down to Zero. Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping Their Mothers Alive. Geneva; 2011.
6. United Nations, Sacchs JD. Investing in Development, A Practical Plan to Achieve the Millennium Development Goals, Overview. New York; 2005.
7. Mahy M, Stover J, Kiragu K, et al. What will it take to achieve virtual elimination of mother-to-child transmission of HIV? An assessment of current progress and future needs. Sex Transm Infect. 2010 Dec 2010;86(Suppl 2):ii48-55.
8. The Inter-agency Task Team for Prevention and Treatment of HIV Infection in Pregnant Women, and their Children. Preventing HIV and Unintended Pregnancies: Strategic Framework 2011-2015. 2012.
9. WHO, UNICEF, UNFPA, Bank TW. Trends in Maternal Mortality: 1990 to 2008. Geneva; 2010.
10. WHO. Women and Health. Today's Evidence, Tomorrow's Agenda. Geneva; 2009.
11. Liang K, Gui X, Zhang YZ, Zhuang K, Meyers K, Ho DD. A case series of 104 women infected with HIV-1 via blood transfusion postnatally: high rate of HIV-1 transmission to infants through breast-feeding. J Infect Dis. 2009 Sep 1;200(5):682-6.
12. Dunn DT, Newell ML, Ades AE, Peckham CS. Risk of human immunodeficiency virus type 1 transmission through breastfeeding. Lancet. 1992 Sep 5;340(8819):585-8.
13. Van de Perre P, Simonon A, Msellati P, et al. Postnatal transmission of human immunodeficiency virus type 1 from mother to infant. A prospective cohort study in Kigali, Rwanda. N Engl J Med. 1991 Aug 29;325(9):593-8.
14. Humphrey JH, Marinda E, Mutasa K, et al. Mother to child transmission of HIV among Zimbabwean women who seroconverted postnatally: prospective cohort study. BMJ. 2010;341:c6580.
15. Newell ML, Coovadia H, Cortina-Borja M, Rollins N, Gaillard P, Dabis F. Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis. Lancet. 2004 Oct 2-8;364(9441):1236-43.
16. Hugonnet S, Mosha F, Todd J, et al. Incidence of HIV infection in stable sexual partnerships: a retrospective cohort study of 1802 couples in Mwanza Region, Tanzania. J Acquir Immune Defic Syndr. 2002 May 1;30(1):73-80.
17. Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011 Aug 11;365(6):493-505.
18. Msuya SE, Mbizvo EM, Hussain A, Uriyo J, Sam NE, Stray-Pedersen B. Low male partner participation in antenatal HIV counselling and testing in northern Tanzania: implications for preventive programs. AIDS Care. 2008 Jul;20(6):700-09.
19. Farquhar C, Kiarie JN, Richardson BA, et al. Antenatal couple counseling increases uptake of interventions to prevent HIV-1 transmission. J Acquir Immune Defic Syndr. 2004 Dec 15;37(5):1620-6.
20. Clayden, P. i-Base H. High rates of HIV acquisition in pregnancy and post partum in Francistown, Botswana. CROI - Conference on Retroviruses and Opportunistic Infections. Vol Monthreal2009.
21. Kurth AE, Celum C, Baeten JM, Vermund SH, Wasserheit JN. Combination HIV prevention: significance, challenges, and opportunities. Curr HIV/AIDS Rep. 2011 Mar;8(1):62-72.

22. Merson M, Padian N, Coates TJ, et al. Combination HIV prevention. Lancet. 2008 Nov 22;372(9652):1805-6.

23. Wilcher R, Petruney T, Reynolds HW, Cates W. From effectiveness to impact: contraception as an HIV prevention intervention. Sex Transm Infect. 2008 Oct;84(Suppl 2):ii54-60.

24. Reynolds HW, Janowitz B, Homan R, Johnson L. The value of contraception to prevent perinatal HIV transmission. Sex Transm Dis. 2006 Jun;33(6):350-6.

25. UNFPA. How Universal is Access to Reproductive Health? A review of the evidence. New York; 2010.

26. Tubiana R, Le Chenadec J, Rouzioux C, et al. Factors associated with mother-to-child transmission of HIV-1 despite a maternal viral load <500 copies/ml at delivery: a case-control study nested in the French perinatal cohort (EPF-ANRS CO1). Clin Infect Dis. 2010 Feb 15;50(4):585-96.

27. WHO, UNAIDS. Guidance on Providers Initiated HIV Testing and Counseling in Health Facilities. Geneva; 2007.

28. Jurgens R, Cohen J, Girard F, Beyrer C. Increasing access to HIV testing and counselling while respecting human rights. HIV AIDS Policy Law Rev. 2007 Dec;12(2-3):63-6.

29. Swamy M. UN agencies issue new guidelines for HIV testing. HIV AIDS Policy Law Rev. 2007 Dec;12(2-3):39-40.

30. Kagaayi J, Makumbi F, Nakigozi G, et al. WHO HIV clinical staging or CD4 cell counts for antiretroviral therapy eligibility assessment? An evaluation in rural Rakai district, Uganda. AIDS. 2007 May 31;21(9):1208-10.

31. McGrath N, Kranzer K, Saul J, et al. Estimating the need for antiretroviral treatment and an assessment of a simplified HIV/AIDS case definition in rural Malawi. AIDS. 2007 Nov;21(Suppl 6):S105-13.

32. Miiro G, Nakubulwa S, Watera C, Munderi P, Floyd S, Grosskurth H. Evaluation of affordable screening markers to detect CD4+ T-cell counts below 200 cells/mul among HIV-1-infected Ugandan adults. Trop Med Int Health. 2010 Apr;15(4):396-404.

33. Carter RJ, Dugan K, El-Sadr WM, et al. CD4+ cell count testing more effective than HIV disease clinical staging in identifying pregnant and postpartum women eligible for antiretroviral therapy in resource-limited settings. J Acquir Immune Defic Syndr. 2010 Nov;55(3):404-10.

34. Mandala J, Torpey K, Kasonde P, et al. Prevention of mother-to-child transmission of HIV in Zambia: implementing efficacious ARV regimens in primary health centers. BMC Public Health. 2009;9:314.

35. WHO. Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants. Programatic Update. Geneva; 2012.

36. de Vincenzi I. Triple antiretroviral compared with zidovudine and single-dose nevirapine prophylaxis during pregnancy and breastfeeding for prevention of mother-to-child transmission of HIV-1 (Kesho Bora study): a randomised controlled trial. Lancet Infect Dis. 2011 Mar;11(3):171-80.

37. Kumwenda NI, Hoover DR, Mofenson LM, et al. Extended antiretroviral prophylaxis to reduce breast-milk HIV-1 transmission. N Engl J Med. 2008 Jul 10;359(2):119-29.

38. Sterne JA, May M, Costagliola D, et al. Timing of initiation of antiretroviral therapy in AIDS-free HIV-1-infected patients: a collaborative analysis of 18 HIV cohort studies. Lancet. 2009 Apr 18;373(9672):1352-63.

39. Kuhn L, Aldrovandi GM, Sinkala M, Kankasa C, Mwiya M, Thea DM. Potential impact of new WHO criteria for antiretroviral treatment for prevention of mother-to-child HIV transmission. AIDS. 2010 Jun 1;24(9):1374-7.

40. Lallemant M, Jourdain G, Le Coeur S, et al. A trial of shortened zidovudine regimens to prevent mother-to-child transmission of human immunodeficiency virus type 1. Perinatal HIV Prevention Trial (Thailand) Investigators. N Engl J Med. 2000 Oct 5;343(14):982-91.

41. Hoffman RM, Black V, Technau K, et al. Effects of highly active antiretroviral therapy duration and regimen on risk for mother-to-child transmission of HIV in Johannesburg, South Africa. J Acquir Immune Defic Syndr. 2010 May 1;54(1):35-41.

42. Tshabalala M, Manasa J, Zijenah LS, et al. Surveillance of transmitted antiretroviral drug resistance among HIV-1 infected women attending antenatal clinics in Chitungwiza, Zimbabwe. PLoS One. 2011;6(6):e21241.

43. Fogel J, Hoover DR, Sun J, et al. Analysis of nevirapine resistance in HIV-infected infants who received extended nevirapine or nevirapine/zidovudine prophylaxis. AIDS. 2011 Apr 24;25(7):911-17.

44. Coffie PA, Ekouevi DK, Chaix ML, et al. Maternal 12-month response to antiretroviral therapy following prevention of mother-to-child transmission of HIV type 1, Ivory Coast, 2003-2006. Clin Infect Dis. 2008 Feb 15;46(4):611-21.

45. Read JS. Cesarean section delivery to prevent vertical transmission of human immunodeficiency virus type 1. Associated risks and other considerations. Ann N Y Acad Sci. 2000 Nov;918:115-21.

46. Read JS, Newell MK. Efficacy and safety of cesarean delivery for prevention of mother-to-child transmission of HIV-1. Cochrane Database Syst Rev. 2005(4):CD005479.

47. Landesman SH, Kalish LA, Burns DN, et al. Obstetrical factors and the transmission of human immunodeficiency virus type 1 from mother to child. The Women and Infants Transmission Study. N Engl J Med. Jun 20 1996;334(25):1617-1623.

48. Gaillard P, Mwanyumba F, Verhofstede C, et al. Vaginal lavage with chlorhexidine during labour to reduce mother-to-child HIV transmission: clinical trial in Mombasa, Kenya. AIDS. 2001 Feb 16;15(3):389-96.

49. Alvarez JR, Bardeguez A, Iffy L, Apuzzio JJ. Preterm premature rupture of membranes in pregnancies complicated by human immunodeficiency virus infection: a single center's five-year experience. J Matern Fetal Neonatal Med. 2007 Dec;20(12):853-7.

50. Wiysonge CS, Shey MS, Shang JD, Sterne JA, Brocklehurst P. Vaginal disinfection for preventing mother-to-child transmission of HIV infection. Cochrane Database Syst Rev. 2005(4):CD003651.

51. Ahoua L, Ayikoru H, Gnauck K, et al. Evaluation of a 5-year programme to prevent mother-to-child transmission of HIV infection in Northern Uganda. J Trop Pediatr. 2009 Feb;56(1):43-52.

52. Manzi M, Zachariah R, Teck R, et al. High acceptability of voluntary counselling and HIV-testing but unacceptable loss to follow up in a prevention of mother-to-child HIV transmission programme in rural Malawi: scaling-up requires a different way of acting. Trop Med Int Health. 2005 Dec;10(12):1242-50.

53. Ginsburg AS, Hoblitzelle CW, Sripipatana TL, Wilfert CM. Provision of care following prevention of mother-to-child HIV transmission services in resource-limited settings. AIDS. 2007 Nov 30;21(18):2529-32.

54. Chinkonde JR, Sundby J, Martinson F. The prevention of mother-to-child HIV transmission programme in Lilongwe, Malawi: why do so many women drop out. Reprod Health Matters. 2009 May;17(33):143-51.

55. Moth IA, Ayayo AB, Kaseje DO. Assessment of utilisation of PMTCT services at Nyanza Provincial Hospital, Kenya. SAHARA J. 2005 Jul;2(2):244-50.

56. Kasenga F, Hurtig AK, Emmelin M. Home deliveries: implications for adherence to nevirapine in a PMTCT programme in rural Malawi. AIDS Care. 2007 May;19(5):646-52.

57. Plipat T, Naiwatanakul T, Rattanasuporn N, et al. Reduction in mother-to-child transmission of HIV in Thailand, 2001-2003: Results from population-based surveillance in six provinces. AIDS. 2007 Jan 11;21(2):145-51.

58. Geddes R, Knight S, Reid S, Giddy J, Esterhuizen T, Roberts C. Prevention of mother-to-child transmission of HIV programme: low vertical transmission in KwaZulu-Natal, South Africa. S Afr Med J. 2008 Jun;98(6):458-62.

59. Chilongozi D, Wang L, Brown L, et al. Morbidity and mortality among a cohort of human immunodeficiency virus type 1-infected and uninfected pregnant women and their infants from Malawi, Zambia, and Tanzania. Pediatr Infect Dis J. 2008 Sep;27(9):808-14.

60. Violari A, Cotton MF, Gibb DM, et al. Early antiretroviral therapy and mortality among HIV-infected infants. N Engl J Med. 2008 Nov 20;359(21):2233-44.

61. WHO. Consensus IUATLD statement on the revised world health organization recommendations regarding BCG vaccination in HIV-infected infants, Proceedings of the IUATLD BCG working Group: 38th World Union Conference; 2007 Nov 8 -12; Cape Town;2008.

62. Stringer EM, Chi BH, Chintu N, et al. Monitoring effectiveness of programmes to prevent mother-to-child HIV transmission in lower-income countries. Bull World Health Organ. 2008 Jan;86(1):57-62.

63. Rollins N, Little K, Mzolo S, Horwood C, Newell ML. Surveillance of mother-to-child transmission prevention programmes at immunization clinics: the case for universal screening. AIDS. 2007 Jun 19;21(10):1341-7.

64. Rollins NC, Becquet R, Bland RM, Coutsoudis A, Coovadia HM, Newell ML. Infant feeding, HIV transmission and mortality at 18 months: the need for appropriate choices by mothers and prioritization within programmes. AIDS. 2008 Nov 12;22(17):2349-57.

65. Kilewo C, Karlsson K, Ngarina M, et al. Prevention of mother-to-child transmission of HIV-1 through breastfeeding by treating mothers with triple antiretroviral therapy in Dar es Salaam, Tanzania: the Mitra Plus study. J Acquir Immune Defic Syndr. 2009 Nov 1;52(3):406-16.

66. Mofenson LM. Prevention of breast milk transmission of HIV: the time is now. J Acquir Immune Defic Syndr. 2009 Nov 1;52(3):305-8.

67. Bedri A, Gudetta B, Isehak A, et al. Extended-dose nevirapine to 6 weeks of age for infants to prevent HIV transmission via breastfeeding in Ethiopia, India, and Uganda: an analysis of three randomised controlled trials. Lancet. 2008 Jul 26;372(9635):300-13.

68. Shapiro RL, Hughes MD, Ogwu A, et al. Antiretroviral regimens in pregnancy and breast-feeding in Botswana. N Engl J Med. 2010 Jun 17;362(24):2282-94.

69. Chasela CS, Hudgens MG, Jamieson DJ, et al. Maternal or infant antiretroviral drugs to reduce HIV-1 transmission. N Engl J Med. 2010 Jun 17;362(24):2271-81.

70. WHO, UNAIDS, UNFPA, UNICEF. Guidelines on HIV and Infant Feeding. Principles and recommendations for infant feeding in the context of HIV and a summary of evidence. 2010.

71. Mellors JW, Munoz A, Giorgi JV, et al. Plasma viral load and CD4+ lymphocytes as prognostic markers of HIV-1 infection. Ann Intern Med. 1997 Jun 15;126(12):946-54.

72. O'Brien WA, Hartigan PM, Martin D, et al. Changes in plasma HIV-1 RNA and CD4+ lymphocyte counts and the risk of progression to AIDS. Veterans Affairs Cooperative Study Group on AIDS. N Engl J Med. 1996 Feb 15;334(7):426-31.

73. Palella, Jr FJ, Delaney KM, Moorman AC, et al. Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. HIV Outpatient Study Investigators. N Engl J Med. 1998 Mar 26;338(13):853-60.

74. Braitstein P, Brinkhof MW, Dabis F, et al. Mortality of HIV-1-infected patients in the first year of antiretroviral therapy: comparison between low-income and high-income countries. Lancet. 2006 Mar 11;367(9513):817-24.

75. Lawn SD, Myer L, Orrell C, Bekker LG, Wood R. Early mortality among adults accessing a community-based antiretroviral service in South Africa: implications for programme design. AIDS. 2005 Dec 2;19(18):2141-8.

76. Nash D, Katyal M, Brinkhof MW, et al. Long-term immunologic response to antiretroviral therapy in low-income countries: a collaborative analysis of prospective studies. AIDS. 2008 Nov 12;22(17):2291-302.

77. Sutcliffe CG, van Dijk JH, Bolton C, Persaud D, Moss WJ. Effectiveness of antiretroviral therapy among HIV-infected children in sub-Saharan Africa. Lancet Infect Dis. 2008 Aug;8(8):477-89.

78. FHI 360. Health System Strengthening: from Strategy to Action. Arlington, USA; 2011.

79. Price JE, Leslie JA, Welsh M, Binagwaho A. Integrating HIV clinical services into primary health care in Rwanda: a measure of quantitative effects. AIDS Care. 2009 May;21(5):608-14.

80. El-Sadr WM, Abrams EJ. Scale-up of HIV care and treatment: can it transform healthcare services in resource-limited settings? AIDS. 2007 Oct;21(Suppl 5):S65-70.

81. WHO, UNAIDS, UNFPA, UNICEF. Guidelines on HIV and Infant Feeding. Principles and recommendations for infant feeding in the context of HIV and a summary of evidence. Geneva; 2010.

82. WHO. Antiretroviral Therapy for HIV Infection in Infants and Children: Towards Universal Access. Recommendations for Public Health Approach. 2010 Revision. Geneva; 2010.

83. WHO, UNICEF, IATT on PMTCT. Pediatric Advocacy Toolkit: For Improved Pediatric HIV Diagnosis, Care and Treatment in High HIV Prevalence Countries and Regions. Geneva; 2011.

84. WHO. Antiretroviral Therapy for HIV Infection in Adults and Adolescents. Recommendations for Public Health Approach. 2010 Revision. Geneva; 2010.

# ANNEX 1:

# PMTCT STANDARDS

# Standards of Care (SOC) for Programs on Prevention of Mother-to-Child Transmission (PMTCT) of HIV

| STANDARD | MEASUREMENT OF STANDARD | | DATA | ASSESSMENT | | |
|---|---|---|---|---|---|---|
| | Definition | Numerator | Data Elements Needed | Result of Quarterly Measurement | | |
| | | Denominator | Data Source | Action | | |
| **1 All pregnant women should be screened for HIV and/ or offered HIV testing and counseling during ANC** | Proportion of women screened or tested and given results at ANC | # of pregnant women who are screened or tested for HIV and given results in ANC | • Date of 1st ANC visit<br>• Date of HIV testing<br>• Date HIV test results given | < 90% | 90 to 94% | ≥ 95% |
| | | # of women attending 1st ANC | PMTCT register | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **2 All pregnant women should be screened for HIV and/ or offered HIV testing and counseling during labor and delivery (L&D)** | Proportion of women screened or tested and given results at L&D | # of pregnant women who are screened or tested for HIV and given results at L&D | • Date of L&D visits<br>• Date of HIV testing<br>• Date HIV test results given | < 90% | 90 to 94% | ≥ 95% |
| | | # of women attending L&D | L&D/ PMTCT register | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **3 All HIV+ pregnant women should have CD4 count results available within 1 month before expected delivery date** | Proportion of HIV+ pregnant women with CD4 results available at the ANC/ PMTCT site | # of HIV+ women with CD4 results available at ANC/ PMTCT site | • Date of HIV-positive result<br>• Date CD4 results are on site | < 80% | 80 to 94% | ≥ 95% |
| | | # of HIV+ women registered at ANC/PMTCT site | PMTCT register & CD4 log book | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **4 All HIV+ pregnant women should receive ARV according to national guidelines** | Proportion of HIV+ pregnant women who received ARV drugs (prophylaxis or lifelong ART) according to national guidelines | # of HIV+ pregnant women who received ARV drugs (prophylaxis of lifelong ART) according to national guidelines | • HIV test results<br>• Type of ARV regimen dispensed | < 80% | 80 to 94% | ≥ 95% |
| | | # of HIV+ women registered at ANC/PMTCT site | PMTCT register & CD4 log book | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **5 All HIV+ pregnant women with CD4 ≤ 350 cells/mm³ should initiate HAART during pregnancy** | Proportion of HIV+ pregnant women with CD4 ≤ 350 initiating HAART during pregnancy | # of HIV+ pregnant women initiating HAART | • Pregnant women with CD4 test<br>• Test results of CD4 ≤ 350<br>• HAART number<br>• ARV regimen | < 80% | 80 to 94% | ≥ 95% |
| | | # of HIV+ pregnant women with CD4 ≤ 350 | PMTCT register, ART clinic register, lab CD4 logbook | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **6 All HIV+ pregnant women with CD4 ≤ 350 cells/mm³ should initiate Cotrimoxayole Preventive Therapy (CPT) according to national guidelines** | Proportion of HIV+ pregnant women with CD4 ≤ 350 initiating CPT | # of HIV+ pregnant women with CD4 ≤ 350 initiating CTX prophylaxis | • Pregnant women with CD4 test<br>• Test results of CD4 ≤ 350<br>• CPT number | < 80% | 80 to 94% | ≥ 95% |
| | | # of HIV+ pregnant women with CD4 ≤ 350 | PMTCT register, ART clinic register, lab CD4 logbook | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |

| STANDARD | MEASUREMENT OF STANDARD | | DATA | ASSESSMENT | | |
|---|---|---|---|---|---|---|
| | Definition | Numerator | Data Elements Needed | Result of Quarterly Measurement | | |
| | | Denominator | Data Source | Action | | |
| **7 All newborns to HIV+ mothers should receive ARV according to the national guidelines** | Proportion of HIV-exposed newborns who received ARV prophylaxis according to national guidelines | # of newborns to HIV+ mothers that initiated ARV according to the national guidelines | • HIV+ women that delivered<br>• Newborns to HIV+ mothers<br>• New borns with ARVs" | < 80% | 80 to 94% | ≥ 95% |
| | | # of newborns to HIV+ mothers registered at ANC/ L&D/PMTCT site | PMTCT register, L&D register and ART register | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **8 All infants born to HIV+ mothers should initiate CPT after 6-weeks postnatal according to national guidelines** | Proportion of HIV-exposed infants 6-weeks or older who are receiving CPT | # HIV-exposed infants 6-weeks or older who are receiving CPT | • HIV+ women that delivered<br>• Newborns to HIV+ mothers<br>• New borns with CPT | < 80% | 80 to 94% | ≥ 95% |
| | | # of infants, 6-weeks or older, born to HIV+ mothers registered at ANC/L&D/ PMTCT site | PMTCT register, L&D register and ART/care register | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **9 All infants/ children born to HIV+ mothers should access HIV early infant diagnosis (EID) as early as 6-weeks postnatal according to national guidelines** | Proportion of HIV-exposed infants 6-weeks or older who had blood collected for EID | # HIV-exposed infants 6-weeks or older whose blood was collected for EID | • HIV+ women that delivered<br>• Newborns to HIV+ mothers<br>• New borns with DBS collected | < 80% | 80 to 94% | ≥ 95% |
| | | # of infants, 6-weeks or older, born to HIV+ mothers registered at ANC/L&D/ PMTCT site | PMTCT register, DBS register, L&D register and ART/care register | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **10 All HIV-exposed infants/ children whose DBS was collected for PCR should receive results within 4 to 8 weeks** | Proportion of HIV-exposed infants/children whose DBS was collected for EID that received the PCR results | # HIV-exposed infants/children whose DBS was collected for EID that received the PCR results | • HIV+ women that delivered<br>• Newborns to HIV+ mothers<br>• New borns with DBS collected<br>• PCR results | < 80% | 80 to 94% | ≥ 95% |
| | | # HIV-exposed infants/ children whose DBS was collected for EID | PMTCT register, DBS register, L&D register and ART/ care register | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **11 When breastfeeding is the feeding option, all mothers or infants should receive ARVs during the breastfeeding period or according to national guidelines** | Proportion of HIV+ breastfeeding women (or HEI infants) receiving PMTCT prophylaxis during breastfeeding | # of HIV+ breastfeeding women or their HEI who receive ARV prophylaxis during breastfeeding | • Documented BF<br>• Infant age<br>• Maternal/infant post partum ARV prophylaxis | < 80% | 80 to 94% | ≥ 95% |
| | | # of HIV+ breastfeeding women | PMTCT register, L&D register and HEI follow-up register | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |
| **12 All HIV+ postpartum women with unmet need for family planning should be offered a contraceptive method** | Proportion of HIV+ postpartum women willing to delay pregancy that are using family planning methods | # HIV infected postpartum women willing to delay pregnancy that received a family planning method | • PMTCT data<br>• Postpartum visits<br>• FP screening questionnaire<br>• Family plannning method | < 80% | 80 to 94% | ≥ 95% |
| | | # HIV+ postpartum women willing to delay pregnancy | PMTCT register, L&D register , postpartum register, and ART register | Investigate why | Confirm trend at next period | On target! Any lesson to learn from? |

**CONSIDERATIONS**

These standards are an attempt to translate the goals of MTCT elimination into operational targets

They are generic and will need country adaptation and fine-tuning

They do not necessarily capture every single step of the PMTCT cascade; the 12 proposed standards are supposed to gauge the level of performance of PMTCT

Standards proposed do not necessarily gauge the coverage of PMTCT at the population level; clients not accessing PMTCT are not part of the proposed denominators

These standards can be assessed monthly or quarterly as it fits specific context; investigating the reason for low performance or outlining lessons might take several weeks

Some standards like EID or FP might be challenging to measure and might require special investigations

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