

## Chapter 9C-2: Safe Motherhood and Prevention of Vertical Transmission: Antenatal Care – Treatment

Antiretroviral treatment (ART) for women living with HIV is vital to ensuring safe motherhood and reducing vertical transmission. But not all pregnant women access treatment. For women in high-income countries where access to triple therapy during pregnancy has been the standard of care and is near universal, rates of vertical HIV transmission are as low as 0.4%, for example, in Canada (Forbes et al., 2012) and 0.46% in Ireland and the UK (Townsend et al., 2014). While access to treatment in low- and middle-income countries has increased steadily since 2000, it has been hampered by availability of medications and standardized treatment eligibility criteria that traditionally prioritized prevention of HIV transmission to the infant over treatment for the health of the woman. Each year, as many as 42,000 women living with HIV die of HIV and pregnancy-related complications (Glass and Birx, 2016). However, significant progress has been made, with 93% of pregnant women in 22 priority countries who have accessed combination ART (or cART, formerly called HAART). In fact, though short of the 90% goal, a 60% reduction in new infections among infants was achieved in 2015 (UNAIDS, 2016).

### ***Treatment Guidance Has Changed Dramatically***

WHO's September 2015 guidance states that "ART should be initiated in all pregnant and breastfeeding women living with HIV at any CD4 cell count and continued lifelong," (WHO, 2015f: 13), a treatment regimen also known as Option B+. WHO's 2015 guidance also states that the preceding Option B guidance\* "is no longer relevant" (WHO, 2015f: 32), due to the results of the Insight START study which showed that

immediate initiation of cART resulted in a 53% reduction in serious illness or death compared to waiting to initiate treatment until CD4 counts decreased to below 350 per cubic millimeter (INSIGHT START Study Group, 2015). While pregnant women were not included in the study, this study's strong findings informed the WHO, September 2015 guidelines. In Malawi, where Option B+ was pioneered by Malawi's Ministry of Health in 2011, recent data shows vertical

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*This section does not provide medical or clinical guidance, which is available from WHO, but rather a public health perspective on what works for women in access and adherence to ART in the context of antenatal care.*

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\*Option B, WHO's guidance in 2013, stated that for all HIV-infected pregnant women who are not eligible for ART, ARV prophylaxis option B consists of triple ARV drugs provided to pregnant women starting from as early as 14 weeks of gestation until one week after all exposure to breast milk has ended (WHO, 2013).

transmission among women starting ART in the first or second trimester was 4.1% compared to 13.3% among those starting treatment postpartum. In addition, among the 46.5% of women on ART prior to pregnancy, mother-to-child transmission was 1.4% compared to 20.3% among the 5.8% of women living with HIV who had never started ART (Tippett Barr et al., 2016).

Global inequality may be reduced now that there is global agreement on when to start treatment. However, not all women will benefit immediately. The reality is that, in 2015, fewer than one out of 10 people living with HIV live in a country where ART upon HIV diagnosis is current policy or practice (Health Gap, 2015).

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*“The clinic ‘encouraged me that I will have a baby just like anyone else... I feel very happy...’”*  
*-Zambian woman (Haerizadeh et al., 2014: 23)*

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This landscape is rapidly changing, however, as Country Operational Plans supported by PEPFAR will now require adoption of ‘Test and Start’ as of 2016 (PEPFAR, 2015). Many countries have struggled to keep up with changing treatment guidelines. For example, in 2012, Malawi phased out single dose Nevirapine as the standard of care (Government of Malawi, 2013 cited in van Lettow et al., 2014), despite the fact that it was no longer recommended by WHO as of 2006 (Paredes et al., 2013). “With each change, Lower and Middle Income Countries (LMICs) attempt, with the best intentions, to harmonize their guidelines with global recommendations.” (Kellerman et al., 2013: S226). However, rapidly changing protocols often “outpaced the ability of the health system to appropriately adapt” (Colvin, 2014: p. 9), with weak systems to disseminate and implement new guidance.

Even if policies were to keep up with the latest guidelines, treatment access may still be limited. If countries adopt the 90/90/90 target goals (where by 2020, 90% of people living with HIV know their status; 90% of all people diagnosed with HIV receive sustained ART, and 90% of all people receiving ART will have viral suppression (UNAIDS, 2014b)), 30.4 million adults and 1.68 million children would receive ART by 2020. This would cost US\$45.8 billion, with a funding gap for ART commodities alone ranging from \$14 billion to \$16.8 billion (Dutta et al., 2015). While modeling studies suggest that Option B+ is cost effective compared to other cART regimens (Karnon & Orji, 2016), “...ART rationing is a current front-line reality in many locations” (Wall et al., 2016: para 25). Donors, country governments, implementing partners, and communities will need to work together to develop cost efficient strategies to expand treatment for all.

### ***Antiretroviral Medications are Beneficial, But Drug Resistance Remains a Concern for Women Living with HIV***

Concerns about taking cART during pregnancy are outweighed by the benefits. Some studies (Mofenson, 2015 cited in Luzuriaga and Mofenson, 2015) in addition to U.S. guidelines note the potential increased risk of preterm delivery with cART, but “given the clear benefits for maternal health and reduction in perinatal transmission,” cART should be used (USHHS, C-12). Studies

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have shown that for women living with HIV who access ART prior to pregnancy or very early in pregnancy, their fetuses/infants have no differences in rates of birth defects with first trimester use of ART compared with ART initiation later in pregnancy (USHHS, 2015: c-6).

2015 WHO guidelines also note that pre-exposure prophylaxis (PrEP) may be used during pregnancy (WHO, 2015g) and that no increase occurred in adverse pregnancy related events among women taking PrEP in early pregnancy. A study of 431 pregnant women on pre-exposure prophylaxis in Kenya and Uganda found no statistically significant differences in pregnancy incidence, birth outcomes and infant growth compared to a placebo (Mugo et al., 2014). Since HIV acquisition in pregnancy continues to be an issue globally, PrEP may be an additional HIV prevention tool to be used by women during pregnancy. A recent modeling study found that providing PrEP is “likely cost-effective, although more data are needed about adherence and safety” (Price et al., 2016: S145). Other interventions to increase safer conception include suppressed viral load in the partner, screening and treatment for STIs, limiting unprotected sex to times of peak fertility, knowledge for both men and women of when is a woman’s peak fertility, and voluntary medical male circumcision (Matthews et al., 2012; Ngure et al., 2014; Mmeje et al., 2015). [See also *Pre-Conception*]

For those living with HIV, starting lifelong treatment is a commitment with serious health implications. Initiating treatment and then stopping may lead to development of drug resistance, with worse health outcomes (Psaros et al., 2015), particularly if a woman initiates treatment with CD4 counts under 350 (Paredes et al., 2013). [See also *Treatment*] Since Option B+ calls for lifelong treatment, women living with HIV are at lesser risk of developing drug resistance, unless they stop and start the recommended treatment, are non-adherent, face drug stockouts, receive inappropriate regimens, etc.. Some women may face worse outcomes on cART due to earlier WHO-recommended regimens during previous pregnancies. Single dose Nevirapine, which was the mainstay of prevention of vertical transmission programs prior to 2006, was found to increase the risk of developing resistance once a woman accessed treatment, particularly if she accessed treatment within three years (Paredes et al., 2013). Some studies have found that low numbers of women who started cART and then stopped postpartum had resistance (Palombi et al., 2015); other studies found that 2013 WHO guidance of Option B (where women started and stopped triple therapy – see footnote) may be particularly prejudicial for their health (Giuliano et al., 2013). Results are still awaited from the PROMISE study which should assess the impact on women living with HIV on stopping and starting different ART regimens during pregnancy on their long term survival (NIAID, 2012 cited in Sawe and Lockman, 2013). It is important to note that stock-outs of drugs may also affect resistance if women are unable to access treatment for intermittent and sustained

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*“Before I start on Option B+, I should be informed of all options and all of the advantages... so that I make informed decisions based on the benefits that are there” -Ugandan woman living with HIV (Matheson et al., 2015: p. 2)*

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lengths of time (Paredes et al., 2013). [See also *Treatment*] Overall, it is difficult to know to what degree drug resistance is a problem in the Global South. Resistance is better monitored with viral load testing than with CD4 count, but this testing is expensive and is not yet rolled out in many low- and middle-income countries despite WHO recommendations published in 2013 to switch from CD4 to viral load monitoring.

***All Women Living with HIV Need Timely Access to ART, Ideally Prior to Pregnancy***

Between 2009 and 2014, there were a total of 3.8 million newly infected women of reproductive age (UNAIDS, 2015: 9). Data show that cART initiation prior to pregnancy is most likely to reduce vertical transmission; and the earlier initiated in pregnancy, the more likely cART will reduce vertical transmission (Del Bianco et al., 2014 cited in Gouvea et al., 2015). But the likelihood of vertical transmission is dramatically reduced if a pregnant woman living with HIV is initiated and adherent for at least several months.

Adolescent girls are especially important in antenatal care treatment programming because of their increased vulnerability. A study in South Africa with 1,099 HIV-negative women followed for two years found that girls under age 15 who became pregnant were three times more likely than older pregnant women to acquire HIV, particularly if they had suffered from sexual abuse (Christofides et al., 2014). Adolescent girls experience high rates of HIV acquisition and young women living with HIV may benefit the most from timely access to HIV testing and cART prior to their first pregnancy. [See also *Prevention and Services for Adolescents and Young People*]

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*“ART has helped to keep me alive and educate my children. I also hope that my child on ART will be healthy and grow” -Pregnant woman living with HIV in Uganda (UNAIDS, 2014c: 10).*

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Women who are part of key populations, such as women who use drugs and women who are sex workers, also need intensified programming to ensure ART access. “Motherhood is common among female sex workers,” yet sex workers fear health services or avoid services, due to stigma and discrimination (Papworth et al, 2015; S154). In low- and middle-income countries, sex workers are 12 times more likely to be living with HIV, yet have low access to cART (Baral et al., 2012a). A cross-sectional study of 500 women in Russia noted that pregnancy may be associated with increased motivation to discontinue drug use and sex work (Girchenko et al., 2015). Sex workers in Cote d’Ivoire, have high rates of HIV and pregnancy, making them particularly vulnerable to high rates of mortality, morbidity and vertical transmission. Among 466 sex workers, 88.6% reported at least one previous pregnancy and 10.7% were living with HIV (Schwartz et al., 2015a). Yet much of the attention on sex workers in Cote d’Ivoire is focused on HIV prevention efforts, rather than their treatment needs (Schwartz et al., 2015a). [See also *Female Sex Workers*]

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All women who plan to become pregnant would benefit from pre-conception care [See *Pre-Conception*], but these services are not widespread. Further research is needed to define where it is most optimal for newly diagnosed women living with HIV to access cART. While accessing cART within antenatal care is important, loss to follow up may be higher among women who first access cART within antenatal care but then face challenges transitioning to cART in other settings. In addition, the needs of pregnant women may not be met by access to cART outside of antenatal care (Parker et al., 2015; Minnear et al., 2014; Tenthani et al., 2014; Suthar et al., 2013). How to structure health services so that women's needs are met [See *Structuring Health Services to Meet Women's Needs*] remains an ongoing challenge.

### ***Women's Lives Are as Important as Their Children's***

Globally, “much of the emphasis on women within the epidemic has been on their role as mothers. Pregnancy – actual or anticipated – has been a critical driver for the diagnosis, treatment and care of women with HIV. Protection of the fetus, either from vertically acquired HIV infection or from the potential harm of antiretroviral medication, has taken center stage” (Anderson, 2012: 59). Focus group discussions among women living with HIV in Malawi found that Option B+ is presented to women as a program primarily to protect the baby, with their health unimportant (Hsieh, 2013).

Maternal HIV status and health is key to survival for infants and children in the post-neonatal period. A recent study in Malawi found that the mother's HIV-positive status correlated with more than one-third of deaths of children up to age four. Children whose mothers died were at greater risk of dying than those whose mothers were alive (Chihana et al., 2015). In addition, children prenatally exposed to HIV who do not seroconvert are also at an increased risk of death, likely due to decreased transfer of antibodies or other protective immune factors. Viral suppression from longer ART use may reduce that risk but further investigation is needed (Watts, 2016). Launched in 2011, the Global Plan Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive aimed to eliminate new HIV infections among children by 2015 and keep their mothers alive. The Global Plan focused on the 22 countries with the highest estimated numbers of pregnant women living with HIV. This Global Plan was a landmark for specifically focusing on the health of mothers, rather than just on the infants, with a goal of reducing the number of HIV-related maternal deaths by 50%. But the Global Plan has also been criticized for both a narrow focus on prenatal HIV prevention, rather than affirming the health, autonomy and rights of women living with HIV, as well as failing to protect fundamental human rights of women living with HIV to voluntary, confidential uptake of ART with informed consent (Welbourn, 2014; Chitembo et al., 2012).

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*“Policymakers and clinicians have tended to ignore women and children outside PMTCT settings”*  
(Prendergast et al., 2015: s49)

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In 2016, PEPFAR Technical Considerations for Country Operating Plans state “the message for pregnant women must change immediately to “lifelong treatment will save your life and being on treatment early improves your chances of survival as well as prevents infection of your baby during pregnancy and throughout breastfeeding” (PEPFAR, 2016: 28). A global review, funded by the Gates Foundation, conducted by scientists at WHO and elsewhere, found that what matters to pregnant women globally is achieving maternal self-esteem, competence and autonomy, as well as preventing and treating illness and death (Downe et al., 2015) – and pregnant women living with HIV are no different in this regard. Community and civil society input (Shaffer et al., 2013), along with input of women living with HIV, is needed on how best to support newly diagnosed pregnant women living with HIV.

Few countries have comprehensive registers that follow the mother-infant pair after delivery to measure longer-term cART adherence (UNAIDS, 2015). In order to adequately assess if mothers are adhering well and are being kept alive, national governments should continue to track:

- What % of pregnant women living with HIV access ANC and cART (Dourado et al., 2014; Hlarlathie et al., 2014);
- What % of pregnant women living with HIV are virally suppressed with cART;
- What % of women living with HIV who remain virally suppressed with cART by number of years postpartum.

### ***Women Need Information, Support and Respect in Decision-Making About Antiretroviral Therapy***

While WHO does not specify how quickly a pregnant woman should initiate cART upon an HIV-positive diagnosis, countries that are implementing Option B+ are interpreting the guidance to mean immediately. Yet initiating treatment upon diagnosis may be too challenging for some pregnant women. Women in South Africa noted that they faced a triple burden of transitioning into pregnancy, accepting a new

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*“I was really in favour of early treatment and to have this Option B+. But now my worry is: are we being given this as an option or is this being pushed on us with no option?” -Woman living with HIV in Zimbabwe (ATHENA et al., 2015: 3).*

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HIV-positive serostatus and recognizing the need to start lifelong ART as soon as possible (Stinson and Myer, 2012). Notably, the INSIGHT START Study Group cautioned, “Patients may wish to consider and differently weigh multiple factors when making the decision to initiate lifelong anti-retroviral therapy” (The INSIGHT START Study Group, 2015: 804). And US 2015 guidance notes: “The decision about when to initiate ART should be carefully considered by health providers and their patients...women’s choices after counseling to use or not use ARV drugs during pregnancy should be respected” (USHHS, 2015: c-26 and c-27).

Women living with HIV may choose to delay treatment for a variety of reasons despite the benefit of continuous ART for their health (Phillips et al., 2014; Kieffer et al., 2014), but will

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still need to be provided with ongoing monitoring and support. In a qualitative study in South Africa, the majority of women emphasized that accepting lifelong ART treatment was more difficult than accepting their positive HIV status. "...women may be insufficiently able ...to accept the full consequences of a positive HIV test and the need to start lifelong ART all at once" (van Lettow et al., 2014: p. 7). Scientists have recognized that when women decline to initiate ART, "no one should ever be pressured to initiate treatment..." (Kellerman et al., 2013: p. 5).

Insufficient counseling or respect for women's decision-making time can drive women away from accessing treatment. A recent study in Ethiopia found that a key factor associated with loss to follow up on Option B+ was starting treatment on the same day as diagnosis: 28.1% of 418 pregnant women started on cART received cART only once and never returned to the health facility (Mitiku et al., 2016). However, in a different pilot program with intensive counseling, pregnant women living with HIV were willing to initiate within one to four days, with 97% of 100 women initiating ART prior to delivery (Myer et al., 2012). Common barriers to ART initiation included concern about side effects and the practicalities of ART, fear of stigma, partner abandonment and abuse after disclosing their status, and perceived lack of support from families and partners, and laws and policies that criminalize HIV. For example, in Uganda, it is mandatory for pregnant women to be tested for HIV, If she does not disclose her positive serostatus and/or practice safe sex with her male partner, she can be both fined and imprisoned for up to five years. Her male partner, however, is exempt from HIV testing if he so chooses (Republic of Uganda, 2014).

In interviews with women living with HIV in Malawi and Uganda, women warned "starting patients on treatment before they feel ready would not be conducive to adherence, retention or good health" (Matheson et al., 2015: p. 3). Women in Malawi and Uganda felt that Option B+ was a misnomer, that it is not an individual option but a government mandate that is potentially coercive.

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*"I think the (doctor) did not want me to become pregnant but it is my right to do so" -Pregnant women living with HIV in Thailand (Liamputtong and Haritaborn, 2014: 1169).*

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"Young women spoke of being pressured to start treatment before they were ready," negatively affecting their adherence (Hsieh, 2013: 25). Women reported wanting more counseling to make the momentous decision to start lifelong ART (Hsieh, 2013). Women were told by providers that they needed to start lifelong treatment the same day they tested HIV-positive, though some providers provided women with the chance to think about it overnight (Hsieh, 2013). Yet "rights to privacy and bodily integrity still require that people living with HIV control their own medical decisions...communities have no right to coerce people living with HIV into treatment" (Kavanagh et al., 2015: 83).

All women, and particularly women living with HIV, need accurate information about their pregnancies and their rights. They should know that they have the right to bear children and that

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pregnancy does not accelerate HIV disease progression (Westreich et al., 2013 cited in Kendall and Danel, 2014). Sterilization must never be presented to women living with HIV as an option to prevent vertical transmission. A community based research project from Mexico, Nicaragua, El Salvador and Honduras found that of 285 women living with HIV, 23% experienced pressure to sterilize post-diagnosis (Kendall and Albert, 2015). The People Living with HIV Stigma Index found high rates of stigma and discrimination in Uganda, but this was not disaggregated by pregnancy status. However, 365 of the sample (30%) reported that they were advised to not have children after being diagnosed as HIV-positive and 121 (11%) reported to have been forced to undergo sterilization because of their HIV-positive serostatus (Uganda AIDS Commission & UNAIDS, 2013). Such practices impede women from accessing health facilities to seek services and are gross human rights violations.

The large majority of women globally will want to initiate cART during pregnancy, both for their own health and to prevent vertical transmission. However, for those women who only learn their HIV-positive serostatus in labor or who fear that initiating cART will subject them to violence (see below), infant prophylaxis immediately postpartum can reduce the risk of vertical transmission. Infant prophylaxis is the standard of care, according to WHO guidance, even if a woman is virally suppressed on cART. Provision of ART prophylaxis to infants will not prevent infants from acquiring HIV prior to labor and delivery, though. A study of 1,684 infants enrolled in a randomized controlled trial from Brazil, South Africa, Argentina and the US found that duo or triple therapy was more effective at preventing vertical transmission than monotherapy for formula feeding infants whose mothers had not received ART before labor. “Although our study identified improved prophylactic alternatives for infants born to late-presenting HIV-infected mothers, the present approach does not substitute for the prevention and early identification of HIV-1 infection in women, with prompt initiation of ART during pregnancy” (Nielsen-Saines et al., 2012: 2375). Infant prophylaxis should continue throughout breastfeeding if the mother is not on ART.

### ***Fear of Disclosure, Violence Can Influence Treatment Initiation and Adherence***

Pregnant women living with HIV still remain highly stigmatized in many countries. While “disclosure of one’s HIV status can help to improve uptake and retention in prevention of mother-to-child transmission of HIV services...” (Tam et al., 2015: 436), some women are reluctant to disclose, particularly to their sexual partners (Croce-Galis et al., 2015). As one woman living with HIV, diagnosed during pregnancy, put it: “...I won’t tell him, because I need him, because he helps me with money. I can’t lose him now because I can’t manage to have this baby if he doesn’t support me” (Sewnunam and Modiba, 2015: 63). In some cases, disclosure may place a pregnant woman at risk. For example, pregnant women in Zimbabwe have faced violence for testing without their partner’s consent (Shamu et al., 2014).

A systematic review of factors influencing initiation, adherence and retention on ART while pregnant or postpartum found that a significant barrier was “fear of domestic violence after

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disclosure” (Hodgson et al., 2014: Table 3). Another systematic review and meta-analysis of intimate partner violence (IPV) and engagement in HIV care and treatment among women found that IPV was associated with lower ART use, half the odds of self-reported ART adherence and significantly worsened viral suppression among women (Hatcher et al., 2015). Staying on ART is challenging, as some women find it difficult to take home ART medications for fear that their partners find it (Mugasha et al., 2014). A recent study of 1,951 pregnant women in Zimbabwe who disclosed their HIV status found that 32.8% reported interpersonal violence and abuse sometime between disclosure and delivery. The study found that male control of women’s sexual decision-making was associated with interpersonal violence during pregnancy and with unequal gender power (Shamu et al., 2014; Shamu et al., 2012 cited in Shamu et al., 2014).

Disclosure interventions must “protect women’s rights, autonomy and safety” (Spangler et al., 2014: S235). “...In the absence of specific interventions to respond to violence or promote safety, women who are at risk of violence may be better off being supported in a decision not to disclose their status” (Kennedy et al., 2015: p. 7). Little evaluated work exists on disclosure by pregnant women to other family members besides sexual partners and how this could increase support for women (Busza et al., 2012). [See also *Strengthening the Enabling Environment: Addressing Violence Against Women*]

Gender-based violence has other harmful effects for safe motherhood for women living with HIV. A recent analysis found significantly higher odds of unintended pregnancies among women who faced intimate partner violence (Pallitto et al., 2013). Experience of intimate partner violence decreased the odds of skilled birth attendance in Kenya (Goo and Harlow, 2012) and, in a recent systematic and meta-analysis, was associated with a significant decrease in condom use (Maxwell et al., 2015). This presents particular challenges for pregnant women who want to remain HIV-negative as HIV acquisition by women during pregnancy greatly increases the risk of vertical transmission since acute infection leads to high viral loads prior to testing HIV-positive (Nesheim et al., 2013; Dinh et al., 2015). [See *Treatment*]

### ***Addressing Gender Norms and Supporting Women May be Key to Eliminating Vertical Transmission***

Women may face other gender related barriers to accessing health services (Croce-Galis et al., 2015), as one woman noted in Cote d’Ivoire, who said that her husband would not give her the funds to get transport to services (Schechter et al., 2014). Another study in Tanzania among postpartum women living with HIV who were not adherent noted “many were entirely dependent on their partner for financial support and with minimal negotiation power” (Ngarina et al., 2013: p. 5). A barrier to initiation, adherence and retention on ART for pregnant women living with HIV is that she may be required to ask permission to access services (Hodgson et al., 2014; Hlarlathie et al., 2014). According to recent modeling, Option B+ is more effective in reducing heterosexual transmission (Khanna et al., 2015) but women living with HIV have stated that they

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feel burdened that they are the ones on treatment and who have to remain adherent, as opposed to their male partners. [See also *Strengthening the Enabling Environment*]

Key to gender transformative programming in Safe Motherhood and Prevention of Vertical Transmission is for women's lives to be valued – not just to keep babies healthy. One qualitative study on why women do not remain adherent postpartum in South Africa found that women believed that their own health was less important and that once they accomplished having a healthy HIV-negative baby, their own health postpartum did not matter (Clouse et al., 2014). As one woman put it: “When they see that their babies are well, they don't see a need to come to the clinic anymore” (Clouse et al., 2014: e14). Another woman stated: “Most of the pregnant women take their medication only to prevent passing on the virus to the baby and do not care about their health” (Clouse et al., 2014: e14). A study from Tanzania found that women who had detectable viral load at 24 months postnatally did not acknowledge lack of adherence until confronted with the information on their viral load. Once they acknowledged that they had not been adherent, they expressed that once they had an HIV-negative child, they were ready to die – “Not that I forgot to take them. I thought it was okay if I died...After I stopped breastfeeding that is when I lost hope completely” (Ngarina et al., 2013: p. 4). A qualitative study of pregnant women living with HIV in South Africa also found that the primary motivation for initiating cART in pregnancy was the well being of their child, and women may be more adherent to cART if they understand how a healthy mother is key to a healthy child (Black et al., 2014). Women may also need additional psychological and peer support. [See also *Adherence and Support* and *Care and Support*]

Community-based support programs for pregnant women living with HIV can be helpful. A recent study of implementation of community-based adherence clubs for stable ART patients, which provided ART to 2,133 patients, 71% female, with a strong emphasis on peer-based support and patient self management, found that one year later, only 6% of patients were lost to follow up and fewer than 2% of patients experienced viral load rebound (Grimsrud et al., 2015). How to link pregnant women postpartum to such community-based interventions remains a challenge (Onono et al., 2015). A recent review of maternal health globally found that community women's groups can have important effects on reducing mortality and morbidity (Prost et al., 2013 cited in Downe et al., 2015; Marcos et al., 2012). Community-based interventions for pregnant women living with HIV outside of the health facility have generally not been part of national scale up efforts (Ezeanolue et al., 2016). A randomized controlled trial is underway to assess whether clinic or community-based peer support programs improve health outcomes (Rosenberg et al., 2014). [See also *Pre-Conception* and *Care and Support*]

### ***Additional Efforts are Needed to Better Engage Men in Supporting Safe Motherhood and Prevention of Vertical Transmission***

Little work has been done to explain vertical transmission to male partners and how men can support pregnant partners living with HIV (Auvinen et al., 2014b). While in some studies,

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PMTCT uptake is associated with male support, other studies have found that women without any partner involvement were more likely to complete the PMTCT cascade (Kim et al., 2012). PEPFAR’s Gender Strategy notes the importance of not “penalizing women who are not accompanied by men” (PEPFAR, 2013: 14). Interviews with male partners of pregnant women living with HIV in South Africa found that men felt responsible for their children, but that long clinic lines and the view that clinics for maternal health care are women-only spaces reduced the likelihood that men will access services through antenatal care (Koo et al., 2013a). However, many younger fathers admitted that they had felt unprepared for the responsibilities of fatherhood and would have been enthusiastic about receiving information about fatherhood, with HIV as a part of this (Koo et al., 2013a). A card inviting men to be a great partner, love their partner, love their baby and love themselves was seen as the most welcoming of several potential invitations (Koo et al., 2013b). Remarkably little is known about couples and their relationships in the context of HIV and how to improve couple communication around sensitive topics around risk, sex and transmission (Ramirez-Ferrero and Lusti-Narasimhan, 2012).

More nuanced efforts are needed to engage men in prevention of vertical transmission. Mandating men to attend antenatal care may be counterproductive and prejudice women without partners. Preparing men and women to be parents and have healthy educated children, is key to the well being of future generations. “Sometimes the labor pain may begin when you are with your spouse and you tell him to accompany you to the hospital since you can’t walk on foot. He will respond that he is busy and moreover he doesn’t have money to take you to the hospital” (Mason et al., 2015: p. 5). Yet many men in another qualitative study noted that while they are excluded from maternal health services, they felt a sense of duty to care for their pregnant wives – but providers did not approach men who waited for their wives during ANC or childbirth (Villar-Loubet et al., 2013).

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*“Because we are seeing Option B+ they are giving the medicine to only a woman who is pregnant. Men will say “It’s me who made that woman pregnant. Why am I not started on treatment too?” -Woman living with HIV in Uganda or Malawi (Hsieh., 2013).*

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Men are important to both maternal and child health, yet men are unlikely to attend the birth of their child – and are relegated to remain outside the room where a woman gives birth or even to the parking lot of the health facility – despite women’s wishes for support from their male partner during childbirth and delivery (Levtov et al., 2015). While cultural beliefs or fear of violence may lead women to want to exclude men from delivery and childbirth, it is often the health facility – and the infrastructure of the health facility – that makes men unwelcome at the birth of their child.

In a qualitative study of married men in Uganda, men noted that they would not disclose an HIV-positive serostatus to their pregnant wives, fearing abandonment also: “I can’t tell her, she will

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run away and leave me with the children” (Duff et al., 2012:230). Women living with HIV may fear disclosing to a partner if he cannot access treatment also. But in some countries the increased access by pregnant women to cART may prejudice access by men. A recent abstract at the 2016 Conference on Retroviruses and Opportunistic Infections (CROI) found that Option B+ has widened the gap between male and female cART coverage in Malawi (Jahn, 2016b). A review of gender inequality through male involvement in maternal health found 13 studies which showed that men were viewed mostly as gatekeepers for women’s health and used men to facilitate health seeking behavior by female partners; as instruments rather than people with their own needs in terms of the birth of their child (Comrie-Thomson et al., 2015). Wide adoption of ‘Test and Start’ policies could improve availability of treatment for men.

### ***Progress Has Been Made in Improving Maternal Health But More Is Needed***

Significant progress in maternal health has been made globally: maternal deaths have been reduced from 376,000 in 1990 to an estimated 292,982 maternal deaths in 2013 (Kassebaum et al., 2014). A significant increase has also been seen in the number of women with skilled birth attendants from 56% in 1990 to 74% in 2015 (van den Broek, 2016) - another key marker of maternal health. But though progress on maternal health has been achieved, only 16 countries (seven of which were developing countries) met the Millennium Development Goal related to reducing maternal mortality (Kassebaum et al., 2014), which was to reduce maternal mortality by three quarters by 2015. Instead, maternal mortality was reduced by 44% (WHO, 2015).

Perinatal care is critically important to maternal health, yet almost 40% of pregnant women do not have the recommended four antenatal visits and 27% of pregnant women did not have skilled attendants at birth in 2013 (WHO, 2015; Kearns et al., 2015). Women are more likely to initiate treatment when they have access to maternal health care facilities and services. For example, a study of 220 women living with HIV in Ethiopia found that mothers who delivered at a health facility, compared to delivering at home, were 18 times more likely to receive services for safe motherhood and prevention of vertical transmission (Lerebo et al., 2014). Similarly, in Kenya, of 247 women living with HIV who delivered in the last year and participated in a community-based survey, those women with more ANC visits were more likely to access cART (Kohler et al., 2014). Antenatal care in pregnancy can also be protective against STIs, particularly with lab-based screening and treatment (Adachi et al., 2015). This is vital given that STIs, such as syphilis, may increase the risks of vertical transmission, as well as negatively impact the health of the mother and her sexual partner(s). [See also *Preventing, Detecting and Treating Critical Co-Infections*]

Once women give birth, postnatal care is often lacking: based on data in 17 resource-poor countries, only an estimated 40% of mothers receive postnatal care within 48 hours (Darmstadt et al., 2014). In addition, 2.2 million women in low- and middle-income countries between 2005 and 2015 gave birth alone, including in some countries with significant numbers of pregnant women living with HIV, such as Nigeria, India, Ethiopia, Uganda and Kenya. Those pregnant

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women who are poorest and with the most need are the least likely to access skilled attendance at birth (WHO, 2015f) and therefore will not have had any interventions related to safe motherhood for women living with HIV (Orobaton et al., 2016). Women and their families need information on why antenatal care is important for maternal and child health and what they can expect to receive as part of antenatal care, without high costs as a barrier or long waits to access care (Mason et al., 2015).

The true numbers of pregnant women living with HIV are likely underestimated, as “...empirical data about how the HIV epidemic has affected maternal mortality in Africa are few...” (Myer, 2013: 1700). Separate funding silos for maternal health from HIV programs may hinder needed collaboration in preventing maternal deaths, including from HIV. Importantly, the Global Fund supports funding synergistic maternal/newborn/child health (MNCH) interventions that impact HIV (Hope et al., 2014). But structures to monitor and evaluate maternal health remain separate from HIV (Hope et al., 2014). Pregnant women living with HIV will need to access care outside of maternal health services after the postpartum period. Key questions to address are: How are women transferred in and out of adult ART services before and after pregnancy? What support is needed for women who are not ready to initiate ART? What will support women to remain adherent, during pregnancy, postpartum and for the remainder of their lives? (Colvin et al., 2014).

### ***It IS Possible to Eliminate Vertical Transmission***

Between 2009 and 2015, there has been a 46% decline in the number of AIDS-related deaths among women of reproductive age in the 21 priority countries (UNAIDS, 2016), a remarkable achievement.

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*“Eliminating mother-to-child HIV transmission (MTCT) is now considered a realistic public health goal for resource limited settings”*  
(Woldesenbet et al., 2015: para 1)

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Some countries have achieved the global criteria for the elimination of vertical transmission or rates of transmission similar to resource-rich countries. An evaluation in South Africa found that at infant immunization clinics, the rates of transmission at six weeks postpartum was 3.5% (Goga et al., 2015). In June 2015, Cuba became the first country to be validated as having met the global criteria for eliminating vertical transmission as a public health problem, that is, in 2014, fewer than 50 new infections in 100,000 live births; a rate of under 5% in breastfeeding women and less than 2% among women who do not breastfeed (WHO, 2015a, cited in UNAIDS, 2015; Gulland, 2015). Even where countries have not met the criteria for elimination of vertical transmission, many countries have made large strides: for example, in Botswana, the percentage of infants who are born to women living with HIV declined from 21% in 2003 to a transmission rate of 2.6% in 2015 (UNAIDS, 2016).

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This progress demonstrates that with sustained resources and attention, it will be possible to eliminate vertical transmission.

*The following interventions and gaps are drawn from a review of the literature and ranked by strength of evidence. [See Methodology]*

### **9C-2. What Works—Safe Motherhood and Prevention of Vertical Transmission: Antenatal Care – Treatment**

1. Initiating cART as early as possible to achieve low viral load is optimal, improves maternal health, and reduces risk of vertical transmission.
2. Peer counseling by mother mentors may improve treatment adherence among pregnant women living with HIV.
3. Community health workers and community-based support can increase uptake of safe motherhood interventions for women living with HIV and reduce vertical transmission.
4. PMTCT-Plus (family-focused) HIV care can increase the numbers of women and their partners who access treatment and remain adherent.
5. Integrating ARV therapy into antenatal care, rather than referring women separately for HIV treatment, can reduce time to treatment and increase adherence for pregnant women living with HIV.
6. National scale-up of cART in pregnancy improves maternal and infant outcomes.

### **9C-2. Evidence**

1. **Initiating cART as early as possible to achieve low viral load is optimal, improves maternal health, and reduces risk of vertical transmission.** [See also *Pre-Conception*] Note: Risk of vertical transmission rises after 28 weeks of pregnancy (7 months), so initiating ART at least by month 6 of pregnancy reduces risk (Luzuriaga and Mofenson, 2016).

- A sub-study of 217 HIV-positive, pregnant women from the PACOME study, a randomized, non-blinded clinical trial conducted from December 2009-December 2011 in **Benin**, found that ART should be initiated prior to the start of the last trimester of pregnancy in order for a woman to achieve undetectable plasma viral load before delivery. “The longer the ART was taken, the higher the probability to achieve virologic suppression at the end of pregnancy” (para. 32). In order to be included in the study sample, women had to be living with HIV and between 16-28 weeks gestation. The observation period extended from 7 months prior to 1 year after the implementation of the new Beninese recommendations in June 2010, which changed the recommendation of starting ART from 28 weeks to 14 weeks of pregnancy. Plasma viral load was assessed twice in each woman: once at enrollment and once in late pregnancy. Self-reported adherence to ART was collected at each of 3 antenatal care visits. The primary outcome of interest was third trimester viral load, which was used as a proxy to measure efficacy and categorized as detectable (>40 copies/mL) versus undetectable (≤40

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copies/mL). Most women were at an advanced stage of HIV. At the time of delivery, 71% of women had an undetectable viral load. The probability of having an undetectable viral load was more than 4-fold increased if the treatment lasted for 8 weeks or more. Three infants had a positive PCR result, and the mothers of these three infants all had viral load over 30,000 copies/mL, i.e. this showed poor health for the mothers and they were more likely to transmit HIV. Women enrolled after June 2010 were more likely to achieve virologic suppression than those enrolled prior to June 2010, which shows that starting ART at 14 weeks as opposed to 28 weeks is highly beneficial. Factors increasing the probability of obtaining virologic suppression included older age, higher weight, high antenatal care attendance (more than 6 visits during pregnancy), ART adherence, early initiation of ART, and higher CD4 cell count at enrollment (Denoeud-Ndam et al., 2013). (Gray II) (*pregnancy, treatment, viral load, Benin*)

- A study of 1,684 infants enrolled in a randomized controlled trial from **Brazil, South Africa, Argentina,** and the **United States** found that higher maternal viral load was significantly associated with vertical transmission based on multivariate analysis (Nielsen-Saines et al., 2012). (Gray II) (*treatment, infants, Brazil, South Africa, Argentina, United States*)
- A matched case control study of fifty cases and 135 controls conducted at 31 public facilities in **Kenya** found that women who first learned their HIV status during pregnancy were 2.85 times less likely to adhere to ART and 2.42 times more likely to have a home delivery compared to women who were on combination ART prior to pregnancy (Onono et al., 2015). (Gray IIIa) (*pregnancy, treatment, Kenya*)
- A hospital-based retrospective cohort study of 202 pregnant women living with HIV from 2008 to 2012 in **Ethiopia** found that women who initiated HAART before pregnancy (30 days before the estimated date of conception) had better immunological and clinical outcomes compared to women who initiated HAART during pregnancy. The women had a median CD4 count of 210 cells/mm<sup>3</sup> before HAART initiation. The average duration of treatment among those that initiated HAART before pregnancy (56.4%) was 32.03 months, compared to 4.07 months among those that initiated HAART during pregnancy. Among all of the participants, 16.3% had a poor immunological outcome, defined as a decrease in CD4+ lymphocyte count between the initiation of HAART and delivery. Women with an unknown HIV status prior to pregnancy (29.7%) were 0.15 times less likely to have a good immunological outcome compared to women who knew their HIV status before pregnancy. In addition, participants with a CD4 count of less than 200 cells/mm<sup>3</sup> before HAART initiation were 0.023 times less likely to have a good immunological outcome compared to the women who had a CD4 count greater than 200 cells/mm<sup>3</sup>. Poor immunological outcomes were also associated with women in WHO clinical stage III at baseline (32.2%). Of the 202 women, 29.7% had poor clinical outcomes, defined as a change from a lower WHO clinical stage to a higher stage between HAART initiation and delivery. Women who initiated HAART during pregnancy were 0.349 times less likely to have good clinical outcomes compared to women who initiated HAART before pregnancy. In addition, women who remained on HAART for 13 to 18 months were 0.193 less likely to have good clinical outcomes compared to those who remained on treatment for more than 18 months. Of the 2.3% of infants who acquired HIV, their mothers were on HAART for one month. Of the participants, those in WHO clinical stage III before HAART initiation were 7.673 times more likely to have a poor clinical outcome compared to women in clinical stage I. Baseline CD4 count of less than 200 cells/mm<sup>3</sup>, baseline WHO clinical stage III, and unknown HIV status prior to pregnancy were all identified as predictors of maternal treatment outcomes (Ijigu, et al. 2015). (Gray IIIb) (*pregnancy, treatment, CD4 counts, Ethiopia*)

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- An observational cohort study, from 2000-2012 in **Ukraine**, of 8,884 HIV-positive mother and live-born infant pairs found that ART treatment should be started as early as possible, when an HIV-positive women's CD4 count is still high. Majority of the women in this study (83%) started ART treatment in their third trimester of pregnancy and 54% were giving birth to their first child. A third of the women who received HIV treatment were receiving combination ART. Of the 8,884 infants born, 12% were classified as low birth weight, 9% were preterm, and 10% were small for gestational age. Preterm pregnancy was associated with injecting drug use. Analysis of a subgroup of 3,119 women, who had known CD4 counts, showed that high CD4 counts were associated with reduced risk of preterm delivery (Bagkeris et al., 2015). (Gray IIIb) (*pregnancy, treatment, infants, Ukraine*)
- A prospective cohort study from 2000-2011 among 8,075 mothers living with HIV in **France** found that the earlier ART was started, the lower the rate of vertical transmission, whether or not a women's viral load was less than 50 copies/mL. ART was nearly as effective when started in the first trimester as when it was started before pregnancy. In this study, there were no cases of vertical transmission among the 2,651 infants born to women who were receiving ART prior to conception and had a viral load less than 50 at delivery. The overall rate of vertical transmission was 0.7%. The rate of vertical transmission increased from 0.2% for women starting ARTs before conception, to 0.4% among those initiating in the first trimester, 0.9% among those initiating in the second trimester, and 2.2% among those initiating in the third trimester. The incidence of preterm delivery was 16% in this study, which is much higher than the general population rate. However, the risk of preterm delivery did not differ according to timing of ART initiation. The findings of this study provide strong evidence for initiating therapy as soon as possible during a women's pregnancy (Mandelbrot et al., 2015). (Gray IIIb) (*pregnancy, treatment, France*)
- A pre/post quasi-experimental study of pregnant women in Lilongwe, **Malawi** found that a greater proportion of the 14,532 women accessing ANC after the implementation of Option B+ (October 2011-March 2013) were enrolled into PMTCT services, were on ART during pregnancy, were more rapidly initiating ART, and were retained on treatment through delivery in comparison to the 13,926 women accessing ANC before the availability of Option B+ (October 2009-March 2011). The study aimed to compare service uptake and antenatal outcomes in women living with HIV pre- and post-Option B+ implementation by using routine data collected for patients enrolled in the Tingathe study. Time to ART initiation was significantly shorter post-Option B+ with 58.4% of women starting on the day of enrollment. Although more women withdrew from PMTCT services after Option B+ was available, the significant increase in enrollment with Option B+ resulted in a higher proportion of all women living with HIV receiving treatment. This study also found that those enrolled on Option B+ had higher rates of withdrawal and loss to follow up compared to women who accessed ANC before Option B+ was available. "Women may be reluctant to start ART when there is no clear indication to start for their own health, and as others have suggested, perhaps women find PMTCT coercive and so initially enroll only to withdraw later" (p. e81-e82). The study suggests that the simplification of treatment with Option B+ has resulted in several improvements in the antenatal PMTCT cascade (Kim et al., 2015). (Gray IIIb) (*pregnancy, treatment, Malawi*)
- A review from 2010 to 2011 using records from early infant diagnosis in **Cameroon** found that of a total of 2,505 mother infant pairs from 59 sites, found that access to Option B+ reduced vertical transmission to 4.3% compared to 31.3% among mother-infant pairs who did not receive ART (Temgoua et al., 2015). (Gray IIIb) (*pregnancy, treatment, infants, Cameroon*)
- An analysis of 12,486 infants delivered by women living with HIV from 2000 to 2011 in the **U.S.** and **Ireland** found that transmission risk was significantly lower (.09%) in women with viral loads under

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50 copies/mL compared with a risk of 1% in women with viral loads of 50-399 copies/mL, regardless of ARV regimen or mode of delivery (Townsend et al., 2014). (Gray IIIb) (*pregnancy, treatment, viral load, United States, Ireland*)

- A study in **South Africa** using routine clinic records from 2010 to 2013 of 19,432 low-income women who came to ANC services found that Option B+ led to higher numbers of pregnant women living with HIV initiating ART at CD4 counts above 350. When eligibility for ART was based on CD4 counts of under 200, 18% of women who presented for ANC had initiated ART with CD4 counts under 200 when this was the cut-off for eligibility. But under Option B+, 92% of women presenting to ANC had initiated ART prior to CD4 counts of under 200 (Myer et al., 2015). An economic assessment found it to be cost-effective (Zulliger et al., 2014). (Gray IIIb) (*pregnancy, treatment, CD4 counts, South Africa*)
- An observational study of 311 pregnant women living with HIV in **Malawi** and receiving treatment under the Option B guidelines (not B+), from 2008- 2009, found that 6 of 8 (75%) of the infants who acquired HIV had mothers with a CD4 > 350, highlighting the importance of ART treatment for HIV-positive women regardless of CD4 count. ART was initiated as soon as possible among women with a CD4 < 350 and, among women with a CD4 > 350, at 25 weeks gestation or as soon as possible after they presented to a clinic. HIV transmission in this study was rare; the rate of HIV acquisition by infants was 3.2%. Half of the cases of HIV transmission were detected between 6 and 12 months postpartum, a time when almost all mothers in the study reported they had finished breastfeeding, and under Option B, were no longer on ART. A maternal baseline CD4 < 350 was the only predictor of infant mortality, which suggests that a healthier mother can improve infant survival. Almost one-third (30%) of women who discontinued treatment at 6 months postpartum, under the Option B guidelines, had to resume it by 24 months, either because of a new pregnancy or low CD4 count. One in five women reached the CD4 count criteria for treatment by 18 months of discontinuation of ARTs. The probability of loss to follow up was 16.4% at 2 years, and a CD4 count > 350 was a predictor, which suggests that Option B may have a negative effect on women returning to care. In this study, effective treatment initiated in the last trimester of pregnancy was not sufficient to reduce the risk of vertical transmission (Giuliano et al., 2013). (Gray IIIb) (*pregnancy, treatment, Malawi*)
- A retrospective, observational cohort study of 10,150 pregnancies, from 2002-2010, among 8,661 women living with HIV in **Malawi** and **Mozambique** found that mortality among women who received triple ART for less than 30 days prior to delivery was 3-fold that of women who received triple ART for 3 months or more prior to delivery. Data from pregnant women living with HIV who attended any of the 16 Drug Resource Enhancement Against AIDs and Malnutrition Program (DREAM) study centers for prenatal care were evaluated in this study. A total of 8,172 women initiated triple ART during prenatal care, while 1,978 women were already on triple ART prior to pregnancy. Short-term mortality, defined as death of the mother during pregnancy or within 42 days after delivery, was significantly reduced with longer duration of antenatal triple ART. Women who received triple ART for the shortest duration, 0-30 days prior to delivery, had the highest mortality rate at 2.2%. Women who initiated triple ART 31-90 days prior to delivery had a lower mortality rate of 1.1%. However, the women who were on triple ART treatment for at least 3 months before delivery had the lowest mortality rate of 0.6%. The study also found that the major factors associated with long-term maternal mortality for women living with HIV, defined as death of the mother between 42 days to four years after delivery, were less than 30 days of triple ART before delivery. In this study, women on ART before pregnancy did not have a higher mortality rate than women initiating ART during prenatal care, despite having a more advanced disease with lower CD4 count, which shows the significant benefit of women initiating ART for their own health, rather than just during pregnancy. The DREAM

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study has routinely provided HAART to all women living with HIV for PMTCT in several sub-Saharan African countries since 2002, irrespective of CD4 cell count, during prenatal care and breastfeeding (Liotta et al., 2013). (Gray IIIb) (*pregnancy, treatment, CD4 cell count, Malawi, Mozambique*)

- Retrospective data from 2,692 mother-infant pairs in **Canada** from 1997, when cART became the standard of care, until 2010, found that the rate of transmission for mothers who received cART was 0.4% if the mother living with HIV had more than four weeks of cART. The transmission rate was 9% for women who received less than four weeks of cART (Forbes et al., 2012). (Gray IIIb) (*pregnancy, treatment, Canada*)
- A prospective cohort study, which followed 1,393 ART naïve pregnant women living with HIV, from 2003-2007 in **Cameroon, Côte d'Ivoire, Kenya, Mozambique, Rwanda, South Africa, Uganda, Zambia, and Thailand** found that 1 in 4 women who received ARV prophylaxis during pregnancy and were discontinued from treatment at delivery became eligible for ART, under Option B, within 24 months of delivery. All 1,393 women in the study had a CD4 count  $\geq 250$  and 903 had CD4 count  $\geq 400$ . Majority of the women were on either single-dose nevirapine (45%) or short course ART prophylaxis (38.2%) while just 12.3% received triple ARV. By 2004, sites in Bangkok, Thailand and Eldoret, Kenya offered triple ARV prophylaxis. All women were taken off treatment at delivery, as per WHO guidelines at the time, and CD4 count decline was measured at 12 and 24 months postpartum. Among women who had a CD4 count  $\geq 250$  at enrollment, 4.5% had declined to CD4  $< 200$  at 12 months and 11.6% had declined to CD4  $< 200$  at 24 months. Among women who had a CD4 count  $\geq 400$  at enrollment, 11.9% had a CD4  $< 350$  at 12 months and 27.5% had declined to CD4  $< 200$  by 24 months. Women who received triple ART had a higher probability of CD4 decline by 24 months compared to those receiving other antiretroviral regimens, which suggests that triple ART interruption may be associated with a more rapid decline than other ART regimens. The majority of women (60.3%) on triple ART who had CD4 of 400-499 at enrollment declined to  $< 350$  by 24 months postpartum. After discontinuation of triple ART, women lost on average 20 CD4 cells/mm<sup>3</sup> per week in the first 8 weeks and 2 CD4 cells/mm<sup>3</sup> per week thereafter. Higher CD4 cell count at enrollment was associated with a reduced probability of immunological decline; for each increase in 100 cells/mm<sup>3</sup>, the probability of reaching CD4  $< 200$  was reduced by 40%. This study shows that a substantial proportion of women who receive ARTs during pregnancy will rapidly decline in CD4 cell count within 24 months if discontinued from treatment after delivery (Ekouevi et al., 2012). (Gray IIIb) (*pregnancy, treatment, Cameroon, Côte d'Ivoire, Kenya, Mozambique, Rwanda, South Africa, Uganda, Zambia, Thailand*)
- A 2007-2010 retrospective cohort study in **Zambia** analyzed data on 1,813 HIV-positive pregnant women attending antenatal clinics to assess various exposures of mother-to-child-transmission. The study found that the odds of vertical transmission increased 5.5-fold among women on HAART for 4 weeks or less before delivery, compared to those on HAART for 13 weeks or more. For each additional week on HAART (up to 13 weeks) before delivery, the odds of transmission were reduced by 14%. In this cohort, mother-to-child-transmission of HIV occurred in 3.3% of infants (59 in 1813). Mother-infant pairs were considered eligible for this study if mothers began HAART during pregnancy and if their infants had an HIV test result assessed by PCR from 3-12 weeks of age. Infant HIV status was the primary outcome. Electronic records provided comprehensive mother and newborn data through the first six weeks, which included HAART initiation, gestational age, demographic characteristics, infant birth weight and CD4 cell count. HAART duration was categorized as 4 weeks or less, 5-8 weeks, 9-12 weeks or 13 weeks or more. Maternal age, infant weight at birth, maternal BMI or hemoglobin levels, maternal CD4 count and gestational age were not found to be associated

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with infant HIV infection by 12 weeks (Chibwesa et al., 2011). (Gray IIIb) (*pregnancy, treatment, CD4 counts, Zambia*)

- A retrospective cohort study from 2004-2008 followed 418 HIV-positive mothers and their infants who participated in a routine PMTCT program in **Cameroon**. The study found that ART regimens lasting less than four weeks during pregnancy led to a 4.7-fold higher risk of early vertical transmission prior to ten weeks of age for the infant. (Tchendjou et al., 2010). (Gray IIIb) (*pregnancy, treatment, HAART, Cameroon*)
- A study from **Malawi** analyzing the national evaluation of the Option B+ program found that women on ART prior to pregnancy had low rates of vertical transmission (Tippett Barr et al., 2016: CROI Abstract) (*pregnancy, treatment, ART, Malawi*)
- Preliminary results from a study in **Swaziland** found that Option B+ resulted in more women initiating ART (94% of 1043 women) than on Option A (35% of 1272 women). (Abrams et al., 2016: CROI Abstract). (*pregnancy, treatment, Swaziland*)

## 2. Peer counseling by mother mentors may improve treatment adherence among pregnant women living with HIV.

- A cluster randomized controlled trial in **South Africa** found that peer mentors supporting women living with HIV and their infants resulted in significantly fewer depressive symptoms and fewer underweight babies, as well as greater adherence to the guidance at the time on prevention of vertical transmission. The women who received the intervention were 1.08 times more likely to not be depressed than those receiving the standard of care ( $p = 0.002$ ). Eight clinics were randomized for pregnant women living with HIV to either receive standard of care or an intervention with peer mentors of women living with HIV who had received training. There were eight meetings that discussed establishing healthy routines; adhering to ART; couple disclosure; consistent condom use; and infant bonding. Peer mentors were trained, and had weekly supervision. After twelve months, outcomes for 181 women in the standard of care and 106 women who attended at least one session with peer mentors was analyzed (Rotheram-Borus et al., 2014). (Gray II) (*pregnancy, peer support, treatment, South Africa*)
- An evaluation of a mentoring program in health facilities of mothers living with HIV in **Uganda** found a statistically significant increase in retention in care of women living with HIV on triple ART (90.9%) compared to health facilities without this support (63.6%). Additionally, there was a statistically significant reduced rate of vertical transmission, from 6.8% in facilities with mentor mothers, compared to 8.7% where there were no mentor mothers. The study was conducted in 31 health facilities with mentor mothers and 32 health facilities without mentor mothers. A total of 1,150 mother and baby pairs who received services between 2011 and 2014 evaluated. Pregnant women living with HIV who attended health facilities with mentor mothers were more likely to have the WHO-recommended four antenatal care visits during pregnancy and give birth with a skilled birth attendant. A survey of 400 pregnant women in facilities with and without mentor mothers from 2012 to 2014 found that women living with HIV reported statistically significant improved psychosocial wellbeing in facilities with mentor mothers, with reported improved coping self-efficacy, safer sex, and reduced levels of depression. The study found that mentor mothers were a cost-effective intervention, with US\$1 spent on mentor mothers averting \$11.40 in associated treatment costs (Zikusoka et al., 2015). (Gray IIIa) (*pregnancy, peer support, treatment, Uganda*)

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- A review of 21,939 patients in **Malawi** who started ART under Option B+ at one of 540 facilities from 2011 to 2012 in Malawi found that facilities that offered additional adherence counseling as required by national guidelines, which included peer counseling by mother mentors, had lower rates of early loss to follow up (Tenthani et al., 2014). (Gray IIIa) (*pregnancy, peer support, treatment, Malawi*)
- A cross-sectional study of adherence among 277 pregnant women living with HIV in 2014 in **Ethiopia** found that the odds of adhering to Option B+ were 4.7 times higher among women who received counseling on the importance of adherence to ART from mother support groups and clinic staff (Ebuy et al., 2015). (Gray IIIb) (*pregnancy, peer support, treatment, Ethiopia*)
- Focus group discussions with 106 women living with HIV who had given birth in the prior three years from **Nigeria, Kenya and Namibia** found that women reported that the information from mentor mothers was more useful than information than that received by health providers and led to more needed support (ICW and GNP+, 2015). (Gray IV) (*pregnancy, peer support, Nigeria, Kenya, Namibia*)
- A qualitative study found in **Uganda** found that peer educators may increase retention of pregnant women living with HIV, increasing adherence and support (ICW et al., 2015). (Gray V) (*peer support, treatment, adherence*)

### 3. Community health workers and community-based support can increase uptake of safe motherhood interventions for women living with HIV and reduce vertical transmission.

- A cluster randomized controlled trial of women living with HIV in **South Africa** found that 644 women who received home visits by community health workers were significantly more likely to avoid birth related complications, take actions to reduce vertical transmission and have healthier infants, as well as use condoms more consistently, in comparison to 169 women who received standard of care at clinics. The odds of completing all the tasks to reduce vertical transmission were 1.95 higher among those women visited by community health workers. The tasks to reduce vertical transmission were standard of care at the time, such as administering Nevirapine at birth to the infant, correctly medicate infants and breastfeed exclusively for the first six months. Mothers and infants were followed for six months postpartum. Community health workers were selected for good communication skills and were trained for one month using role-playing and key health information. Community health workers were paid US \$150 per month. On average, community health workers made six antenatal visits and five postnatal visits per woman, averaging 31 minutes per visit. “By having community health workers identified with a maternal, child health and nutrition program, much of the stigma associated with HIV is side-stepped” (le Roux et al., 2013: 1468). (Gray II) (*pregnancy, treatment, infants, community-based support, South Africa*)
- A pilot program in **South Africa** with 50 pregnant women living with HIV who had support from case managers and text messages were statistically significantly more likely (90% vs. 63%) to have had their infants tested for HIV postpartum than a comparison group of 50 pregnant women living with HIV. All women had a cell phone. In the intervention group, case managers who were lay counselors, sent a pre-scripted text message until six weeks post-partum. Case managers also made a phone call prior to delivery and two phone calls postpartum. Women could request a phone call at no charge from the case manager. The program cost US\$364 in cell communication over four months plus US\$29 per cell phone for the case manager. Women found the intervention acceptable and that it provided needed

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emotional support as well as a resource to ask questions. Messages included, “A healthy baby starts with a healthy mother! Be sure to take your tablets every day. ...Congratulations on your new baby. I hope this is a special time for you” (Schwartz et al., 2015b: 2032). (Gray IIIa) (*pregnancy, treatment, community-based support, South Africa*)

- A study in **Kenya** where community health workers tracked 650 pregnant women living with HIV through a mobile health tool using text messages to remind women of their appointments found a significantly lower rate of vertical transmission (0%) than a comparison group (9%) and women were twice as likely to attend more antenatal care visits. Women who missed appointments were visited at their home by community health workers, but the study did not assess if the women felt this was too invasive, violated their privacy or resulted in any adverse outcomes, although the texts did not refer to HIV serostatus. In addition, not all women have access to a phone or their phone is shared with others in their household (Mushamiri et al., 2015). (Gray IIIa) (*pregnancy, treatment, community-based outreach, Kenya*)
- An evaluation assessed the effect of HIV programs supported by PEPFAR on maternal health services in 257 facilities in eight **African** countries from 2007-2011 found that facilities that offered support groups for women living with HIV had 6% more deliveries at the facility than facilities that did not have support groups (Kruk et al., 2012). (Gray IIIa) (*pregnancy, treatment, community-based support, Africa*)
- A cohort study of 1,105 pregnant women living with HIV in **South Africa** from 2009 to 2012 found that the rate of ART initiation was 57% greater among the 264 women who received a community-based support intervention. Community-based support healthcare workers visited pregnant women at their homes to provide HIV education and ART counseling, promote PMTCT, and address various psychosocial barriers to ART, including lack of partner involvement, non-disclosure, stigmas, fear of ART, nutrition insecurity, depression, gender based violence and social assistance grant eligibility. ART- eligible women were visited by the community-based support healthcare workers three times during the ART initiation week, then visited weekly for a month, and then visited once a month. The median baseline CD4 cell count was 305 cells/ $\mu$ L among women who received the community based support intervention and 361 cells/ $\mu$ L among women who did not receive the intervention. Among all participants eligible to initiate triple ART, 5.4% of those that received the community based support intervention did not initiate ART, compared to 30.3% among those that did not receive the intervention. Participants who received community-based support were more likely to initiate ART with less delay, with a median of 26 days compared to 39 days among those that did not receive the intervention. In addition, ART coverage among all women at delivery was 64.8% among those that received community based support and 38.5% among those that did not (Fatti et al, 2016). (Gray IIIb) (*pregnancy, treatment, community-based support, South Africa*)
- A project from 2011 to 2013 in **Malawi** to increase use of Option B+, i.e. treatment for life, that worked in five districts found that women’s community-based support groups, was positively correlated with increased maternal use of ART as measured with cross sectional data. Additional interventions included health working training and mentorship, improved lab systems and couples testing and counseling. The study results did not include those pregnant women living with HIV who did not have at least one ANC visit. Prior to Option B+ cART uptake was 23% among women living with HIV; following implementation of the program, ART uptake increased significantly to 96% by 2013. However, access to transport or funds for transport remains an issue for pregnant women living with HIV (Herce et al., 2015). (Gray IIIb) (*pregnancy, treatment, community-based support, Malawi*)

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- A pilot program in **Malawi** using community health workers (CHW) resulted in increased uptake of ART as per guidelines of the time, i.e. ART eligibility at CD4 counts under 250. Before the intervention, only 8.8% of pregnant women received ART as per eligibility; following the intervention, 40% of pregnant women living with HIV received ART per eligibility. Over 24 months, 1,688 pregnant women living with HIV were enrolled. Of 499 women eligible for ART, 72.8% were initiated on ART. Prior to giving birth, 1,264 women received ARV prophylaxis. Community health workers were tasked with providing community education and ensuring that pregnant women living with HIV were on ART. The two-week CHW training included adherence counseling and reducing stigma. CHWs tracked women at clinics and at their homes from initial HIV diagnosis until cessation of breastfeeding or ART initiation for infants with HIV, verifying that women ingested ART. NOTE: While the study did not address this, this may have been seen as coercive by some women: “We also need to prevent women from refusing care and dropping out, for whatever reason” (Kim et al., 2012: 10). (Gray IIIb) (*pregnancy, community-based support, treatment, Malawi*)
- A nationally representative household survey in 2009 in **Rwanda** of mothers who attended ANC at least once during their most recent pregnancy found that HIV-free survival of HIV-exposed children was correlated with being a member of an association of people living with HIV, after adjusting for maternal, child and health system factors. HIV exposed children born to mothers living with HIV were tested. Of 1,448 HIV-exposed children surveyed, 4% were reported dead by nine months of age. Of 1,340 children alive, 4% tested HIV-positive. HIV-free survival of HIV-exposed children was 91.9% (Ruton et al., 2012). (Gray IIIb) (*infants, treatment, community-based support, Rwanda*)
- A randomized study of 10 PMTCT sites between 2013 and 2015 in the Maternal-Infant Retention for Health study in **Kenya** found that women who received lay counselor home visits and support had a significantly lower loss to follow up six months post partum compared to standard of care. Lay counselors provided individual health education at clinics and during home visits, appointment reminders, physical tracing after a missed clinic appointment and individual adherence support to 170 women and compared this to 170 women who did not have lay counselor support. At six months post partum, 130 mother-infant pairs remained in care with lay counselors compared to 112 in the standard of care. Loss to follow up was significantly lower among women who had lay counselors - 18.8% compared to 28.2% in those with standard of care (Fayorsey et al., 2016). (CROI Abstract) (*pregnancy, treatment, community-based support, Kenya*)

#### 4. **PMTCT-Plus (family-focused) HIV care can increase the numbers of women and their partners who access treatment and remain adherent.** Note: This should not be implemented in any way that prejudices women who do not want to disclose to partners (see overview).

- A study of 4,278 adults (3,613 women) enrolled in HIV care through the MTCT-Plus Initiative from 2003 to 2008 in **11 African countries** found that women with other family members enrolled in the program had the lowest loss to follow-up rates over the course of the study (16.7%). Among women, 8.7% of the lost to follow up rates were attributed to not having a family member co-enrolled. The program was family-focused and provided comprehensive HIV care, including ART for eligible participants (according to national or WHO guidelines), as well as physical examinations, and CD4 cell counts. All participants’ partners and family members living with HIV were also eligible for the program. The median age of participants was 27 years of age among women and 33 years of age among men. All participants had a CD4 count greater than or equal to 200 cells/ mm<sup>3</sup> (median of 441 cells/ mm<sup>3</sup>), were in WHO clinical stage I or II, and had at least one follow up visit after the initial enrollment visit. Of the women, 46.4% were pregnant at baseline and 55.2% were pregnant at some

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point during the study period. At 12 months follow up, the median loss to follow up (12 months since last visit) was 8.2%, ranging from 0.3% in Uganda to 21.8% in Kenya. At 24 months, median loss to follow up was 15.6%, ranging from 1.5% in Uganda to 35.9% in Kenya. This number was higher among women, with a median of 8.4% and 16% at 12 and 24 months follow up, compared to 7.1% and 13.5% among men. At the end of the study, 26.4% of the original sample were lost to follow up, with 1.4% known to have died before initiating ART, 30.2% had initiated ART, 8.1% were documented to have withdrawn from the program, and 38.2% had never initiated ART but were alive and in care. Across both genders, younger participants were found to be at a higher risk of loss to follow up, with those between 15 and 24 years of age at a higher risk than those over 30 years old. In addition, women with a higher CD4 count (350-500 cells/ mm<sup>3</sup>) were 1.5 times more likely to be lost to follow up than those with a CD4 count less than 350 cells/ mm<sup>3</sup>. Being pregnant at a previous clinic visit was also associated with a higher risk of being lost to follow up, with 33.2% of loss to follow up among women attributed to pregnancy. Among all participants, living in a household with four or more people was found to decrease the risk of becoming lost to follow up. In addition, men with electricity in their home and women with employment outside of their home were less likely to be lost to follow up (Gwynn et al, 2015). (Gray IIIb) (*pregnancy, treatment, PMTCT Plus, Africa*)

- A study in **Northern Uganda** from 2002-2011 analyzed results from 24 health facilities in Northern Uganda with 140,658 women who attended ANC. The increased ANC attendance in the first few years “paralleled increased access to, and sustained sensitization about the availability of PMTCT services” (p. e143). Male partner attendance increased from 5.9% in 2002 to 75.8% in 2011. HIV-prevalence in HIV-exposed infants decreased from 10.3% in 2002 to 5.0% in 2011. The Uganda Ministry of Health program created Family Support Groups, which were implemented to promote community support to HIV sero-discordant and concordant couples and their infants. These groups discussed health education and implemented social support and income-generating activities in collaboration with the health facility. Men had also been included through peer counseling by other men and the creation of male-friendly spaces in ANC clinics. Even though conflict was prevalent in the region until 2006 these PMTCT program outcomes were comparable or better than non-conflict areas. Therefore, “a comprehensive PMTCT program emphasizing social and community engagement alongside medical care and support can succeed in a remote setting with multiple challenges” (p. e138). The Ugandan Ministry of Health increased antenatal care and decreased rates of vertical transmission (Bannick-Mbazzi et al, 2013). (Gray IIIb) (*pregnancy, treatment, PMTCT Plus, Uganda*)
- A systematic review that included 20 articles that met the inclusion criteria found that providing family focused care increased women’s uptake of HIV-related services. Studies took place in **South Africa, Kenya, Tanzania, Zambia, Botswana, and Côte d’Ivoire** (Ferguson et al., 2012). (Gray IIIb) (*PMTCT-Plus, treatment, South Africa, Tanzania, Zambia, Botswana, Côte d’Ivoire*)
- A study from **Côte d’Ivoire** evaluating an MTCT-plus program from 2003 to 2005 found a significant increase in antiretroviral treatment initiation and high rates of retention in care for women and their partners. Of the 605 women enrolled during the study period, fewer than 2% of women and 9% of their partners were receiving antiretroviral treatment prior to enrollment in the program, in comparison to 41.5% of women and 65% of their partners after enrollment at the close of the study period. Retention rates were also high: only 2.5% of women and 5.5% of partners initiating ART were lost to follow-up, while 2% of women and 0% of partners not eligible for ART were lost to follow-up (Tonwe-Gold et al., 2009). (Gray IIIb) (*PMTCT-Plus, treatment, Côte d’Ivoire*)

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**5. Integrating ARV therapy into antenatal care, rather than referring women separately for HIV treatment, can reduce time to treatment and increase adherence for pregnant women living with HIV.** [*See also Structuring Health Services to Meet Women's Needs*] Note: A review found that no one model of care fully addressed all barriers for women, but the most effective models focused on the period of transition between pregnancy and postpartum (Colvin et al., 2014).

- A quasi-experimental nonrandomized study in **Zambia** from 2011 to 2013 found that the average time to ART initiation among ART-naïve pregnant women living with HIV who attended ANC and HIV integrated clinics was 22.2 days, compared to 31.8 days among ART-naïve pregnant women living with HIV who attended standard of care ANC services. The intervention included training 132 ANC providers in ART initiation and management. Participants in the study were assigned to lay counselors who made regular home visits throughout pregnancy and breastfeeding to assist with navigating the health system, promote adherence, and provide patient support (Herlihy, 2015). (Gray IIIa) (*treatment, antenatal care, Zambia*)
- A **Cochrane review** with three studies on integrating ANC and ART found that the proportion of pregnant women initiating ART during pregnancy increased by 32.9% when ANC and ART services were integrated, compared with those pregnant women who were referred to HIV services. In addition, interventions that integrated ART and ANC reduced the delay between HIV diagnosis and initiation of ART from 56 days to 37 days (Lindgren et al., 2012 cited in Lisy, 2013). (Gray IIIa) (*treatment, antenatal care*)
- A review of 279 postpartum women in **South Africa** who started ART in the ANC clinic who were transferred to ART clinics postpartum between 2012 and 2013 found that those who had additional months on ART before delivery had a greater likelihood of engagement in an ART clinic postpartum. Of the women transferred, 32% were transferred to a large ART facility on the same premises as the ANC clinic. After adjusting for age, CD4 cell count and being diagnosed with HIV in the current pregnancy, the relative risk of successfully engaging in care increased by 5% for every additional month on ART before delivery. Based on only lab assessments, 74% were engaged in care after transfer. However, 91% of women self-reported engagement in care postpartum (Phillips et al., 2015). (Gray IIIb) (*treatment, antenatal care, South Africa*)
- A study in **South Africa** using routine clinic records from 2010 to 2013 of 19,432 low-income women who came to ANC services found that service integration of ART with ANC led to high rates of ART initiation as compared a system in earlier years which required referral between ANC services and ART treatment services. Compared with the model with ART eligibility based on CD4 counts under 350, women were approximately seven times more likely to initiate ART in the services that integrated ART with ANC and more than 20 times as likely to initiate ART before delivery under Option B+. Of pregnant women in this community, more than 95% attend ANC prior to delivery. Six service delivery models were evaluated in sequence: 1) ANC services referred all ART-eligible women based on 2006 WHO guidelines to the ART clinic or CD4 counts under 200; 2) ANC referred all ART eligible women based on 2006 WHO guidelines to the ART clinic or CD4 counts under 350; 3) Lay PMTCT counselors worked as patient navigators to support referrals between ANC and ART; 4) ART-trained midwives initiated ART within ANC services; 5) ART-trained midwives initiated ART within ANC services with on site CD4 testing; and 5) Option B+, with CD4 counts used only to determine baseline CD4 but not for ART eligibility and ART provided at ANC if a woman tested positive for HIV (Myer et al., 2015). (Gray IIIb) (*treatment, antenatal care, South Africa*)

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A prospective cohort study of 321 pregnant women living with HIV attending prevention of mother-to-child transmission services from 2011 to 2014 in **Zambia** found that women who attended referral health facilities were more likely to be non-adherent to ART, compared to women who attended non-referral facilities. Women in the study visited 11 health facilities, six of which provided HIV care and treatment and five of which referred antiretroviral eligible women to other health centers that could provide treatment. Of the participants, 48% were already receiving antiretroviral therapy before participating in the study, and 49.5% were newly diagnosed as living with HIV during their current pregnancy (Okawa et al. 2015). (Gray IIIb) (*treatment, antenatal care, Zambia*)

- A retrospective cohort study using routinely collected clinic data in 2008 among 14,617 women in **South Africa** seeking ANC, of whom 30% were living with HIV and 17% had CD4 counts under 200, found that a significantly higher proportion (55% compared to 45%) of women started ART during ANC in integrated care than when women were referred from ANC for ART services (Stinson et al., 2013). (Gray IIIb) (*treatment, antenatal care, South Africa*)
- A study in **Mozambique** found that integration of HIV/AIDS services into ANC services reduced loss to follow up of women living with HIV from PMTCT services to ART services by 70% compared to 25% achieved in vertical sites. The study assessed the changes between 2004 and 2008, when HIV care was delivered through a vertical hospital and HIV care was integrated into primary healthcare. In 2005, only 30% of pregnant women who tested HIV-positive in PMTCT programs enrolled in HIV treatment and care. By the end of 2005, only 20% of eligible mothers had initiated ART. In 2004, freestanding HIV treatment hospitals were constructed in urban centers with their own pharmacies, data systems, health workforce, waiting areas and receptions. Patients identified as HIV-positive from other sectors of the health system, such as PMTCT or HTC, were referred to HIV hospitals to register for HIV care. But in 2005, only 78% of HIV-positive patients referred to HIV hospitals returned for CD4 testing, and only 46% of those who returned for the results of their CD4 tests were found to be eligible to start antiretroviral therapy (Pfeiffer et al., 2010). (Gray IIIb) (*pregnancy, treatment, antenatal care, Mozambique*)
- The International Center for AIDS Care and Treatment Programs (ICAP) collected program data from 32 antenatal clinics in **Rwanda** from 2006-2008, where 2,048 pregnant women living with HIV attended either standard PMTCT sites (where pregnant women were referred to ART clinics that were off-site) or integrated sites, where all services for pregnant women living with HIV were provided at the same clinic, including antiretroviral therapy. The study found that women attending integrated sites were 30% more likely to undergo CD4 cell count testing during pregnancy and twice as likely to enroll in antiretroviral treatment compared to women attending standard sites, where they were referred for antiretroviral treatment. Scale up between 2006 and 2008 resulting in increased CD4 cell count screening during pregnancy increasing from 60% to 70% and initiation of HAART from 35.5% to 97%. No differences were observed regarding HAART initiation for women determined to be eligible (about 85% in both sites) and type of treatment provided, indicating effective referral from standard sites to antiretroviral treatment services. Women were eligible for HAART with a CD4 cell count below 350. About 24% of women were eligible for HAART and 83% initiated HAART during pregnancy, regardless of service delivery (integrated or standard). Both sites provided dual antiretroviral and single-dose nevirapine regimens, while integrated sites also offered HAART and HAART to prevent vertical transmission during pregnancy until delivery or until the end of breastfeeding. Corrective strategies for scale up included providing CD4 machines and trained staff at the district level; with scheduled weekly CD4 sample processing and home visits conducted to track

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women who missed appointments. Most standard sites did not provide CD4 testing and referred eligible women to local ART centers for testing and treatment. The study trained and retrained 297 staff to administer multi-drug antiretroviral therapy and provided regular on-site mentoring. Study sites provided monthly reports (Tsague et al., 2010). (Gray IIIb) (*treatment, antenatal care, Rwanda*)

- A qualitative study in rural **Kenya** found that women living with HIV preferred integrated ANC and HIV services because this way they would not be as easily identifiable as living with HIV, as well as have easier access to comprehensive services (Vo et al., 2012). (Gray IV) (*treatment, antenatal care, Kenya*)

## 6. National scale-up of cART in pregnancy improves maternal and infant outcomes.

- A study in **South Africa** in 2013 found that a national scale-up of prevention of vertical transmission services significantly increased prevention of vertical transmission and treatment of women living with HIV. The overall vertical transmission rate was reported at 3.5% in 2010 and dropped to 2.7% in 2011. South Africa did not implement their first prevention of vertical transmission program until 2002. In 2004, South Africa then moved to comprehensive care management and treatment of all people, including pregnant women, living with HIV. In 2008, the Ministry of Health launched the accelerated prevention of vertical transmission program with a goal of reducing vertical transmission to less than 5% by 2011. In 2010, 30.2% of all pregnant women who sought care at public sector health facilities were living with HIV and by 2011, “70.4% of all maternal deaths in South Africa were associated with HIV infection...” (p. 70). In 2010, the Ministry of Health revised the vertical transmission policy to align with the new WHO recommendations to include lifelong HAART for women living with HIV with CD4+ counts less than 350 cells/mm<sup>3</sup>. A major effort from 2008-2011 shifted practices toward nurses initiating and managing the use of ART by training them to provide ART for all pregnant women at primary care ANC facilities. In 2005, fewer than 50% of all pregnant women were routinely tested for HIV but by 2009 the testing was “virtually universal” (p. 71). Testing of infants to detect infection before 2 months has increased from 36.6% in 2008 to 70.4% in 2011. In addition, the proportion of infants tested who were HIV-positive decreased from 9.6% to 2.5% over the same period. Rapid implementation of changes in PMTCT policy was key to scale up as well as challenging the lack of action by the government until 2001 in court, winning the court case and forcing the government to scale up services (Barron et al, 2013; see also Goga et al., 2015) (Gray IIIb) (*pregnancy, treatment, scale up, South Africa*)
- An observational cohort study, from 2000-2012 in **Ukraine**, of 8,884 HIV-positive mother and live-born infant pairs found that it is important to ensure continuing efforts to improve pregnancy outcomes among women living with HIV, and that some risk factors for adverse pregnancy outcomes are specific to HIV while others are shared with the general antenatal population. The majority of the women in this study (83%) started ART treatment in their third trimester of pregnancy and 54% were giving birth to their first child. A third of the women who received HIV treatment were receiving combination ART. Of the 8,884 infants born, 12% were classified as low birth weight (< 2,500 g.), 9% were preterm (< 37 gestational weeks), and 10% were small for gestational age (lower than the 10<sup>th</sup> percentile). The proportion of women who received no antenatal care declined significantly from 78% in 2000, to 52% in 2001, to 9% in 2012. Furthermore, there was a dramatic shift towards starting ART earlier over the time period of the study. Median gestational age at ART initiation was 34 weeks before 2005, 28 weeks in 2005-08, and 24 weeks in 2009-2012 (Bagkeris et al., 2015). (Gray IIIb) (*pregnancy, treatment, scale up, Ukraine*)

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- A study conducted in **Malawi** from July 2011 to September 2012 analyzed the introduction of the Option B+ prevention of vertical transmission strategy. Because obtaining CD4 counts to assess eligibility for ART can be a barrier, Option B+, which only requires an HIV-positive diagnosis in pregnancy, can increase the numbers of pregnant women who access ART. In Malawi, the number of pregnant and breastfeeding women started on ART per quarter increased by 748% from 1,257 in the second quarter of 2011 (before Option B+ implementation) to 10,633 in the third quarter of 2012 (one year after implementation). Of the 2,949 women who started ART under Option B+ in the third quarter of 2012 and did not transfer care, 2,267 (77%) continued to receive ART at 12 months; a retention rate similar to the rate for all adults in Malawi. To decentralize ART to all health centers providing ANC, 4,839 health-care workers were trained. The total number of all persons started on ART per quarter increased by 61% after implementation of Option B+. The provision of ART at all ANC health centers reduced the transportation and cost barriers to receiving treatment. Members of a nationally coordinated supervision team visited every integrated prevention of vertical transmission and ART site in Malawi quarterly. Patient registers were created to permit longitudinal follow-up and cohort analyses for patients receiving antenatal and HIV care (Chimbwandira et al, 2013) (Gray IIIb) (*pregnancy, treatment, scale up, Malawi*)
- A study in **Jamaica** in 2012 analyzed the successes and challenges of the prevention, treatment, and care of pediatric, perinatal, and adolescent HIV/AIDS in Jamaica. It concluded that Jamaica had achieved its goal of less than 2% vertical HIV transmission rate as well as more than 95% of mothers attending ANC tested for HIV. The vertical transmission rate in 2005 was 10% whereas in 2011 it was only 1.19%. The percent of women receiving ARVs increased from 74% in 2005 to 85% in 2011 while the percent of infants receiving medication to prevent vertical transmission increased from 87% in 2005 to 101% in 2011. The incidence of vertical transmission has dropped to 0.3 cases per 1000 live births. In addition, the number of HIV-exposed infants decreased from 407 in 2005 to 350 in 2011. The use of HAART for pregnant women along with a comprehensive system of care has “greatly decreased HIV/AIDS attributable maternal morbidity and mortality” (p. 398). More than 85% of women received ARTs and 100% of babies received ART chemoprophylaxis (Christie and Pierre, 2012). (Gray IIIb) (*pregnancy, treatment, scale up, Jamaica*)

### **9C-2. Gaps in Programming—Safe Motherhood and Prevention of Vertical Transmission: Antenatal Care – Treatment**

1. Interventions are needed to sustain viral suppression and reduce loss to follow up once a woman has initiated Option B+, including affordable means of monitoring virological response and effective adherence counseling. Research is needed on how long is optimal to provide care within maternal health systems or when to transfer cART provision outside of maternal health systems.
2. Interventions, including community based distribution of cART and/or funds for transport, are needed to reach pregnant women living with HIV who do not access ANC, postpartum care or cART.
3. Promoting HIV testing for male and female adolescents prior to pregnancy or fatherhood may increase those on cART prior to pregnancy, thus decreasing viral load prior to pregnancy and increasing the likelihood of reduced risk of vertical transmission.

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4. Interventions for pregnant women and their partners to stay HIV-negative or reduce HIV transmission are needed.
5. Mandating pregnant women to enroll in ART on the same day they test HIV positive may violate their human rights and may result in loss-to-follow up, increasing the risk of mortality, morbidity and drug resistance.
6. Interventions are needed to reduce the higher attrition rate among pregnant adolescents living with HIV, including those perinatally infected, and provide needed support by parents and others.
7. Strategies need to be identified to empower women to create demand for improved maternal health services and challenge violations of their rights in facility-based childbirth.
8. Ongoing surveillance is needed to assess the impact of cART on infants (both HIV-negative and HIV-positive) exposed in utero and during breastfeeding.
9. Monitoring for drug resistance in low- and middle-income countries is needed during Option B+ scale up.
10. Efforts are needed to effectively implement Option B+ in non-prejudicial ways.
11. Interventions are needed for male involvement that do not such reinforce harmful gender norms or increase risk for violence, stigma or discrimination.
12. Additional support for pregnant women living with HIV who face violence is needed including establishing proper mechanisms for seeking redress, along with more research on mental health and maternal morbidity among women living with HIV.
13. Women and men need accurate information on vertical transmission, treatment adherence strategies, the importance of their viral load and the low risk of vertical transmission if virally suppressed.
14. Strategies, including legal strategies, are needed to empower pregnant women living with HIV to ask questions, be properly informed and to challenge stigma, disrespect and abuse.
15. More effective and timely translation of new PMTCT policy into standard practice is needed.
16. Interventions are needed to provide pregnant and breastfeeding women with more food security in order to increase viral suppression.

1. **Interventions are needed to sustain viral suppression and reduce loss to follow up once a woman has initiated Option B+, including affordable means of monitoring virological response and effective adherence counseling. Research is needed on how long is optimal to provide care within maternal health systems or when to transfer cART provision outside of maternal health systems.** Compared to people who started cART for their own health, a study found that women who started cART while pregnant were 5 times less likely to return to the

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clinics after the initial visit. Women who started cART while breastfeeding were twice as likely to miss their first follow up appointment. On average, 17% of pregnant women who started ART under Option B+ dropped out of care in the first six months of ART and 22% dropped out within one year (Tenhathi et al., 2014). Systems are rarely in place to track mothers six weeks postpartum (Psaros et al., 2015; Waiswa, 2016). A survey found that ART retention was greatest in those facilities where newly diagnosed pregnant women living with HIV were referred from ANC to the ART clinic in the same facility for initiation and follow up or were referred to facilities serving as ART referral sites that did not provide ANC (van Lettow et al., 2014). A review noted that women found challenges in accessing cART either through maternal care systems, postpartum or through HIV care. Input from pregnant and postpartum women living with HIV is needed.

- Gap noted **globally** (Colvin et al., 2014; Nutman et al., 2013 cited in Kendall and Danel, 2014); and, for example in **Zambia** (Bengston et al., 2016, Ngoma et al., 2015); **Brazil** (de Andrade et al., 2016); **Rwanda, Malawi, Kenya and Swaziland** (Woelk et al., 2015); **Zimbabwe** (Dzangare et al., 2015); **South Africa** (Phillips et al., 2015; Clouse et al., 2015; Henegar et al., 2015; Clouse et al., 2013); **Uganda** (Psaros et al., 2015, Mugasha et al., 2014), **Malawi** (Tenthani et al., 2014; van Lettow et al., 2014; Tweya et al., 2014; Koole et al., 2014); **Tanzania** (Ngarina et al., 2014); and **Kenya** (Ayuo et al., 2013).
2. **Interventions, including community based distribution of cART and/or funds for transport, are needed to reach pregnant women living with HIV who do not access ANC, postpartum care or cART.** “Restrictions on women’s mobility and lack of access to transportation and financial resources may limit their ability to seek PMTCT services” (Ghanotakis et al., 2012: table 2).
    - Gap noted, for example in **Kenya** (Mason et al., 2015); **Zimbabwe** (Dzangare et al., 2015); McCoy et al., 2015a); **Botswana** (Dryden-Peterson et al., 2015); **Tanzania** (Gourlay et al., 2015); **Malawi** (Tweya et al., 2014); and **Uganda** (Mugasha et al., 2014; Lubega et al., 2013).
  3. **Promoting HIV testing for male and female adolescents prior to pregnancy or fatherhood may increase those on cART prior to pregnancy, thus decreasing viral load prior to pregnancy and increasing the likelihood of reduced risk of vertical transmission.**
    - Gap noted, for example in **Tanzania** (Gourlay et al., 2015) and in **South Africa** (Fatti et al., 2014; Horwood et al., 2013).
  4. **Interventions for pregnant women and their partners to stay HIV-negative or reduce HIV transmission are needed.** [See also *HIV Testing and Counseling and Treatment*] Pregnancy is a time of high risk for HIV acquisition. Home-based partner education for couples with no reports of interpersonal violence may be more effective than clinic based interventions, especially when women can opt-out of disclosing their sero-status. A systematic review found that incident infection (i.e. recently acquired during pregnancy) resulted in up to a 15-fold higher risk of vertical transmission.

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- Gap noted **globally** (Croce-Galis et al., 2015; USHHS, 2015); and for example, in **Africa, Asia, USA, Europe and Latin America** (Drake et al., 2014); **Mozambique** (De Schacht et al., 2014); **Kenya** (Farquhar, 2016: CROI Abstract); **South Africa** (Dinh et al., 2015; Peltzer and Mlambo, 2013; Petlzer et al., 2013; Johnson et al., 2012); **Mexico** (Rivero and Kendall, 2015); **Uganda** (Saleem et al., 2014); and **Mozambique** (De Schacht et al., 2014).

**5. Mandating pregnant women to enroll in ART on the same day they test HIV positive may violate their human rights and may result in loss-to-follow up, increasing the risk of mortality, morbidity and drug resistance.** Providing enough counseling and information to pregnant women found positive before being initiated on lifelong treatment helps in reducing cases of loss to follow up. Active tracing of women lost to follow up in a way that does not violate consent, confidentiality and human rights, may be warranted. An analysis of national facilities with over 20,000 women started on cART under Option B+ found that loss to follow up was highest in patients who began cART at large clinics on the day they were diagnosed with HIV. After controlling for age and facility type, Option B+ patients who started on ART on the same day of testing were almost twice as likely to never return to the clinic than other Option B+ patients. Note: WHO September 2015 guidelines do not specify when during pregnancy a woman living with HIV should be initiated on cART.

- Gap noted **globally** (Welbourn, 2014) and for example in **Ethiopia** (Mitiku et al., 2016); **Zimbabwe** (Dzangare et al., 2015); **Sub-Saharan Africa** (Bain et al., 2015); **Kenya** (Ferguson et al., 2014); **Malawi** (Tenthani et al., 2014).

**6. Interventions are needed to reduce the higher attrition rate among pregnant adolescents living with HIV, including those perinatally infected, and provide needed support by parents and others.** [See also *Prevention and Services for Adolescents and Young People*] Additional research may also be needed on how to best care for perinatally-infected pregnant women who have decreased virological suppression, increased risk of vertical transmission and increased challenges in remaining adherent. While currently noted in the United States, it is anticipated to be relevant to low- and middle-income countries as more perinatally-infected women give birth.

- Gap noted, for example in **Zimbabwe** (Dzangare et al., 2015) and **South Africa** (Woldesenbet et al., 2015; Hill et al., 2015) and **United States** (Jao et al., 2015; Badell et al., 2013; Munjal et al., 2013 cited in USHHS, 2015).

**7. Strategies need to be identified to empower women to create demand for improved maternal health services and challenge violations of their rights in facility-based childbirth.** This is a particularly acute need for women living with HIV. Studies show that HIV-related stigma may reduce the likelihood of delivering in a health facility.

- Gap noted **globally** (Vogel et al., 2015); and for example in **South Africa** (Schnippel et al., 2015; Clouse et al., 2014; Gross et al., 2012); **Tanzania** (Gill et al., 2015; Wabiri et al., 2013; Gross et al., 2012); **Kenya** (Turan et al., 2012 cited in Turan and Nyblade, 2013); and **South Africa, Kenya, Tanzania, Zambia, Botswana, Ivory Coast** (Ferguson et al., 2012).

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- 8. Ongoing surveillance is needed to assess the impact of cART on infants (both HIV-negative and HIV-positive) exposed in utero and during breastfeeding.** A recent US study had encouraging results that among ARV-exposed uninfected children, no learning issues were noted (Nozyce et al., 2014) and another US-based study found no increased risk for infants exposed to ART (Phiri et al., 2014). A pilot ART registry in Africa has been launched.
- Gap noted **globally** (Luzuriaga and Mofenson, 2016; Williams et al., 2015; de Martino et al., 2015; WHO, 2015a; Bulterys et al., 2014; Mofenson and Watts, 2014; Ahmed et al., 2013); and for example, **Zambia** (Nicholson et al., 2015; Liu et al., 2014); **South Africa** (Liu et al., 2014); **India** (Sangeeta et al., 2014); **Italy** (Florida et al., 2013); **Botswana** (Chen et al., 2012); and **Côte d’Ivoire, South Africa, Thailand** (Ford et al., 2011).
- 9. Monitoring for drug resistance in low- and middle-income countries is needed during Option B+ scale up.** Studies are finding drug resistance among women who are initiating cART or who have initiated cART.
- Gap noted **globally** (Paredes et al., 2013; Ahmed et al., 2013); and, for example in **Tanzania** (Ngarina et al., 2014); **Brazil** (Teixeira et al., 2014; Pilotto et al., 2013); **Malawi** (Palombi et al., 2015; Palombi et al., 2014; Mancinelli et al., 2015); **Gabon** (Caron et al., 2012); and **Zambia** (Kuhn et al., 2009b).
- 10. Efforts are needed to effectively implement Option B+ in non-prejudicial ways.** Women who were sex workers reported being denied care until delivery. Women who were not accompanied by husbands were denied any health services during pregnancy. A sign on health centers read: “Notice: all pregnant women are supposed to come with their husbands/partners at their first visit. You will not be given services without implementing this” (Beckham et al., 2015: 66).
- Gap noted **globally** (Turan and Nyblade, 2013), and for example, in **Kenya, Nigeria and Namibia** (ICW+ and GNP+, 2015); **South Africa** (Sewnunan and Modiba, 2015); **Côte d’Ivoire** (Schwartz et al., 2015a); **Burkina Faso** (Papworth et al., 2015); **Tanzania** (Beckham et al., 2015; Ngarina et al., 2014); **Uganda** (Mugasha et al., 2014); **Cameroon, Nigeria and Zambia** (Haerizadeh et al., 2014); and **Senegal** (Sow, 2014).
- 11. Interventions are needed for male involvement that do not such reinforce harmful gender norms or increase risk for violence, stigma or discrimination.** “Evidence for effectiveness of male involvement in PMTCT programs is scant” (Beckham et al., 2015: 67). One study only evaluated male involvement as accompanying their pregnant partner to ANC care with no HIV related outcomes listed and tasking the woman to require her male partner to come to ANC (Nyondo et al., 2015). Most approaches only reach men through their pregnant spouse, with no services for men beyond HIV testing and use men as an instrument solely to increase access to services by women. Men have been denied involvement in antenatal care, birth and delivery even if the couple so chooses.
- Gap noted **globally** (Ghanotakis et al., 2015; Colvin et al., 2014; Sherr and Croome, 2012; Brusamento et al., 2012 cited in Kendall and Danel, 2014; Ramirez-Ferrero and Lusti-Narasimhan, 20112); and for example, **Zambia** (Auvinen et al., 2014a and b); **South Africa** (Brittain et al., 2015); **Malawi** (Nyondo et al., 2015); **Kenya, Namibia and Nigeria** (ICW and GNP+, 2015) **Tanzania** (Sui et al., 2014 cited in

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Beckham et al., 2015; Auvinen et al., 2013 and Brusamento et al., 2011); and **Sub-Saharan Africa** (Kalembo et al., 2012).

**12. Additional support for pregnant women living with HIV who face violence is needed, including establishing proper mechanisms for seeking redress, along with more research on mental health and maternal morbidity among women living with HIV.**

- Gap noted **globally** (Kendall et al., 2014a; Kendall et al., 2014b; Langer, 2016); and for example, in Nigeria (Iheanacho et al., 2015); **Africa, Asia, Europe and USA** (Kapetanovic et al., 2014); and **Sub-Saharan Africa** (Stringer et al., 2014); **Zimbabwe** (Shamu et al., 2014); and **South Africa** (Groves et al., 2014).

**13. Women and men need accurate information on vertical transmission, treatment adherence strategies, the importance of their viral load and the low risk of vertical transmission if virally suppressed.** Adherence has been challenging for women living with HIV postpartum, even for those initiating ART during pregnancy at CD4 counts under 350, with adequate adherence dropping from 75.7% during pregnancy to 53% postpartum globally (Nachega et al., 2012 cited in Coutsooudis et al., 2013). Knowledge of HIV and vertical transmission has shown to be correlated with increased initiation, adherence and retention for pregnant women living with HIV.

- Gap noted **globally** (Ozra et al., 2015; Kendall and Danel, 2014); and for example, in **Zambia** (Wall et al., 2016); **Malawi** (Hoffman et al., 2016 – Abstract, CROI; Jahn et al., 2016a: CROI abstract; Kawale et al., 2015; Tenthani et al., 2014 cited in Clouse et al., 2014); **Swaziland** (Church et al., 2015); **Sub-Saharan Africa** (Tam et al., 2015; Gourlay et al., 2013); **Mexico, El Salvador, Cameroon** (Awungafac et al. 2015); **Honduras and Nicaragua** (Kendall and Albert, 2015); **Uganda and South Africa** (Wagman et al., 2015 cited in Kennedy et al., 2015; Maman et al., 2014); **Ukraine** (Bailey et al., 2014); **South Africa** (Nachega et al., 2012 cited in Kendall and Danel, 2014; Coutsooudis et al., 2013); **Uganda** (Duff et al., 2012); and **Sub-Saharan Africa, Asia, Latin America, Europe and United States** (Hodgson et al., 2014).

**14. Strategies, including legal strategies, are needed to empower pregnant women living with HIV to ask questions, be properly informed and to challenge stigma, disrespect and abuse.** [See also *Stigma and Discrimination*] Consequences for violating patient confidentiality, redress for women with HIV facing discrimination in facilities, and stigma reduction efforts are needed to increase adherence to cART, prior to, during and post pregnancy, including training for providers.

- Gap noted **globally** (Khosla et al., 2015; Turan and Nyblade, 2013 cited in Kendall and Danel, 2014; Kendall et al., 2014b; Freedman et al., 2014; Busza et al., 2012); and for example, in **India** (Panditrao et al., 2015); **Kenya, Nigeria and Namibia** (ICW and GNP+, 2015); **Cameroon, Nigeria and Zambia** (Hawrizadeh et al., 2014); **Sub-Saharan Africa** (Gourlay et al., 2013); **Kenya, Burkina Faso, Malawi and Uganda** (Hardon et al., 2012); and **Tanzania** (Gourlay et al., 2014; Sando et al., 2014; Watson-Jones et al., 2012).

**15. More effective and timely translation of new PMTCT policy into standard practice is needed.**

- Gap noted for example, in **South Africa** (Goga et al., 2015).

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**16. Interventions are needed to provide pregnant and breastfeeding women with more food security in order to increase viral suppression.** A study found that food insecurity was associated with lower odds of sustained virological suppression.

- Gap noted, for example, in **Zimbabwe** (McCoy et al., 2015b); **Uganda** (Koss et al., 2016; Young et al., 2012); and **Tanzania** (Ngarina et al., 2013).

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<sup>†</sup>Every effort has been made to ensure that all citations in this chapter are contained in this list and that this list is accurate. If something is missing or inaccurate, please see [www.whatworksforwomen.org](http://www.whatworksforwomen.org) for a complete list. If missing or inaccurate there, please contact us.

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