Chapter 9. Safe Motherhood and Prevention of Vertical Transmission

> *"PMTCT is too much about the baby and not enough about the mother."*
>
> —Woman in a PMTCT program, Malawi *(Bwirire et al., 2008: 1997)*

Three vital components of AIDS programming for women living with HIV are ensuring safe motherhood through access to health care before, during and after pregnancy and childbirth; ensuring access to treatment; and ensuring access to services to prevent vertical HIV transmission. While much progress has been made in reducing vertical transmission, more could be done. A recent demographic model showed that if the 25 countries with the largest numbers of HIV-positive pregnant women implement the new WHO Prevention of mother-to-child transmission (PMTCT) recommendations between 2010 and 2015 and provide more effective ARV prophylaxis or treatment (for those eligible) with 90% coverage, one million new child infections could be averted by 2015 (Mahy et al., 2010a). Further, reducing new HIV infections in women of reproductive age, eliminating the unmet need for contraception among women living with HIV, and limiting breastfeeding to 12 months (with ARV prophylaxis) by women living with HIV could avert an additional 264,000 infections.

HIV Contributes to Maternal Mortality

Estimates of maternal mortality for 181 countries from 1980 to 2008 found that of the 342,900 estimated maternal deaths worldwide in 2008, 61,400 were attributed to HIV (Hogan et al., 2010). In 2008, HIV accounted for 11% of maternal deaths, with an estimated 42,000 to 60,000 pregnant women who died because of HIV (UNAIDS, 2011a and UNAIDS, 2011c) and there is increasing evidence that HIV is becoming a major cause of maternal mortality in resource-constrained settings, particularly in sub-Saharan Africa (Moodley et al., 2011). In 2008, an estimated 1.4 million pregnant women living with HIV in low- and middle-income countries gave birth. Sub-Saharan Africa accounted for 91% of all pregnant women living with HIV (UNAIDS, 2009d). Due to scale up of antiretroviral drugs, the estimated number of maternal deaths due to HIV has declined to 56,100 for 2011 (Lozano et al., 2011).

Prevention of Vertical Transmission Hinges on Access to Antenatal and Perinatal Care

Access to perinatal care is vital. In 1990, the percent of women in developing countries delivering with skilled attendants was 54%; by 2008, 63% (UNICEF, 2010a). About 40% of women in developing countries give birth without a skilled attendant; fewer than 40%

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have a postnatal visit by a skilled health worker; and only about 50% of women in low-income countries complete the recommended series of four antenatal visits with a doctor or nurse (Altman, 2011), all of which impact whether a woman has access to services for safe motherhood and prevention of vertical transmission. Conservative estimates are that there will be between 130 million to 180 million births without skilled birth attendants between 2011 and 2015 in South Asia and sub-Saharan Africa, mostly in rural areas (Crowe et al., 2012). For example, less than 70% of women in the Middle East and North Africa region have at least one antenatal checkup, hindering PMTCT efforts (Remien et al., 2009). In Cambodia, 78% of births occur at home or outside medical facilities in which PMTCT services are available (International Treatment Preparedness Coalition, 2009).

Poor women are less likely to access care. The poorest women are least likely to deliver with skilled attendants: in developing countries, only 28% of the poorest 20% delivered with skilled attendants, whereas among the richest 20%, 84% delivered with skilled attendants (UNICEF, 2010a). Once a woman does access a health facility for birth, quality care is critical (Barker et al., 2011; HRW, 2011b; Hulton et al., 2002 cited in Gay et al., 2003).

A recent study in Ethiopia found that women who delivered at home were less likely to have used antiretroviral therapy (ART) to prevent vertical transmission (Mirkuzie et al., 2010). However, a study of 257 health facilities supported by PEPFAR from eight sub-Saharan African countries found that an increase in the number of pregnant ART patients was associated with an increase in facility deliveries by both HIV-positive and HIV-negative pregnant women (Kruk et al., 2012). "….Significant increases in PMTCT coverage among those at risk can only be achieved by substantially increasing uptake of general ANC and delivery services….PMTCT programmes need to be strengthened by investing more generally in maternal health services…" (Kasenga et al., 2009: 1). Some PMTCT projects in Rwanda have, through outreach, community education and some incentives, increased the percent of women delivering in participating health center from 56% in 2007 to 72% in 2008, while the 2008 Rwandan national average was only 45% (Lim et al., 2010).

Prevention of Vertical Transmission Must Focus on Both Mother and Child

Programs to prevent vertical transmission – often referred to as prevention of mother-to-child transmission (PMTCT) programs – have historically focused on infant outcomes, rather than both the mother and infant. In fact, PMTCT, itself, is "a name that implies that mothers are the source of the virus, rather than the latest in a long chain of transmission" (Lewis and Donovan, 2009: iv). (This resource primarily uses the term vertical transmission). However, recently there has been a shift to recognize the importance of pregnant women for their own health (Mbori-Ngacha, 2012). "The crucial link between maternal health and infant survival is now broadly recognized and keeping

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mothers alive and healthy is now an explicit goal of global programming to address vertical transmission" (International Treatment Preparedness Coalition, 2011:5).

A 2008 review on child survival and PMTCT reported that child survival depends largely upon the mother's health and survival. Having a deceased mother has been shown to be a significant risk factor for infant mortality (Kurewa et al., 2010; Sartorius et al., 2010) and the survival of young children (Mepham et al., 2011). Caregiver death from HIV is associated with a three- to four-fold increase in mortality for HIV-negative children (Mermin et al., 2008 cited in Leeper and Reddi, 2010). UNICEF now promotes a change of PMTCT programs on "coverage of ARV prophylaxis to the health of mothers and HIV-free survival of children" (UNICEF et al., 2010: 28), of which antiretroviral treatment is a critical component. In the United States, triple combination therapy has resulted in vertical transmission rates of less than 2% (Dorenbaum et al., 2002 cited in U.S. HHS, 2011). Success has been achieved in some resource-limited settings as well, such as in South Africa: of 2,888 HIV infants exposed, the rate of vertical transmission at 8 weeks postpartum was 4% (Goga et al., 2011). In the absence of HAART, women living with HIV suffer from very high rates of morbidity and mortality up to two years postpartum and beyond (Coutsoudis et al., 2010). As of 2011, UNAIDS has the goal of providing 90% of pregnant women in need of antiretroviral therapy for their own health with life-long antiretroviral therapy (UNAIDS, 2011c).

Vertical Transmission Can Occur At Multiple Points

Vertical HIV transmission can occur in utero, during delivery and during breastfeeding (Buchanan and Cunningham, 2009). These are all points for reducing the probability of transmission while also serving as critical points for addressing women's health needs. While it is impossible for an HIV-negative woman to give birth to an HIV-positive infant, it is possible for a woman to seroconvert during her pregnancy; starting her pregnancy as HIV-negative and becoming HIV-positive through sexual transmission from a sexual partner, unscreened blood transfusions, injecting drug use or rape during the course of pregnancy. In some societies, men are encouraged to have multiple partners while their wife/partner is pregnant or breastfeeding which can lead to a woman seroconverting during pregnancy (Ghanotakis, 2010). Studies also show that significant proportions of women who are pregnant suffer from violence (Dunkle et al., 2004; Guo et al., 2004 cited in Tang et al., 2008; Cripe et al., 2008; Ellsberg, 2006), which can be correlated with acquiring HIV. *See also Strengthening the Enabling Environment: Addressing Violence Against Women]* If a woman is recently (acutely) infected, the likelihood of vertical transmission is increased. *[See Antenatal Care: Treatment]*

Transmission can occur during pregnancy, labor and delivery and during the postpartum period, through breastfeeding for two or three years following birth. A woman can acquire HIV before or after the birth of her child and vertical transmission of HIV is still possible as long as breastfeeding continues. If a woman is HIV-positive and breastfeeds,

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because safe drinking water and replacement feeding are not available to her, or to avoid HIV stigma, her infant born HIV-negative can become HIV-positive. However the transmission can be reduced by ART treatment during the breastfeeding period.

The Four Components of Safe Motherhood and Prevention of Vertical Transmission
Prevention of vertical transmission has been categorized into four components, each of which contributes to preventing HIV acquisition and transmission (UNAIDS, 2011c; WHO, 2010k).

Component 1: Preventing Primary HIV Infection in Women
Primary prevention of HIV among women of reproductive age remains critical to any efforts to reduce vertical transmission. Women who remain HIV-negative cannot transmit HIV to their infants. Further, "children whose mothers have died, regardless of the mother's HIV status, are less likely to survive to their fifth birthday than are children of HIV-infected women who are still alive" (Zaba et al., 2005 cited in Heymann et al., 2007a). The programming in *Prevention for Women, Prevention for Key Affected Populations, Prevention for Young People, and Strengthening the Enabling Environment* addresses this first component of preventing primary HIV infection in women.

Component 2: Preventing Unintended Pregnancy Among Women Living with HIV
Preventing unintended pregnancies is a fundamental right for women and can have a significant impact on reducing perinatal transmission of HIV. Once fully informed of her options, a woman can decide about her reproductive choices and make an informed decision about her fertility. The benefits of family planning include preventing unintended pregnancies; reducing maternal and infant deaths; and greater educational and economic opportunities for women (Halperin et al., 2009a). A 2006 modeling study found that for the same cost as treatment with antiretroviral drugs to prevent perinatal transmission, contraceptive use can avert nearly 30 percent more unintended HIV-positive births (Reynolds et al., 2006a). It is estimated that 22 percent of unintended HIV-positive births are already being prevented through current levels of contraceptive use in sub-Saharan Africa (Reynolds et al., 2006a). Women living with HIV often face stigma and discrimination when planning a pregnancy. "One of the neglected areas in PMTCT globally has been the issue of fertility desires and fertility planning for HIV-positive women and their partners" (McIntyre and Lallemont, 2008b: 137). Interventions related to this component are included in this section as well as in *Meeting the Sexual and Reproductive Health Needs of Women Living With HIV*.

Component 3: Preventing Vertical Transmission of HIV During Pregnancy, Delivery and Postpartum
Well-functioning maternal health programs are essential for all women, but particularly for pregnant women living with HIV. Access to preconception care, HIV testing and counseling that guarantees confidentiality, HIV treatment options, and evidence-based

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options in delivery and for postpartum care are critical to meeting the needs of women living with HIV and preventing perinatal transmission. Interventions related to this component are included in this section.

Component 4: Family Treatment – Providing Care, Treatment and Support to HIV-Positive Women, Their Children and Families

Family treatment (also referred to as PMTCT-Plus) refers to programming that aims to reduce vertical transmission as well as to provide ART services before, during and after pregnancy for women living with HIV and to other family or household members. Globally, maternal-child health facilities have traditionally excluded men even though fatherhood is important in almost all societies and women often want the support of their male partners during pregnancy, labor, delivery and the postpartum period. Good maternal health can also be highly dependent on access to HIV prevention, treatment and care for men, as focusing on men in addition to women protects the health of women and, by extension, their children. Interventions related to this component are included in *Treatment*, *Preventing, Detecting and Treating Critical Co-Infections*, and *Care and Support.*

Most PMTCT Programs Focus On Component 3

Recent modeling from data in 25 highly affected countries indicates that to eliminate new child infections by 2015, major progress is needed in all four components (UNAIDS, 2011a). Despite the importance of components one and two in preventing vertical transmission, "for most programs in the field, PMTCT is in fact focused on the program's third and fourth components" (Msellati, 2009:808), with most emphasis, to date, on component three (Padian et al., 2011b: 272). While this section touches on component two, additional information on preventing unintended pregnancies is in *Meeting the Sexual and Reproductive Health Needs of Women Living With HIV*. The majority of this section focuses on component three – safe motherhood and prevention of vertical transmission. The other components are covered, however, in additional sections as noted above.

Men Play An Important Role in Prevention of Vertical Transmission

In addition, another component is needed. Women are at exceptionally high risk of acquiring HIV while they are pregnant and during the postpartum period (Lockman et al., 2011 cited in WHO et al., 2011b), making efforts to keep women HIV-negative during pregnancy and postpartum imperative. Involving men in PMTCT programs—with the permission of women—can be an important way to increase women's uptake of HIV testing, prevention, treatment and care (Ghanotakis, 2010). Traditionally, PMTCT programs have focused on pregnant women and the role of men has been ignored (Mohlala et al., 2011). Research on male support in the context of PMTCT has usually narrowly focused on male attendance at MCH clinics and male uptake of HIV testing (Maman et al., 2011). One study found that men in South Africa support their partners in

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numerous ways – facilitating access to the MCH clinic, with money, food, reminders to go to the clinic, emotional support, childcare, discussions on infant feeding, and infant testing (Maman et al., 2011). But MCH clinics often preclude men attending, either because the hours conflict with work or because of lack of space for men (Maman et al., 2011). Male views on safe motherhood and vertical transmission are lacking (Auvinen et al., 2010). Involving men in PMTCT programs may also help address some of the gender issues that impact women's acquisition of HIV, as well as in accessing to prevention, testing, treatment and care. *[See also Strengthening the Enabling Environment]*

Yet "we need to acknowledge that male involvement may not always be in the best interests of women" (Maman et al., 2011: 330). Some pregnant women in the study in South Africa had valid reasons for not involving men, such as one woman who was quoted: "My baby's father says if he gets HIV, I would be the one to blame…He says he would kill me" (HIV-positive woman cited in Maman et al., 2011: 329).

Recent work has focused on men and fatherhood (Barker et al., 2010a). A number of programs, such as EngenderHealth's *Men as Partners* or Catholic Medical Mission Board's *Men Taking Action* in Zambia are working to increase the positive involvement of men in maternal health care in general, but few evaluated studies were found for PMTCT programs. PMTCT programs may learn from involving men in other reproductive health programming.

What Works in Safe Motherhood and Preventing Vertical Transmission

A number of proven strategies reduce the risk of HIV transmission from mother to child, as well as reduce primary infection in women, and progress has been achieved: the number of children newly infected with HIV in 2009 (370,000) was 26% lower than in 2001 (UNAIDS, 2011a). Provision of contraception to women who wish to avoid pregnancy is a critical step in preventing vertical transmission. Creating preconception care could improve maternal health, family health and reduce vertical transmission. In order to best advise a woman living with HIV about her options for safe motherhood and prevention of HIV transmission to her future child, it is optimal to reach her prior to pregnancy. However, most women become aware of their positive serostatus once they are pregnant, via HIV testing during antenatal care. Confidential HIV testing with counseling during antenatal care that includes women, and with their permission, their partners, is a critical foundation for reducing vertical transmission of HIV. It allows women to know their serostatus, protect their own health and make appropriate decisions to prevent vertical transmission. During antenatal care, HIV testing, treatment options, syphilis screening, malaria prophylaxis and other essential antenatal care must be fundamental services for pregnant women living with HIV. *[See Preventing, Detecting, and Treating Critical Co-Infections]* Access to emergency obstetric care is also essential for pregnant women living with HIV. Maternal use of ARV therapy for her own health saves the lives of both mother and child and reduces orphan deaths in the long term. *[See*

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Treatment and Antenatal Care: Treatment] HAART for pregnant women dramatically reduces perinatal transmission; reduces the risk of resistance to antiretroviral drugs related to monotherapy or duo therapy; and the risk of virological failure of HAART for HIV-positive children (Russo et al., 2009). In 2010, WHO released new rapid advice recommending ARV use for treatment or prophylaxis for pregnant women: http://www.who.int/hiv/pub/mtct/rapid_advice_mtct.pdf.

"Prevention of MTCT [mother-to-child-transmission] of HIV infection cannot be viewed in isolation from optimization of maternal health and survival" (Mofenson, 2010b: S131). Improvement of maternal health services globally will be necessary to reach all women and infants who need services, ensuring safe motherhood and prevention of vertical transmission. "The complex and interrelated challenges of MCH against the devastating global backdrop of HIV require comprehensive models of care that combine HIV/AIDS and MCH initiatives" (Leeper and Reddi, 2010: 2148). "A strong commitment toward both coverage and quality of services is required to serve the many women and infants in need" (Baek and Rutenberg, 2010: 303). "…Practitioners on the ground increasingly recognize that quality HIV care cannot be provided without improvements in TB, antenatal, malaria, outpatient and inpatient care services, and basic administrative systems" (Pfeiffer et al., 2010: 3). PMTCT programs "require attention to strengthening maternal and child services as a whole, synergizing with efforts to avert maternal and neonatal mortality" (De Cock et al., 2011). All the interventions noted in *"What Works, Safe Motherhood*" (Gay et al., 2003) take on additional importance for HIV-positive women [www.policyproject.com/pubs/generalreport/SM_WhatWorksps2.pdf]. For recent evidence and information on maternal health, see also WHO et al., 2011c; WHO, 2010a; WHO, 2009g; WHO, 2006c and the website of the Maternal Health Taskforce: www.maternalhealthtaskforce.org

Not All Of The Science Related to PMTCT Is Resolved

In many respects, programming for PMTCT is quite advanced and yet for some aspects of PMTCT, current research provides incomplete and complex guidance, adding to the ongoing challenge of programming to meet the needs of women and to reduce vertical transmission. Many unknowns remain about HIV in pregnancy and how best to provide appropriate and good care to women and their infants. Topics such as perinatal ARV therapy and breastfeeding continue to raise questions. Some of the scientific evidence points to contradictory conclusions. "…After more than two decades of intensive research into HIV, the precise mechanism or even route of the vertical transmission of the virus remains unknown" (de Vries and Peek, 2008: 679). But pregnancy is a time where many women have multiple contacts with health providers, "creating an opportunity to assess and address women's sexual risk and HIV and STI status" (Kershaw et al., 2006: 310). However, one fact remains clear: it is vital that HIV-positive women are given counseling and support with the most accurate and comprehensive information available to date so that they can make informed decisions about their health and the health of their

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children and that access to ARV should be available for protecting both babies and mothers.

This Section is Organized According to How Women Access Services
The evidence for what works in safe motherhood and preventing vertical transmission is organized according to the way women access health services, particularly maternal health services: prevention of unintended pregnancies, preconception planning; antenatal care (testing and counseling, treatment); delivery; and postpartum. As noted above, other components such as preventing primary HIV infection in women are addressed in the sections. The topic of pediatric HIV treatment is not covered in this website. Improving health systems and providing evidence-based interventions to ensure safe motherhood and prevention of vertical transmission is critical for all women, and especially so for women living with HIV.

A. Preventing Unintended Pregnancies
B. Pre-Conception
C. Antenatal Care:
   1. Testing and Counseling
   2. Treatment
D. Delivery
E. Postpartum

What Works in Safe Motherhood and Prevention of Vertical Transmission

9A. *Safe Motherhood and Prevention of Vertical Transmission:* Preventing Unintended Pregnancies

Reducing unmet need for family planning so that all women who do not want to become pregnant now or in the future have access to contraception could have a significant effect on preventing perinatal transmission of HIV – in part because many women do not know their HIV status. "Increasing voluntary contraceptive use had been an underused approach, despite clear evidence that preventing pregnancies in HIV-infected women who do not wish to become pregnant is an effective strategy for reducing HIV-positive births…The lack of attention to contraception as an effective HIV prevention strategy is particularly disconcerting given that the evidence of contraceptive efficacy is juxtaposed by high levels of unintended pregnancies among women living with HIV. Unintended pregnancies account for 14–58% of all births in countries where the burden of HIV is the greatest" (Wilcher et al., 2008: ii54).

"The broader benefits of reducing unintended pregnancies in women [living with HIV] extend beyond the prevention of new HIV infections in infants: women with access to

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family planning services are able to decide on the number and spacing of their children, to avoid induced abortion (safe and unsafe) and reduce their own chances of acquiring STIs as well as limiting their potential for onward transmission to sexual partners" (Saxton et al., 2010: 2371). Dual-use contraception – using both condoms and an effective contraceptive method – should be promoted for both HIV-negative and HIV-positive people who wish to avoid an unintended pregnancy (McCall and Vicol, 2011).

Additional information about contraception services for women living with HIV, along with linkages to HIV services can be found in *Meeting the Sexual and Reproductive Health Needs of Women Living With HIV* and *Structuring Health Services to Meet Women's Needs.*

9A. What Works—*Safe Motherhood and Prevention of Vertical Transmission:* Preventing Unintended Pregnancies

1. Preventing unintended pregnancies can reduce perinatal transmission.

9A. Evidence

1. **Preventing unintended pregnancies can reduce perinatal transmission.**[1] *[See also Meeting the Sexual and Reproductive Health Needs of Women Living with HIV]*

   - An analysis that modeled the potential benefits of adding family planning to national strategies to achieve universal access to PMTCT found that focusing on unintended pregnancies as well as preventing vertical transmission is highly cost-effective. Modeling was based on 14 countries which contain four-fifths of all HIV-positive pregnant women living in 139 countries: **South Africa, Nigeria, Mozambique, Democratic Republic of Congo, Uganda, United Republic of Tanzania, Kenya, Zambia, Ethiopia, Malawi, Zimbabwe, India, Cameroon,** and **Côte D'Ivoire.** The average level of unmet need for contraception is 23% in these 14 countries and 17% globally. Even if all women in need accessed the most efficacious antiretroviral regimen available, this would prevent 240,000 infant HIV infections in the 14 countries with the highest HIV prevalence (300,000 globally) at a cost of US$131 million (US$208 globally). However, almost 72,000 infant infections would still occur in the

[1] Although this evidence is based on modeling, it is based on the well-established correlation between contraceptive use and fertility rates using a linear regression of the contraceptive prevalence rate (CPR) on the total fertility rate (TFR) (Ross and Frankenberg, 1993). Included in the total fertility rate is unintended pregnancy, including among women who are HIV-positive and may or may not know their status. Therefore expanding access to contraception among all women will result in a reduction in unintended pregnancy, including among women who are HIV-positive and do not know their status when they get pregnant. The analysis by Reynolds et al., 2008 also assessed the cost per HIV-positive birth averted by family planning and PMTCT services. However because the analysis compared the cost of family planning with the cost of nevirapine, which is no longer recommended for us in PMTCT programs, that part of the analysis is not included here.

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14 countries (over 90,000 globally). Preventing unintended pregnancies costs only US$26 million in the 14 countries (over US$33 million globally). Costs of treatment were based on 28 weeks of ARVs, including AZT, 3TC, and sdNVP. (Halperin et al., 2009a) (Gray V) *(pregnancy, PMTCT, contraception, South Africa, Nigeria, Mozambique, Democratic Republic of Congo, Uganda, Tanzania, Kenya, Zambia, Ethiopia, Malawi, Zimbabwe, India, Cameroon, Côte d'Ivoire)*

- In the fifteen PEPFAR countries, **Botswana, Mozambique, Namibia, South Africa, Zambia, Ethiopia, Kenya, Rwanda, Tanzania, Uganda, Côte d'Ivoire, Nigeria, Guyana, Haiti and Vietnam**, the annual number of unintended HIV-positive births currently averted by contraception use is over 220,000. Unintended births are composed of both those that were unwanted (i.e. wanted no more children) and those that are mistimed (i.e. pregnancies that were wanted later). This analysis used estimates of (1) contraceptive and HIV prevalence; (2) the number of women of reproductive age; (3) the number of annual births to HIV-infected women; (4) the rates of pregnancy and vertical HIV transmission; and (5) the proportions of unintended and unwanted births. The product of these estimates is the number of HIV-positive births currently averted by contraceptive use and the number of unwanted and unintended HIV-positive births (Reynolds et al., 2008). (Gray V) *(pregnancy, contraception, PMTCT, Botswana, Mozambique, Namibia, South Africa, Zambia, Ethiopia, Kenya, Rwanda, Tanzania, Uganda, Côte d'Ivoire, Nigeria, Guyana, Haiti and Vietnam)*

- A study by the US CDC in **Uganda** found that unwanted pregnancies may account for almost a quarter of all HIV-positive infants in Uganda. "Satisfying family planning needs should be seen as an additional key PMTCT strategy. Estimation of the contribution of unmet family planning needs was done through Spectrum, a UNAIDS/WHO demographics software by entering the official national adult HIV prevalence; ARV uptake for PMTCT; total fertility rate and the wanted total fertility rate (the total fertility rate after removing unwanted fertility). In 2006, the authors estimated 100,900 women with HIV were pregnant with 19,200 vertical transmissions, 44,900 children needing ART and 16,700 pediatric AIDS deaths. PMTCT averted an estimated 1,200 vertical infections, 700 children needing ART and 2,000 AIDS deaths. The projected scale up from 2006 to 2015 of PMTCT based on single dose nevirapine may avert 23,100 deaths, whereas unmet family planning needs may account for a projected 33,800 infections; 4,700 children needing ART in 2015 alone; and 20,500 deaths. Between 2008 and 2012, family planning will reduced the need for pediatric ART by 13.1%. Every day, family planning averts approximately 20 vertical infections and 9 pediatric deaths. In addition, improved access to family planning would reduce the high maternal mortality and abortion rates, which are illegal and "are often carried out informally with greater risk for the mother" (Hladik et al., 2009: 6). (Gray V) *(pregnancy, contraception, family planning, PMTCT, Uganda)*

- A demographic model using data from 25 low- and middle-income countries—where 91% of HIV-positive pregnant women live—found that if in addition to providing 90% of HIV-positive pregnant women with ART or more effective ARVs as recommended by WHO, new HIV infections among reproductive age women were reduced by 50% and unmet need for family planning for HIV-positive women was eliminated, these interventions would avert approximately 1,174,000 of 2.1 million new child HIV infections between 2010 and 2015, resulting in a 73% overall reduction in new child infections between 2009 and 2015. If no ARV prophylaxis were provided to prevent vertical transmission, an estimated 454,000 infants would acquire HIV; with the same 2009 levels of ARV prophylaxis, 367,000 infants would acquire HIV, and if 90% of women were reached with services matching 2010 WHO guidelines, primary new infections among women was reduced by 50% and the unmet need

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for family planning was eliminated, only 95,000 infants would acquire HIV by 2015. Approximately 36 million unintended births between 2010 and 2015 would be avoided and 1,209,000 fewer HIV-positive pregnant women would required ARVs (Mahy et al., 2010a) (Gray V) (*pregnancy, treatment, PMTCT*)

9A. Gaps in Programming—Reducing Unintended Pregnancies

1. Additional efforts are needed to provide information and more contraceptive options to women living with HIV (or whose serostatus is unknown) who do not desire to have a child or wish to space the next pregnancy.
2. Programs must adhere to the longstanding international agreement to voluntarism, informed consent, and ensuring the right of individuals and couples to decide freely and responsibly the number and spacing of their children.
3. Providers need training on meeting the contraceptive needs of women and couples with HIV, including providing non-directive, informed choice counseling and reducing stigma and discrimination for women living with HIV.
4. Interventions to increase dual protection and dual method use are needed.
5. Efforts are needed to capitalize on opportunities to integrate family planning and HIV services.
6. Policy guidelines, including in service delivery guidelines, need to specify how family planning should be addressed in HIV prevention, treatment and care.
7. Women living with HIV need information and access to services for emergency contraception and post-abortion care (PAC) services.
8. Additional strategies are needed to address the cultural, gender and other contextual barriers that influence the behavior or decisions of people living with HIV to engage in unsafe sex.
9. Interventions are needed to meet the contraceptive needs of different groups of women who are living with HIV, such as sex workers, migrants, young women, etc.

1. **Additional efforts are needed to provide information and more contraceptive options for women living with HIV (or whose serostatus is unknown) who do not desire to have a child or wish to space the next pregnancy.** *[See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]*

2. **Programs must adhere to the longstanding international agreement to voluntarism, informed consent, and ensuring the right of individuals and couples to decide freely and responsibly the number and spacing of their children.** *[See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]*

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3. **Providers need training on meeting the contraceptive needs of women and couples with HIV, including providing non-directive, informed choice counseling and reducing stigma and discrimination for women living with HIV.** *[See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]*

4. **Interventions to increase dual protection and dual method use are needed.** *[See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]*

5. **Efforts are needed to capitalize on opportunities to integrate family planning and HIV services.** *[See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]*

6. **Policy guidelines, including service delivery guidelines, need to specify how contraception should be addressed in HIV prevention, treatment and care.** *[See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]*

7. **Women living with HIV need information and access to services for emergency contraception and post-abortion care (PAC) services.** *[See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]*

8. **Additional strategies are needed to address the cultural, gender and other contextual barriers that influence the behavior or decisions of people living with HIV to engage in unsafe sex.** *[See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]*

9. **Interventions are needed to meet the contraceptive needs of different groups of women who are living with HIV, such as sex workers, migrants, young women, etc.** *[See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]*

9B. *Safe Motherhood and Prevention of Vertical Transmission:* Pre-Conception

Although many women do not learn their HIV status until they become pregnant, for those women who know they are HIV-positive prior to choosing to become pregnant, pre-conception assessments may inform both her and her partner of the safest way to become pregnant without HIV transmission to the infant or HIV transmission between serodiscordant couples. Therefore, throughout their reproductive years, women living with HIV need ongoing comprehensive pre-conception care that is incorporated into

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primary care services so they can make informed choices about pregnancy prior to conception.

Many Women Living with HIV Want Children, and Many Do Not

A study of 1,433 HIV-positive women on treatment in Cameroon in 2007 found that more than half wished to have a child or another child in the future (Marcellin et al., 2010a). Focus groups in South Africa found men and women to be very careful in weighing the choice to have a child and acutely mindful of the long-term consequences for themselves, their partners and their future child (London et al., 2008); however studies have found that women and men living with HIV do not always seek pre-conception counseling due to fear of stigmatization by health care providers. Many women living with HIV face heavy pressure from providers and others not to become pregnant (Orner et al., 2011a; Orner et al., 2010), including pressure for sterilization procedures. *[See Meeting the Sexual and Reproductive Health Needs of Women Living with HIV]* For people who living with HIV, marrying and having children offer the opportunity to lead normal lives. For women who are living with HIV, it may be possible to keep their positive serostatus confidential, but it is not possible to hide whether or not one is married or has children (Smith and Mbwkwen, 2010). Stigma is a large obstacle that must be overcome in order to minimize the risk of perinatal transmission at the earliest possible point.

Fertility may be reduced among women who are living with HIV, but it is unclear whether this is related to non-biological factors such as reduced sexual exposure as a result of marital dissolution that sometimes occurs when a woman tests positive for HIV (Chen and Walker, 2010; Magadi and Agwanda, 2010). A review in 2010 of literature on this topic for South Africa concluded that HIV does result in reduced fertility (Basu et al., 2010). Another study in South Africa found that among 674 women, those women living with HIV were much less likely to want to have children, even with access to HAART: 31% of HAART users wanted children, 29% of those not on HAART wanted children but 68% of women without HIV wanted children (Kaida et al., 2011). While there is no direct biological reason concerning why HIV-positive women may be less fertile, people living with HIV are at increased risk of also acquiring other sexually transmitted infections (STIs) and STIs have been correlated with infertility (Hardee et al., 2012). *[See also Prevention for Women: Treating Sexually Transmitted Infections]*

There is Conflicting Evidence Regarding the Risk of Acquisition During Pregnancy

Women should also know that studies conflict regarding an increased risk of HIV acquisition during pregnancy (Reid et al., 2010; Morrison et al., 2007; Gray et al., 2005), but that pregnancy does not increase the risk of early death (Allen et al., 2007a). A recent study has shown that even after adjusting for unprotected sex and contraceptive use, pregnancy was associated with a two-fold increased risk of HIV transmission from the female to male partner (Mugo et al., 2011). Ensuring that a pregnant woman has initiated

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antiretroviral therapy prior to becoming pregnant can reduce transmission to her HIV negative male partner. *[See also Antenatal Care: Treatment]* "Early initiation of ART is important to achieve undetectable viral load well before delivery; thus, women should be encouraged to plan pregnancies and attend antenatal care sufficiently early to diagnose HIV infection, assess the HIV stage, and initiate ART or antiretroviral prophylaxis as soon as possible" (Kesho Bora Group, 2011: 179). In addition, because TB is a risk factor for increased vertical transmission (Gupta et al., 2011), women living with HIV who wish to conceive should be considered for routine TB preventive therapy (Marais, 2011). In the future, pre-exposure prophylaxis may be used by women without HIV to reduce the risk of HIV transmission by HIV-positive male partners so that women could become pregnant while reducing their risk of acquiring HIV *[See also Prevention for Women],* though safety needs to be assessed (Mastro et al., 2011).

Providing serodiscordant couples with preconception counseling is an especially urgent need. Though a meta-analysis of studies from both high and low-resource settings found no relationship between pregnancy and HIV disease progression, "HIV sero-discordant couples face complicated choices between fulfilling reproductive desire and risking HIV transmission to their partners and children" (Matthews et al., 2010: 1975). One study found an increased risk of HIV seroconversion in discordant couples in which the woman became pregnant, suggesting that the intention to conceive may increase the risk of HIV acquisition (Brubaker et al., 2010). A review of pre-conception options for serodiscordant couples recommended that peak fertility may be achieved through pre-exposure prophylaxis and timed unprotected intercourse, along with screening and treatment of STIs, male circumcision and delayed conception until the HIV-positive partner is on treatment and virally suppressed with CD4 counts higher than currently recommended for HIV treatment in resource-poor countries (Matthews et al., 2010). Self-insemination can minimize the risk of transmission to partner and infant when a woman is HIV-positive and her partner is seronegative. When HIV transmission to the male partner is to be avoided, self-insemination of ejaculated sperm is advised. "…the data on the safety of unprotected intercourse in the HIV-infected serodiscordant couples attempting to conceive are rather limited…" (Semprini et al., 2008: 374). A report in Chile found that an HIV-positive woman used artificial insemination from her HIV-negative husband and gave birth to a healthy HIV-negative infant (Vivo Positivo and Center for Reproductive Rights, 2010). Fertility guidelines have been developed in South Africa by the HIV Clinicians Society to assist clinicians in low- and medium-resourced settings to discuss

> *"It is also important to know your status even before you become pregnant so that you can at least know the ways of not letting the baby get infected."*
>
> —Kenyan woman *(Center for Reproductive Rights and Federation of Women Lawyers – Kenya, 2007)*

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conception between HIV-discordant couples (Bekker et al., 2011 cited in Mastro et al., 2011).

Pre-Conception Care Can Protect Women's Health

Pre-conception care should include counseling on barrier methods of family planning to decrease transmission of HIV and prevent secondary infection, skills to negotiate condom use, assessment of a woman's nutritional status, education and counseling on perinatal HIV transmission and pregnancy risks, and support and counseling for partner disclosure on HIV status before pregnancy. "One of the difficulties in counseling serodiscordant couples on natural conception involving unprotected intercourse is that the risk to the uninfected partner is difficult to quantify but can certainly not be quoted as zero" (Fakova et al., 2008). If both partners are HIV-positive, there is a potential that one partner can acquire superinfection, one that is possibly drug-resistant, from the other partner, and artificial insemination can be considered (Sherr, 2010). Specific recommendations include for health care providers to "ask about pregnancy intentions to every woman, every visit," and to discuss "the risks and effects of pregnancy on…[preexisting] medical condition[s], and the effects of the medical condition on pregnancy outcomes…so that the patient can make an informed decision about becoming pregnant… Education and counseling for HIV-infected women about perinatal HIV transmission risks, strategies to reduce those risks, the potential effects of HIV or its treatment on pregnancy, and the risk of transmission during breastfeeding, allows patients to be fully aware of the issues concerning HIV infection and pregnancy before conception" (Aaron and Criniti, 2007).

"For those with access to fertility centers, longitudinal data show that conception can occur with a very low risk of HIV transmission… While the experience with assisted reproductive health technologies is encouraging, access to these treatments remains limited even for those individuals in resource-rich settings… Teaching couples about ovulation and intercourse timed to fertile periods offers a means for decreasing the number of unprotected sexual encounters" (Matthews and Mukherjee, 2009: S7).

While maternal health services traditionally do not provide pre-conception care but rather start once a woman is pregnant with antenatal care, women with HIV can benefit from pre-conception care. As PMTCT programs are scaled up, including pre-conception care as part of maternal health services should be considered. Increasingly, services will also be needed to provide counseling and support for perinatally infected adolescents who will want to know their options for pregnancy, birth and infant feeding to minimize the probability of transmission to the infant and yet protect their own health (Birungi, 2009a,b). Maternal health providers often lack the knowledge needed to guide women living with HIV through a safe pregnancy process and may discriminate against women living with HIV. Training is needed to ensure that providers will support women's choices in reproductive health. [*See also Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]* Existing guidelines in countries such as South Africa,

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Canada and the United States (Bekker at al., 2011; US HHS, 2011; Loutfy et al., 2012) could possibly be adapted for wider use, depending upon country contexts.

9B. What Works—*Safe Motherhood and Prevention of Vertical Transmission:* Pre-Conception

Promising Strategies:

1. Discussing the risk of vertical transmission with providers and/or other HIV-positive women with seronegative children can increase women's confidence about preventing vertical transmission of HIV.
2. When a couple is serodiscordant or both male and female partners are HIV-positive and wish to conceive, having an undetectable viral load and limiting unprotected sex to peak fertility (with the possible use of pre-exposure prophylaxis) may result in the lowest risk of perinatal transmission.
3. Sperm washing may be used for an HIV-negative woman wishing to become pregnant with an HIV-positive male partner without acquiring HIV herself.

9B. Evidence

Promising Strategies:

1. **Discussing the risk of vertical transmission with providers and/or other HIV-positive women with seronegative children can increase women's confidence about preventing vertical transmission of HIV.**

   - A 1999-2001 study carried out with 329 HIV-positive women in **Thailand** found that some pregnant HIV-positive women (number not specified) who were originally advised to abort by providers (number not specified) but were then counseled on PMTCT subsequently chose to access PMTCT and have a child. One woman said: "A doctor told me about AZT and its effectiveness, that for every 10 children, only 3 to 5 children would contract HIV [an erroneous statement]. I wanted to try. I really needed my child so the information I learned from the doctor made me happier and I decided to keep my pregnancy and wait for the day that I would meet my child" (p. 39). The women were interviewed using a structured questionnaire. In-depth interviews were conducted among 60 HIV-positive women. Four participatory workshops were held on data analysis and report writing. Women interviewed were selected non-randomly from support groups, clinics, ANC clinics, NGOs and communities using dimensional sampling method. The dimensions used were age (15-25, 26-35, 36-49) and number of years from diagnosis. Women who met the criteria for both dimensions were selected based on convenient or snowball sampling techniques. Six focus group discussions were held with six to eight men (Yoddumnern-Attig et al., 2004). (Gray IV) *(PMTCT, Thailand)*

   - Evaluation of the mothers2mothers (m2m) program in **South Africa** found that the m2m program provided a strong continuum of care to the women and infants. Compared to non-participants, m2m participants had greater psychosocial well-being and greater use of PMTCT

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services and outcomes. Postpartum program participants were significantly more likely to have disclosed their status to someone than non-participants, and to have done so prior to delivery. m2m seeks to reduce PMTCT, empower pregnant and postpartum women to improve their health and the health of their babies, fight stigma and encourage and support disclosure. The program offered education and psychosocial support to HIV-positive pregnant women and new mothers, assisted women to access PMTCT services, and followed up to ensure care of mothers and infants after delivery (Baek et al. 2007). (Gray IV) *(PMTCT, support groups, South Africa)*

- A study in **Cuba** found 28 of 55 women interviewed who had given birth in Cuba, said that their worries about transmitting HIV to their child subsided after discussing their pregnancy with doctors, learning about treatment and meeting HIV-positive women who had had HIV-negative children (Castro et al., 2007). (Gray V) *(PMTCT, treatment, Cuba)*

2. **When a couple is serodiscordant or both male and female partners are HIV-positive and wish to conceive, having an undetectable viral load and limiting unprotected sex to peak fertility (with the possible use of pre-exposure prophylaxis) may result in the lowest risk of perinatal transmission.** *[See also Treatment: Staying Healthy and Reducing Transmission]*

- A 2004-2007 study in **Switzerland** with 53 HIV-serodiscordant couples, with the male HIV-positive, used pre-exposure prophylaxis, HAART and timed unprotected intercourse resulted in a pregnancy rate of 66% after five attempts and 244 documented unprotected events of vaginal intercourse and no instances of HIV transmission to the HIV-negative woman. The HIV-positive male partner was on fully suppressive HAART. Pre-exposure prophylaxis "was used as a theoretical risk reduction strategy in a situation where the a priori risk is considered to be extremely low" (Vernazza et al., 2011: 2007). (Gray IIIb) *(pregnancy, serodiscordant, sexual partners, Switzerland)*

- A 2004-2008 prospective cohort study reported on 143 HIV-positive women in **South Africa** and found that women who conceived while on HAART had a risk of vertical transmission to their infant of 0.7% compared to 5.7% for women who initiated HAART while pregnant. No vertical transmissions to infants occurred from women who received HAART for more than 32 weeks prior to delivery. Women were observed at combined antenatal and antiretroviral clinics at two hospitals in Johannesburg. Mothers and infants were followed until infant HIV testing at 4-6 weeks postpartum (Hoffman et al., 2010a). (Gray IIIb) *(pregnancy,treatment, transmission, South Africa)*

- A study of 68 HIV-positive women in **Saudi Arabia**, with the majority of pregnancies planned "and coordinated with care providers to ensure tolerance, adherence, and response to antiretroviral therapy before conception" (Edathodu et al., 2010: 16) resulted in no infants becoming vertically infected (Edathodu et al., 2010). (Gray V) *(pregnancy, treatment, Saudi Arabia)*

- A 2008 review of the global literature on gynecologic issues for HIV-positive women found that there is a 4.3% probability of transmission within HIV-positive couples trying to conceive using timed intercourse (timing sex without condoms when the woman is most fertile in order to increase the likelihood of pregnancy). Viral load should be undetectable, STIs should be treated and ovulation predictors should be used to accurately time sexual

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contact. However, "there are very little data on which to based recommendations to the HIV-positive seroconcordant couple" (Cejtin, 2008: 726). (Gray V) *(treatment, pregnancy)*

- A randomized three-arm trial of oral pre-exposure prophylaxis among 4,758 HIV serodiscordant heterosexual couples from **Kenya** and **Uganda** was conducted, during which 288 pregnancies occurred. The Data and Safety Monitoring Board recommended discontinuation of the placebo arm of the trial because of the demonstration of the efficacy of pre-exposure prophylaxis. "Given the high efficacy for HIV protection in the Partners PrEP study, PrEP may offer a method for HIV-uninfected women with HIV-infected partners to reduce HIV risk during conception, which warrants further evaluation" (Mugo et al., 2012). (Abstract) *(pregnancy, treatment, pre-exposure prophylaxis, Kenya, Uganda)*

3. **Sperm washing may be used for an HIV-negative woman wishing to become pregnant with an HIV-positive male partner without acquiring HIV herself.**

- Sperm washing isolates HIV-1 free spermatozoa tested for the presence of HIV and different assisted reproductive techniques can be used, such as intrauterine insemination. No cases of seroconversion were shown in 4,000 cycles of sperm washing (Bujan et al., 2007; Barreiro et al., 2006 cited in Coll et al., 2008). (Gray IIIb) *(serodiscordant, sperm washing, pregnancy, Thailand)*

- A study in **Italy** from 2001 to 2003 with 43 couples with seropositive male and seronegative females where sperm samples were washed and used for fertilization resulted in a pregnancy rate of over 51%, with no seroconversion detected (Mencaglia et al., 2005). (Gray V) *(sperm washing, Italy)*

- A Cochrane review concluded that evidence has shown that sperm washing has not led to seroconversion in women or their offspring, but noted that the strength of evidence is limited to observational data (Eke and Oragwu, 2011). (Gray V) *(serodiscordant, sperm washing, pregnancy)*

9B. Gaps in Programming—Pre-Conception

1. Women and their sexual partners need access to comprehensive pre-conception care so they can make informed decisions about pregnancy before conception.
2. Interventions are needed to support the autonomous decision-making of HIV-positive women who are caught between the contradictory pressures of family, community and health care providers.
3. Some HIV-positive men and women would consider adoption.
4. Additional research is needed on the use of pre-exposure prophylaxis to prevent HIV transmission for conception purposes.
5. High dose folates are needed for women of childbearing age on efavirenz.
6. Women and their sexual partners need to know and understand how seroconversion can

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occur during pregnancy.

1. **Women and their sexual partners need access to comprehensive pre-conception care so they can make informed decisions about pregnancy before conception.** Studies found that HIV-positive women could not access pre-conception advice on safer pregnancy options, as health providers discouraged pregnancy. Studies found that significant numbers of pregnant women did not know any way to prevent vertical transmission and face dilemmas with balancing the desire for children with fear of risking acquiring HIV or transmitting HIV to their partner or infant. Studies also showed that women did not understand the relationship between high CD4 counts and reducing the risk of HIV transmission.

    - Gap noted, for example, in **South Africa** (Matthews et al., 2011); **Uganda** (Beyeza-Kashesya et al., 2009); **Kenya** (Awiti Ujiji et al., 2010; Awiti Ujiji et al., 2011); **Mozambique** (Hayford and Agadjanian, 2010); **Vietnam** (Chi et al., 2010a); **South Africa** (London et al., 2008); **China** (Luo and He, 2008); **globally** (Hirsch, 2007; Delvaux & Nöstlinger, 2007).

2. **Interventions are needed to support the autonomous decision-making of HIV-positive women who are caught between the contradictory pressures of family, community and health care providers.** Studies found that HIV-positive women and men need information and social support to make decisions that reflect their own preferences in the face of pressure to bear children. A review of the published literature from 1990 to 2008 found that the refusal of health workers to discuss reproductive options in a non-biased way negatively impacts HIV-positive women. Studies also found that HIV-positive men lacked information on pre-conception and felt they could not request this information from health providers.

    - Gap noted, for example, in **Nigeria** (Smith and Mbakwem, 2010); **Uganda** (Kisakye et al., 2010); **Vietnam** (Oosterhoff et al., 2009; Oosterhoff et al., 2008a); **Brazil** (Paiva et al., 2003); and **South Africa** (Nduna and Farlane, 2009).

3. **Some HIV-positive men and women would consider adoption.** A study found that HIV-positive men and women would consider adopting a child as an alternative to having a biological child.

    - Gap noted, for example, in **South Africa** (Cooper et al., 2009).

4. **Additional research is needed on the use of pre-exposure prophylaxis to prevent HIV transmission for conception purposes.** Knowledge is needed on optimal dosing, teratogenicity, cost, adherence, resistance and risk compensation.

    - Gap noted **globally** (Matthews et al., 2010).

5. **High dose folates are needed for women of childbearing age on efavirenz.** Iron folate prevents neural defects, a potential risk of using efavirenz.

Gay, J., Croce-Galis, M., Hardee, K. 2012. What Works for Women and Girls: Evidence for HIV/AIDS Interventions. 2nd edition. Washington DC: Futures Group, Health Policy Project. www.whatworksforwomen.org

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- Gap noted, for example, in **numerous developing countries** (Ford et al., 2010a).

6. **Women and their sexual partners need to know and understand how seroconversion can occur during pregnancy.** *[See Antenatal Care: Testing and Counseling]*

9C. *Safe Motherhood and Prevention of Vertical Transmission*: Antenatal Care

> *"I planned to get pregnant because my husband and I wanted to have a child. After my doctor informed me that I was infected with HIV, I discussed with my husband about my pregnancy. I was fearful that my child would be infected, but I thought I could accept that chance. Therefore, we made a decision to keep my child" (HIV-positive woman in Thailand cited in Youngwanichsetha et al., 2010: 908).*

Good antenatal care is essential for safe motherhood. Clinical exams, rapid syphilis tests, tetanus toxoid, supplementation with iron and folic acid are all considered the standard of care for pregnant women (Villar et al., 2001). Of critical importance is to inform women, their partners, families and communities of the danger signs during pregnancy and ensure access to emergency obstetric care. Antenatal care is also an opportunity for HIV counseling and testing. Women who test HIV-negative still need information and support to remain HIV-negative. *[See Prevention for Women, Prevention for Key Affected Populations, and Strengthening the Enabling Environment]* Women who test HIV-positive need to be informed of their treatment options, both for their own health and to prevent vertical transmission. Women who test HIV-positive also need information and counseling concerning infant feeding options. Improving quality of care in maternal health services can increase the likelihood that women will go to health facilities in case of obstetric emergencies, thus increasing the chances of positive maternal and infant health outcomes (Gay et al., 2003). Women living with HIV also need sexual and reproductive health services and treatment for critical co-infections. Further efforts are needed to screen and treat pregnant women for co-infections that potentially increase mortality for women and their infants**.** *[See also Meeting the Sexual and Reproductive Health Needs of Women Living With HIV* and *Preventing, Detecting and Treating Critical Co-Infections]* "Given that the primary users of antenatal services in sub-Saharan Africa are young women under the age of 30 years, transforming delivery of PMTCT programs with greater emphasis on couple counseling, preventing unwanted pregnancies, keeping HIV-negative mothers uninfected, early initiation of HIV-infected mothers on antiretroviral treatment and ensuring safe infant feeding practices could make a substantial difference to current maternal and infant mortality rates and life expectancy patterns in women in these settings" (Abdool Karim et al., 2010: Se 125-126).

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Syphilis co-infection can be especially dangerous in pregnancy, particularly for HIV-positive pregnant women. There is some evidence that HIV-syphilis co-infection may increase the risk of perinatal HIV transmission. While numerous countries have policies to provide universal screening for syphilis for pregnant women, not enough women are actually screened and treated in practice. In 2007, WHO estimated that syphilis prevalence in pregnant women in Africa ranges from 4–15% (WHO and UNAIDS, 2007). As a result, infants are dying from syphilis despite access to ARVs for mothers and infants (Peeling et al., 2004). Universal screening and treatment for syphilis in pregnancy could prevent 492,000 syphilis-related stillbirths and perinatal deaths per year in sub-Saharan Africa (Saloojee et al., 2004). Syphilis testing and treatment in conjunction with HIV testing can prevent congenital syphilis and may reduce HIV transmission. Screening for TB in pregnancy, especially in settings of high HIV prevalence, is also needed (Mnyani and McIntyre, 2010; Smart, 2012a).

Antenatal care is also an opportunity to discuss with pregnant women and their partners the benefits of infant male circumcision, which may reduce HIV acquisition and transmission when the infant becomes sexually active. Male circumcision has now been shown in three randomized clinical trials to reduce the risk of HIV acquisition for men by 50–60% (Auvert et al., 2005; Bailey et al., 2007; and Gray et al., 2007). Male circumcision at birth as part of postnatal care could result, upon sexual initiation and for his lifetime, in a reduction in the risk of HIV acquisition and transmission (Weiss et al., 2009; Nagelkerke et al., 2007). *[See also Prevention for Women: Voluntary Medical Male Circumcision]*

"Structural factors in country health systems are one of the largest challenges to implementing effective programs for prevention of MTCT of HIV infection. At the country level, maternal, newborn, and child health services, in which programs for prevention of MTCT are targeted, are usually separate from programs, laboratories, and services for treatment and care of HIV infection. Thus, antepartum and postpartum care systems are not equipped to test all women for HIV, conduct CD4 cell count testing to stage disease in HIV-infected women, and provide antiretroviral treatment to women who need it and antiretroviral prophylaxis to others" (Mofenson, 2010a: S144). *[See also Structuring Health Services to Meet Women's Needs]*

9-1. *Safe Motherhood and Prevention of Vertical Transmission:* Testing and Counseling

In 2007, only an estimated 18% of pregnant women were offered HIV tests (International Treatment Preparedness Coalition, 2009). "The purpose of antenatal VCT [voluntary counseling and testing] should be to help a woman prepare for a possible positive HIV diagnosis [and] to provide her with information about PMTCT options (de Bruyn and

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Paxton, 2005: 145). In developing country settings, between eight and ten percent of women report having received PMTCT interventions (Pai and Klein, 2009).

HIV Testing for Pregnant Women Must Respect Their Rights

> *"I revealed my status to my partner...my partner helped me through this difficult time, we became highly dependent on each other as we were both HIV+ and thanks to the medication the children are HIV-negative" (Woman patient on ARVs in South Africa, cited in Gilbert and Walker, 2010: 142).*

Until recently, testing and counseling had been offered based on opt-in principles that relied on women to seek counseling and testing. Many programs have now shifted to routine or "opt-out" testing in which clients are routinely tested in various health care settings unless they decide not to be tested. *[See HIV Testing and Counseling for Women]* "The rationale behind the switch to opt-out testing is that stigmatization will be decreased (that is, women do not feel they are singled out for HIV testing if everyone undergoes the test) and higher percentages of women are then tested" (de Bruyn, 2005: 4). Additional rationales for opt-out testing are that opt-out testing is less resource intensive to scale-up and thus can be made available to more women (WHO and UNAIDS, 2007) and also that there is a public health argument for testing as many women and men as possible so that appropriate prevention and care services can be provided with regard to status (de Cock et al., 2003). "A disadvantage of opt-out testing is that it may be routinely imposed and women may not realize they can refuse the test or dare to do so…" (de Bruyn, 2005: 4). This practice must be carefully monitored to ensure women's rights are respected. A recent study among pregnant women in Ukraine found that providers told women that they had to get HIV testing in order to access financial support during antenatal care. But even if pregnant women refused testing, their child would be tested: "If I refuse to be tested for HIV, then once my child is born he will be tested for HIV irrespective of my consent" (Finnerty et al., 2010: 22).

Steps Must be Taken to Avoid Negative Repercussions for Women Who Test During Pregnancy

Women have often received HIV tests as part of PMTCT programs. While women are often faced with opt-out testing or even mandatory testing during antenatal care, men rarely access health care in situations where they would be subjected to opt-out or mandatory testing. "The ethics of routine testing has a conspicuous gender dimension...women and girls are more likely to present at formal health care services than are men and hence are more likely to come under a routine testing policy. Women and girls are also the most likely to face stigma, violence and abuse when their HIV-positive status becomes known…." (Rennie and Behets, 2006: 84).

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> "There is a great difference between VCT and testing and counseling during pregnancy. In the first case, the woman wants to know her HIV status…In the second case, the pregnant woman has come to learn how her pregnancy is developing…Learning her HIV-positive status this way can be a very difficult experience"
> -Msellati, 2009: 808

While routine testing is showing some promising signs of being acceptable and feasible, it is important to ensure that routine testing does not discourage women from seeking needed medical care or cause unanticipated outcomes for women, such as increased violence. Opt-out testing, while showing an increase in the number of women who are tested during antenatal care, raises concerns about whether women living with HIV will avoid antenatal care services in order not to be tested (Druce and Nolan, 2007). A special analysis of pregnant women in India found that women often go to a different facility than the one nearest to where they live for HIV testing (Kandwal et al., 2010), possibly to avoid HIV stigma and to ensure confidentiality. Other recent qualitative studies have found that women avoid antenatal care altogether in order not to test for HIV, or as one woman from Soweto, South Africa put it: "I didn't book at an antenatal clinic because I was afraid that they would test me for HIV" (Woman cited in Laher et al.,2012: para 33). Some studies have shown that testing in violation of human rights standards discourages women from accessing services or may lead to increased violence against women (Turan et al., 2008a; Bwirire et al., 2008; Zabina et al., 2009; PHR, 2007a; Center for Reproductive Rights and Federation of Women's Lawyers, Kenya, 2007; HRW, 2003b). Women have reported adverse events following testing at antenatal care: "…When I came to this antenatal clinic, I was tested for HIV and found to be positive. When I went home and disclosed my status to my husband…he left me" (Twenty year old mother of two in Malawi, cited in Ostergaard and Bula, 2010: 216).

A recent study in Tanzania found that of 426 pregnant women, women have little authority, with 78.6% reported that they had asked their partners for permission to get an HIV test. A pregnant wife asking to use condoms was seen as endangering the marriage as this was a decision to be made only by the husband (Falnes et al., 2011). "Deep-seated ideas about gender roles emerged as a bigger challenge to partner testing" (Falnes et al., 2011, para 33). Only 3% of male partners accessed testing. One man stated: "Generally our women should not tell us men what to do, even though the advice comes from the doctor" (Male in Falnes et al., 2011: para 34), with men admitting that if their pregnant wife tested HIV-positive, they would blame her, and "chase her out" (Falnes et al., 2011: para 44). Other men however, said if their pregnant wife tested HIV-positive, "If only she is infected, I will care for her till the end." (Falnes et al., 2011: para 46). Yet, despite the increased risk for violence during pregnancy, few PMTCT programs include risk assessments or services for violence (Betancourt et al., 2011). *[See also Strengthening the Enabling Environment: Addressing Violence Against Women]*

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In addition, voluntary consent is called into question when the first time women are offered testing is during labor and delivery (Center for Reproductive Rights, 2005). Yet numerous research studies conducted in Brazil, Mexico, Cameroon, Russia, Rwanda, Nigeria, Uganda, Zambia, Peru and India have demonstrated successful implementation of a rapid HIV testing program in labor and delivery (Kissin et al., 2008; Rahangdale et al., 2007; Sagay et al., 2006 cited in Pai and Klein, 2009). The impact of rapid testing during labor and delivery for the HIV-positive woman has yet to be assessed, however (Jurgens et al., 2007a). Further evaluation of routine and provider-initiated testing is urgently needed to assess whether informed consent and confidentiality is adequately protected (Gruskin et al., 2008a).

HIV Counseling for Both Men and Women Is a Critical Component of Antenatal Care

Counseling on safer sex during pregnancy should be an important part of HIV testing. "…Parents desire healthy children and are willing to modify their behavior to protect them from harm" (Tavengwa et al., 2007: 101). Male partners and/or husbands can influence whether a woman accesses HIV testing (Ghanotakis, 2010). It is therefore critical to involve the male partners of pregnant women—with women's consent. Some ANC clinics and maternity hospitals have no place (literally) for men; and health workers in maternal health clinics rarely have received training in addressing male partners. "In addition, many men believe that their wives' HIV test results would mirror their own. Mass information campaigns should address this incorrect belief" (Msellati, 2009: 809). National guidelines can help. In Rwanda, national guidelines to encourage HIV testing for male partners of HIV-positive women in antenatal care has resulted in 81% of male partners getting tested for HIV (WHO et al., 2011b).

> *"Yes, (he agreed to use a condom) for the sake of the baby" (HIV-positive pregnant woman, cited in Matthews et al., 2011).*

Women are vulnerable to seroconversion during pregnancy. In a study in South Africa, 3.4% of 1,396 women seroconverted during pregnancy or within 12 months after delivery with much higher rates of vertical transmission: 20.5% compared to 9% of women who were not recently infected, a 2.3 greater risk of vertical transmission. Yet only 20% of those recently infected would have qualified for HAART with CD4 counts under 350, suggesting that all women who seroconvert during pregnancy should have access to HAART. However, it is challenging to identify recent seroconversions. *[See HIV Testing and Counseling for Women and Treatment]* None of 1,396 women reported condom use during pregnancy. Recent seroconversion was correlated with financial dependency. Women "…remain vulnerable during pregnancy and postnatally in settings where social norms and economic conditions encourage short-term relationships and multiple partners" (Moodley et al., 2011: 2031). *[See Strengthening the Enabling Environment]*

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For HIV-negative pregnant women, avoiding unsterilized needles, avoiding blood transfusions which have not been screened for HIV; and continued condom use and/or mutual monogamy with one HIV-negative sexual partner are ways remain HIV-negative during the course of pregnancy and the postpartum period. However, fear of violence and lack of ability to assert control, such as feeling forced to have sex, may make it even more difficult for pregnant women to request condom use, as condoms cannot be talked about in the context of contraception (Kershaw et al., 2006). "…Healthcare providers need to address the issue of postpartum sexual activity and contraception early after delivery or even late in the last trimester to provide women with the appropriate knowledge to allow them to make informed decisions regarding their reproductive futures" (Balkus et al., 2007: 28).

For women who test positive, counseling is especially necessary during this time. Providers should also not place undue burdens on women who test positive. For example, in Ethiopia, women who test HIV-positive are told to inform their husbands to come to health services to get tested for HIV (CHANGE, 2009). Dealing with stigma is especially difficult. "…Coping with HIV-related stigma…is especially challenging during pregnancy and postpartum, when women may be preoccupied not only with the physical and psychological effects of having HIV, but also with preventing HIV transmission to their infants and/or avoiding disclosure of their HIV status to their families and communities" (Brickley et al., 2008). However, within the context of HIV testing, counseling is "not simply a human rights imperative: it is a medical intervention that is vital to support pregnant women with prevention efforts, disclosure, living with a life-threatening virus and adherence to treatment" (Gruskin et al., 2008a: 29).

Confidentiality Must Be Maintained

Confidentiality of all test results should be paramount, yet it is not always followed in practice. Stronger efforts are needed to ensure that provision of HIV test results of pregnant women to their male partners or anyone else should only be done with women's expressed permission. Criminal liability for unauthorized disclosure of HIV test results can be one way to increase women's confidence that HIV tests will be confidential: a qualitative study with semi-structured interviews with 25 medical providers and 60 pregnant women who had been tested in the past 60 days plus in-depth interviews with 30 women about HIV testing during their pregnancy in Ukraine found that "most women reported that they were not afraid of their HIV test results being disclosed to anyone…knowing that the confidentiality of their medical information is protected under Ukrainian law) (Finnerty et al., 2010: 19).

Policies should detail the risks of testing and clarity for women who refuse to test. Also, policies should specify whether parental consent is required to test infants. Pregnant women must have the opportunity to learn their HIV status but the autonomy to decline HIV testing without penalty in the health care setting. Confidentiality of test results is

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critical (Maman et al., 2008c). Women who test HIV-positive should be able to access PMTCT services, with follow-up treatment for herself and her child. HIV testing and PMTCT services have been successfully provided to women in all kinds of setting, including in refugee camps (Rutta et al., 2008). Using community volunteers to provide HIV testing to pregnant women may increase the number of women tested, especially where access to clinics is a challenge, as in Zimbabwe (Shetty et al., 2005).

The following interventions are specifically related to HIV testing and counseling in the context of preventing vertical transmission. Please see also *HIV Testing and Counseling for Women* for additional evidence on what works in HIV testing for all women.

9C-1. What Works—*Safe Motherhood and Prevention of Vertical Transmission:* Testing and Counseling

1. Routinely offered testing *that is voluntary and accompanied by counseling* is acceptable to most women.
2. Involving partners, with women's consent, can result in increased testing and disclosure and may reduce risk of vertical transmission and infant mortality.

Promising Strategies:

3. Informed and appropriate counseling during ANC can lead to increased discussion between partners and increased protective behaviors such as condom use.
4. Testing for and treating syphilis in conjunction with HIV testing for pregnant women will reduce congenital syphilis and can reduce perinatal transmission of HIV.
5. Counseling for both pregnant women and future fathers to circumcise male infants may reduce HIV acquisition and transmission when those male infants become sexually active young men.

9C-1. Evidence

1. **Routinely offered testing *that is voluntary and accompanied by counseling* is acceptable to most women.**

    - A systematic review with ten studies from 1998 to 2009 from antenatal care settings in **Europe, USA, Kenya, Botswana, Zimbabwe, Malawi, Ethiopia and Uganda** found that following the introduction of provider-initiated testing, testing increased by a range of 9.9% to 65.6%, with testing uptake of over 85% in eight studies. When reported, pre-test information was provided to between 91.5% to 100% of the women; post-test counseling was provided to 82% and 99.8% of pregnant women. Linkages for ARVs for PMTCT were reported in five studies and ranged from 53.7% to 77.2%. Where reported, provider initiated counseling and testing was considered acceptable by ANC attendees (Hensen et al., 2012). (Gray II)

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(PMTCT, HIV testing, pregnancy, antenatal care, Europe, United States, Kenya, Botswana, Zimbabwe, Malawi, Ethiopia, Uganda)

- A survey on acceptance of HIV testing was conducted in **Hong Kong**'s maternal and child health centers during a two-month period. The response rate was 98.2% and 2,669 valid questionnaires were analyzed. Seventy per cent (N=1,825) of the respondents indicated their acceptance of the test. A significant association was noted between clients' acceptance and access to HIV information by means of posters, pamphlets, videos and group talks. Perceived benefits and health care workers' recommendation were the main reported reasons for acceptance, whereas no or low perceived susceptibility was the main reason for refusal. Acceptance was also positively correlated with level of education and HIV knowledge (Lee et al., 2005). (Gray IIIb) *(PMTCT, HIV testing, Hong Kong)*

- A retrospective analysis of 54,428 PMTCT records from 2002 to 2009 from a hospital in **Uganda** found that there was a significant increase of HIV testing among new ANC attendees from 22% when the policy was VCT to 88% once the policy had changed to routine testing. However, the numbers of male partners who tested remained low (Byamugisha et al., 2010b). (Gray IIIb) *(PMTCT, HIV testing, antenatal care, Uganda)*

- A cross-sectional survey of 388 women who attended antenatal care in **Uganda** in 2009 found that 98.5% reported positive attitudes towards routine HIV counseling and testing, with 99.5% tested for HIV and 98.5% receiving their same day result. However, some women reported they felt pressured to test for HIV. Women were asked: "Nowadays in this clinic, all mothers are tested for HIV unless they say no. What do you think about this system?" (Byamugisha et al, 2010a). (Gray IIIb) *(PMTCT, HIV testing, antenatal care, Uganda)*

- A 2006 study surveyed 485 pregnant mothers who sought antenatal care at maternity hospitals in **Ecuador** and found that 94.3% of women reported they would accept an HIV test with a physician's recommendation compared to 68.3% who were willing to accept an HIV test regardless (Dearborn et al., 2010). (Gray IV) *(PMTCT, HIV testing, Ecuador)*

- A questionnaire administered to 146 women at 10 PMTCT centers in **Zimbabwe** who were interviewed during the period they were waiting for their HIV test result found that 57% were aware of the routine offer of HIV testing at the health institution they were using, with more than 94% aware that they were having an HIV test among other routine tests. Fifty percent of the women who accepted HIV testing directly after group education were not aware of the possibility of opting for individual pre-test counseling. Seven of the nine women who declined HIV testing did not feel that the offer of routine HIV testing would deter them from seeking ANC services. However, "it cannot be demonstrated from this study whether or not some women are not attending ANC services due to the implementation of routine offer of HIV testing, since this study was conducted among women who were already presenting at the health facilities" (Mugore et al., 2008:663). (Gray V) *(PMTCT, HIV testing, antenatal care, Zimbabwe)*

- "Routine but not compulsory" testing was instituted in **Botswana** after a presidential declaration in 2004. After routine testing started, the percentage of all HIV-infected women delivering in the regional hospital who knew their HIV status increased from 47% to 78% and the percentage receiving PMTCT interventions increased from 29% to 56%. ANC attendance and the percentage of HIV-positive women who disclosed their HIV status to others remained stable. Interviews indicated that ANC clients supported the policy (Creek et al., 2007). (Gray

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V) A study to evaluate the first 2.5 years found that routine HIV testing has been widely accepted by the population. There has been a rapid scale-up of routine testing. A total of 60,846 persons were tested through RHT in 2004 versus 157,894 in 2005 and 88,218 in the first half of 2006. Testing rates in the population through routine testing were 40 per 1000 persons, 93 per 1000 persons, and 104 per 1000 persons, respectively. In 2005, 89% of those offered testing accepted, with 69% of those tested being female and 31% male. The proportion of men who tested HIV-positive was 34% versus 30% for women. The main reasons for testing in 2005 were patient's wish (50%), pregnancy (25%), medical examination (7%), clinical suspicion (6%), and sexually transmitted infection (2%). Attendance at voluntary counseling and testing centers has increased parallel to the scale-up of routine testing. Routine testing has been widely accepted by the population, and no adverse effects or instances have been reported. It has provided increased access to preventive services and earlier assessment for antiretroviral treatment (Steen et al., 2007). (Gray V) *(PMTCT, antenatal care, HIV testing, Botswana)*

- In May 2004, PMTCT services were established in the antenatal clinic (ANC) of a 200-bed hospital in rural **Uganda**; in December 2004, ANC PMTCT services became opt-out, and routine opt-out intrapartum counseling and testing was established in the maternity ward. This study compared acceptability, feasibility, and uptake of maternity and ANC PMTCT services between December 2004 and September 2005 and found that counseling and testing acceptance was 97% (3591/3741) among women and 97% (104/107) among accompanying men in the ANC and 86% (522/605) among women and 98% (176/180) among their male partners in the maternity. Thirty-four women were found to be HIV-positive through intrapartum testing, representing a 12% (34/278) increase in HIV infection detection. Of these, 14 received their result and nevirapine before delivery. The percentage of women discharged from the maternity ward with documented HIV status increased from 39% (480/1235) to 88% (1395/1594) over the period (Homsy et al., 2006). (Gray V) *(PMTCT, HIV testing, antenatal care, Uganda)*

- An exploratory cross-sectional survey was conducted in 6 PMTCT sites in rural **Zimbabwe** to assess the acceptability of opt-out HIV testing. Of 520 women sampled, 285 (55%) had been HIV tested during their last pregnancy. Among the 235 women not HIV tested in ANC, 79% would accept HIV testing if opt-out testing was introduced. Factors associated with accepting the opt-out approach were being less than 20 years old, having secondary education or more, living with a partner, and the existence of a PMTCT service where the untested women delivered. Thirty-seven women of 235 (16%) would decline routine HIV testing, mainly because of their fear of knowing their HIV status and the need to have their partner's consent. Among the 285 women already tested in ANC, 97% would accept the opt-out approach (Perez et al., 2006). (Gray V) *(PMTCT, HIV testing, antenatal care, Zimbabwe)*

2. Involving partners, with women's consent, can result in increased testing and disclosure and may reduce risk of vertical transmission and infant mortality.

- A pre-test/post-test study in **India** between 2000 and 2003 in six antenatal care clinics found that counseling that included male partners of pregnant women had a positive impact on male involvement in maternity care and increased dual protection and condom knowledge and use. Of the six clinics, three were used as intervention sites and three as controls. A total of 2,836 women and 1,897 husbands attending the clinics for antenatal care participated in the pre-test survey, however, only 327 women and their husbands completed the intervention and post-test survey and 302 women and their husbands from the control group completed the post-test

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survey. Women and husbands at the intervention site were counseled at individual, couple, and same-sex group levels on a variety of reproductive health issues, including the prevention of STIs and correct condom use. Pregnant women were screened for syphilis and men identified as having urethral discharge and genital ulcers via syndromic management were treated. Twelve doctors and 12 nurse midwives were trained to provide counseling to both couples and individuals at the intervention sites. Women and husbands who attended the control clinics received the standard care for pregnant women, including nutritional information and tetanus vaccination, but no additional counseling was provided. Knowledge related to dual protection benefits of condom use increased among both males and females in the intervention group, however, gender disparities continued to pervade as 89% of the males exhibited dual protection knowledge compared to only 48% of the females. Use of family planning increased significantly during the six-to-nine months postpartum period among intervention participants when compared to controls, 59% versus 45% among women and 65% compared to 48% among men. Of the methods employed for family planning purposes, condoms were the most commonly used in both groups, as 66% of women in both groups and 71% of men in both groups reported using condoms. Additionally, intent to use condoms in the future was found to be higher among the intervention group than among controls. Men in general tended to have more knowledge related to STIs, 66% versus 32% of females, and knowledge and couple communication related to STIs was not found to have increased after the intervention. Lastly, couples who had attended counseling sessions at the intervention clinics were more likely to discuss family planning with their partners than those attending clinics at the control sites, 84% compared to 64%, and intervention couples were also more likely to report making reproductive health related decisions together, as a couple, than were control couples, 91% versus 71% (Varkey et al., 2004). (Gray II) *(antenatal care, counseling, condoms, STIs, India)*

- A randomized controlled trial in **South Africa** from 2006 to 2007 which compared 1) written invitations for the male partners of pregnant women for VCT and 2) a written invitation for her male partner to attend pregnancy information sessions found that written invitations for VCT that were given by pregnant women to their male partners resulted in increased numbers of men who tested for HIV and decreased reports of unprotected sex during pregnancy with no differences in reports of intimate partner violence between the two groups. However, 17 pregnant women reported intimate partner violence. The interventions were accompanied by community sensitization activities includes flyers and posters in places frequented by men, meetings and radio shows. At one week and twelve weeks after randomization, both men and women were interviewed. The pregnancy information session discussed danger signs for mothers and infants; the VCT session consisted of HIV risk behavior, serodisclosure; benefits of testing; and offered VCT. Men who attended the pregnancy information sessions were offered VCT twelve weeks after randomization. At baseline, no male partner attended ANC with his pregnant partner. Of the 500 pregnant women who agreed to invite their male partners for VCT, 175 brought their partners, of whom 161 of the male partners had an HIV test. Of the 500 pregnant women who agreed to invite their male partners to a pregnancy information session, 129 brought their male partners and 57 of these men had HIV testing, with 32% of men having an HIV test in the VCT group and 11% of men having an HIV test in the pregnancy information group. Men who received a written invitation to attend VCT with their pregnant partners were 2.82 times more likely to have an HIV test compared to male partners invited to a pregnancy information session. The VCT invitation letter was associated with increased male attendance at the ANC clinic. "…Potential secondary benefits of male partner attendance include earlier diagnosis and better treatment outcomes for men… and less transmission to female partners and referral for circumcision for HIV-negative men" (Mohlala et al., 2011: 6). (Gray II) *(HIV testing, antenatal care, pregnancy, South Africa)*

- A 1999-2005 prospective cohort study encouraged 456 HIV-positive mothers attending antenatal clinics to invite male partners to counseling and HIV testing in **Kenya**. During the antenatal period, 31% of men attended a clinic visit (140 of 456). After 12 months follow-up of mother-infant pairs, the study found that vertical transmission risk was over 40% lower for infants of women with partner attendance and with reported previous partner HIV testing than those without, when adjusting for maternal viral load. In addition, when adjusting for maternal viral load and breastfeeding, combined risk of HIV or infant mortality was lower with male attendance and report of prior male HIV test. HIV-negative infants born to women with partners who participated had a 58% lower mortality risk, which after adjusting for infant feeding, was further reduced to 63%. However, if the infant was HIV-positive, infant mortality was higher even for those whose partners attended clinic visits. The study followed mothers with current male partners from 32 weeks gestation until delivery and then followed mother-infant pairs monthly for one year. Mothers filled out questionnaires at enrollment, including information on previous partner testing. According to Kenyan national guidelines, all mothers received zidovudine from 34-36 weeks gestation through delivery. Male partners who attended antenatal visits received counseling on vertical transmission and prevention methods, as well as voluntary counseling and HIV testing. About 54% (75 of 140) of male partners accepted an HIV test at an antenatal visit, 56% (42 of 75) of who tested positive. Women reported that 52% of partners had previously been tested for HIV. About 32% of women intended to formula feed, 78% reported disclosure of status to partner and 49% reported discussing PMTCT with partner. Previous male HIV testing was significantly associated with male partner attendance at antenatal visits (adjusted odds ratio 24.5). Women who reported previous male HIV testing were more likely to formula feed their infants. The study followed 392 infants until 12 months postpartum or death and found that 69% of infants were breastfed (314 of 456) for a median duration of six months. By 12 months of age, 19% of infants (82 of 441) tested HIV-positive, with 27 testing positive by 48 hours after birth. At 12 months, 71 infants had died: 28 who were HIV-positive, 31 who were HIV-negative and 12 with unknown HIV status (Aluisio et al., 2011). (Gray IIIa) *(HIV testing, antenatal care, sexual partners, PMTCT, Kenya)*

- In a study conducted in **Kenya** with 1,993 pregnant women who informed their male partners of the availability of HIV testing, 16% of the men came to the ANC clinic. Among these 313 men, 95% received HIV testing with 62% who were counseled individually and 10% of men testing HIV-positive. At two-week follow up, male disclosure of HIV test results to female partners was reported by both partners in 75 of 106 couples (71%). In the remaining 29 couples, men reported that they shared their test results with their female partner but had not done so according to their female partners. Rates of confirmed disclosure by women were significantly higher than by men, 93% compared to 71%. However, the level of serostatus disclosure by men to women is among the highest reported levels in the literature (Katz et al., 2009). (Gray IIIb) *(HIV testing, antenatal care, sexual partners, Kenya)*

Promising Strategies:

3. Informed and appropriate counseling during ANC can lead to increased discussion between partners and increased protective behaviors such as condom use.

- A study in **Côte d'Ivoire** from 2001 to 2005 with 306 HIV-positive, 352 HIV-negative, and 52 pregnant women who refused HIV testing, found that prenatal HIV counseling and testing

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led to increased discussions between partners regarding STIs and sexual risks, and increased condom use when sexual activity was resumed after delivery. After prenatal counseling and testing, HIV-positive women were enrolled in a PMTCT program and were followed for 2 years. Women who tested HIV-negative and untested women received reproductive health related follow-ups for 2 years. Prior to prenatal counseling and testing, two-thirds of HIV-negative and untested women reported having had discussions about STIs with male partners, while afterwards over 90 percent of women reported discussing STIs, suggesting that their partners be tested for HIV, and encouraging condom use in extramarital sexual relations. For HIV-positive women, discussions about STIs with partners increased from 28 percent to 65 percent, 72 percent suggested that their partners be tested for HIV, and 58 percent encouraged condom use in extramarital relations. Additionally, condom use increased from 36 to 59 percent of HIV-negative women, 52 to 57 percent of untested women, and 23 to 49 percent of HIV-positive women when sexual activity was resumed after delivery. However, data were collected from women only and therefore actual discussions with partners may be overrepresented (Desgrées-Du-Loû et al., 2009). (Gray IIIb) *(pregnancy, counseling, HIV testing, communication, condom use, Côte d'Ivoire)*

- An evaluation of UNICEF-funded PMTCT programs in 11 developing countries in 2002 involving review of progress reports, interviews with PMTCT program managers, rapid assessments in **Rwanda** and **Zambia** and site visits in **Honduras** and **India** found that PMTCT programs did not discourage use of ANC but helped women to disclose their HIV testing experience and serostatus to their partners and family, thus fostering discussions and normalizing HIV testing and HIV care (Rutenberg et al., 2003). (Gray V) *(PMTCT, HIV testing, antenatal care, Rwanda, Zambia, Honduras, India)*

4. Testing for and treating syphilis in conjunction with HIV testing for pregnant women will reduce congenital syphilis and can reduce perinatal transmission HIV. [2]

- 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 a positive maternal syphilis test increased the odds of vertical transmission 3.8-fold compared to a negative syphilis test. 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 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 cell count and gestational age were not found to be associated with infant HIV infection by 12 weeks (Chibwesha et al., 2011). (Gray IIIa) *(syphilis, PMTCT, Zambia)*

- A study from 2003 to 2005 in the **Ukraine** with 521 mother infant pairs with known infant HIV-positive serostatus found an association between maternal syphilis and perinatal

[2] Note: While co-infection with syphilis is associated with increased risk of vertical transmission of HIV, it would be unethical to conduct any study that denied known treatment for syphilis to assess whether giving or withholding treatment increased risk of vertical transmission of HIV.

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transmission. Overall, 3.5% of pregnant women had serological test results that were positive for syphilis. The overall HIV perinatal transmission rate was 5.8% and was statistically significantly higher among women who were seropositive for syphilis. Having antenatal serological test results that were positive for syphilis was associated with a five-fold increased risk of MTCT univariably and a nearly 4.5-fold increased risk adjusting for ARV prophylaxis, premature delivery and elective cesarean delivery (Thorne et al., 2008). (Gray IIIb) *(syphilis, PMTCT, Ukraine)*

- A study to determine the association between maternal syphilis and HIV mother-to-child transmission in a prospective cohort study of pregnant women admitted at Queen Elizabeth Central Hospital in **Malawi** found that maternal syphilis was associated with in utero and intrapartum and postpartum perinatal transmission of HIV. Women admitted in late third trimester were screened for HIV (by HIV rapid tests) and syphilis (by rapid plasma regain test and Treponema pallidum hemagglutination assay). HIV-positive women and their infants received nevirapine, according to the HIVNET 012 protocol. They were followed up at 6 and 12 weeks postpartum. Infant HIV infection was diagnosed by DNA PCR. Of the 1,155 HIV-positive women enrolled, 1147 had syphilis test results, of whom 92 (8.0%) were infected with syphilis. Only 751 HIV-positive women delivered live singleton infants who were tested for HIV at birth. Of these, 65 (8.7%) were HIV-infected, suggesting in utero (IU) HIV MTCT. Of the 686 infants who were HIV-negative at birth, 507 were successfully followed up. Of these, 89 (17.6%) became HIV-positive, suggesting intrapartum/postpartum (IP/PP) HIV transmission. Maternal syphilis was associated with in utero HIV MTCT, after adjusting for maternal HIV-1 viral load and low birth weight (LBW). Furthermore, maternal syphilis was associated with IP/PP HIV MTCT, after adjusting for recent fever, breast infection, LBW and maternal HIV-1 viral load. Screening and early treatment of maternal syphilis during pregnancy may reduce pediatric HIV infections (Mwapasa et al., 2006). (Gray IIIb) *(PMTCT, HIV testing, syphilis, Malawi)*

5. **Counseling for both pregnant women and future fathers to circumcise male infants may reduce HIV acquisition and transmission when those male infants become sexually active young men.** *[See also Prevention for Women: Voluntary Medical Male Circumcision]*

- Randomized, controlled trials have determined the level of protective effect of male circumcision on HIV for men. Male circumcision at birth as part of postnatal care could reduce, upon the infant's sexual initiation and for his lifetime, a reduction in the risk of HIV acquisition and transmission. Male circumcision has now been shown in three randomized clinical trials to reduce the risk of HIV acquisition for men by 50 to 60% (Auvert et al., 2005; Bailey et al., 2007; and Gray et al., 2007). (Gray I) *(male circumcision, transmission)*

- A 2008 study in **Botswana** found neonatal male circumcision to be acceptable to 92% of 60 mothers of newborn boys if performed in a clinical setting, with protection from HIV appearing as a major motivating factor. Before their male infant could be circumcised, 51 (85%) of the 60 pregnant women said "their partner would definitely have to agree to the procedure before their male infant could be circumcised." In order to obtain a diverse sample, postpartum mothers were chosen from maternity wards in the capital city, Gaborone, the town of Lobatse, and the villages of Molepolole and Mochudi. Semi-structured interviews assessing prior knowledge, attitudes, and behaviors regarding male circumcision were administered to the mothers. Preceding the interviews, the mothers were given a pamphlet with an illustration

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of male circumcision and detailed information regarding potential risks and benefits of the procedure. Within a year leading up to the study, 57 (95%) out of the 60 women had been tested for HIV and 21 (35%) reported being HIV-positive. Currently, 15% of men in Botswana have been circumcised, but only rarely as neonates. When asked whether their partner was circumcised, 23 (38%) out of the 60 women reported their partner as circumcised and 2 (3%) did not know if their partner was circumcised. Looking specifically at acceptability, 32 (53%) participants thought circumcision of their male infant would be viewed positively by their community and 2 (3%) thought it would be viewed negatively. When asked about the primary decision maker in regards to circumcision of their male infant, 38 (63%) women indentified themselves and 13 (22%) identified their partner. For those women interested in circumcision for their male infant, 58 women chose a hospital or clinic as the preferred location, while 2 chose "home." When asked who should circumcise their male infant, 56 (93%) women chose a "trained physician" (Plank et al. 2010). (Gray IV) *(male circumcision, transmission, Botswana)*

- "…Circumcision prior to sexual debut [of male adolescents] will render the greatest lifetime protection" (Eaton and Kalichman, 2009:191). (Gray V) *(male circumcision)*

9C-1. Gaps in Programming—Testing and Counseling

1. Further interventions are needed to incorporate violence prevention, screening and counseling services into PMTCT testing and counseling.
2. Additional efforts are needed to improve information and counseling about HIV during ANC to ensure that pregnant women and their sexual partners have adequate information.
3. Additional efforts are needed to ensure confidentiality in testing.
4. Increased support is needed for HIV serostatus disclosure, particularly at key times such as delivery, infant weaning, and at the resumption of sexual activity.
5. Further interventions are needed to provide couples counseling and testing to reduce seroconversion during pregnancy.
6. Multiple strategies are needed to promote male involvement in ways that meet pregnant women's needs.
7. Further interventions are needed to reduce barriers to HIV testing.
8. Improved record keeping on HIV counseling, serostatus, and treatment is needed to improve referrals and linkages with other health care services.
9. HIV testing must be linked to access to treatment.
10. Criminalization of HIV transmission may lead pregnant women to not seek testing and care.
11. In some settings, repeat testing of HIV-negative women during pregnancy is warranted.

1. **Further interventions are needed to incorporate violence prevention, screening and counseling services into PMTCT testing and counseling.** *[See also Strengthening the*

Enabling Environment: Addressing Violence Against Women] Studies found high rates of violence, sexual coercion and abuse among HIV-positive pregnant women, particularly when accessing HIV testing or during disclosure.

- Gap noted, for example, in **Uganda** (Were and Hasunira, 2010); **Nigeria** (Ezechi et al., 2009); **Zimbabwe** (Shetty et al., 2008a); **Kenya** (Kiarie et al., 2006; Gaillard et al., 2002:) and **South Africa** (Dunkle et al., 2004).

2. **Additional efforts are needed to improve information and counseling about HIV during ANC to ensure that pregnant women and their sexual partners have adequate information.** Studies found significant numbers of pregnant women received HIV tests with no counseling and reported that HIV testing was a mandatory part of their antenatal care. Studies also found that HIV-positive women feared transmitting HIV to their babies through casual contact. Studies found some providers assured women that treatment guaranteed that there would be no vertical transmission. In addition, studies found that some couples erroneously believed that sex during pregnancy causes miscarriages. Studies have also found that women who have tested HIV-negative at their first antenatal visit had seroconverted to HIV-positive by 12 months following delivery.

   - Gap noted, for example, in **South Africa** (Moodley et al., 2011; Griessel et al., 2010; **India** (Sinha et al., 2008; Van Hollen, 2007; Rogers et al., 2006; Firth et al., 2010); **Democratic Republic of Congo** (Mulongo et al., 2010); **Uganda** (Were and Hasunira, 2010); **Ethiopia** (Ismail and Ali, 2009); **Tanzania** (Falnes et al., 2011); **Nigeria** (Adeleke et al., 2009); **Brazil** (Ramos et al., 2009); **Vietnam** (Nguyen et al., 2008f; Brickley et al., 2008); **Kazakhstan** (Sandgren et al., 2008); **Kenya** (Delva et al., 2006); **Thailand** (Teeraratkul et al., 2005); **India**, **Thailand**, **Philippines** and **Indonesia** (Paxton et al., 2004a); and **Nigeria** (Moses et al., 2009; Onah et al., 2002) and globally in resource-limited settings (Baek and Rutenberg, 2010).

3. **Additional efforts are needed to ensure confidentiality in testing.** Studies found that women were tested without their consent and that providers did not protect women's confidentiality.

   - Gap noted, for example, in **Ukraine** (Finnerty et al., 2010); **Uganda** (Were and Hasunira, 2010); **South Africa** (Peltzer et al., 2010); **Vietnam** (Hardon et al., 2009; Oosterhoff et al., 2008a) and **Turkey** (Ersoy and Akpinar, 2008).

4. **Increased support is needed for HIV serostatus disclosure, particularly at key times such as delivery, infant weaning, and at the resumption of sexual activity.** Studies found that disclosure to partners was low and women reported needing additional support to disclose.

   - Gap noted, for example, in **Côte d'Ivoire** (Tonwe-Gold et al., 2009; Brou et al., 2007).

5. **Further interventions are needed to provide couples counseling and testing to reduce seroconversion during pregnancy.** Studies found that inadequate numbers of

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couples are counseled on safer sex during pregnancy and that despite national guidelines, repeat testing during pregnancy is not routinely done. Studies also found that inadequate spaces for men in antenatal care as well as gender norms that discouraged men from accompanying women to antenatal care discouraged couples testing.

- Gap noted, for example, in **Uganda** (Byamugisha et al., 2010c); **South Africa** (Peltzer et al., 2009; Moodley et al., 2009); **Zimbabwe** (Tavengwa et al., 2007) and in **southern Africa** (Rutenberg et al., 2001).

6. **Multiple strategies are needed to promote male involvement in ways that meet pregnant women's needs.** Studies found that some women found their partners' involvement controlling and/or violent and other women wanted more autonomy in health decision-making. Studies also found men lacked information on vertical transmission and felt excluded from PMTCT programs. Other studies found that women indicated that they could not discuss their HIV serostatus with their husbands.

   - Gap noted, for example, in **South Africa** (Maman et al., 2011); **sub-Saharan Africa** (Auvinen et al., 2010); **Thailand** (Youngwanichsetha et al., 2010) and **Uganda** (Medley et al., 2009b; Mbonye et al., 2010).

7. **Further interventions are needed to reduce barriers to HIV testing.** Studies found that fear of partner notification, risk of domestic violence, the unreliability of rapid HIV tests, test availability, long waiting times at the clinic, costs for transport, lack of childcare and the need for partner consent were barriers to HIV testing. The impact of rapid testing during labor and delivery for HIV-positive women has yet to be assessed and HIV test results were not provided prior to delivery.

   - Gap noted, for example, in a **global** review of PMTCT (Pai and Klein, 2009); **Ecuador** (Dearborn et al., 2010); **Uganda** (Homsy et al., 2007 cited in Pai and Klein, 2009) and **Brazil** (Oliveira et al., 2010b).

8. **Improved record keeping on HIV counseling, serostatus, and treatment is needed to improve referrals and linkages with other health care services.** A study found that record keeping of HIV staging and CD4 counts was inadequate.

   - Gap noted, for example, in a review of maternal care practices in **Africa** (Rollins and Mphatswe, 2008).

9. **HIV testing must be linked to access to treatment.**

   - Gap noted, for example, in **Ecuador** (Dearborn et al., 2010); **Vietnam** (Nam et al., 2010); **Uganda** (Dahl et al., 2008).

10. **Criminalization of HIV transmission may lead pregnant women to not seek testing and care.** A study in Ukraine with pregnant women found that providers told women who tested HIV-positive that they carry criminal liability and others did not access care. A global review found that in some countries, vertical transmission is criminalized.

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- Gap noted, for example, **globally** (Csete et al., 2009); and in **Ukraine** (Finnerty et al., 2010).

11. **In some settings, repeat testing of HIV-negative women during pregnancy is warranted.** One study found that acute infection resulted in high rates of vertical transmission. Another study found that of 750 consecutive pregnant women, with an HIV prevalence of 37.3%, 0.9% of women were acutely infected and thus at a high risk of vertical transmission. HIV RNA assays to detect acute infection are very costly (US$1,313) and have not been used routinely in resource-limited settings.

    - Gap noted, for example, in **Zambia** (Marum et al., 2012, Abstract); **Zimbabwe** (Marinda et al., 2011); **South Africa** (Kharsany et al., 2010b).

9C-2. *Safe Motherhood and Prevention of Vertical Transmission:* Treatment

THIS SECTION (ANC-TREATMENT) HAS BEEN UPDATED. PLEASE SEE THE CURRENT WEBSITE AND THE JULY 2016 UPDATE, AVAILABLE FOR DOWNLOAD AS A SEPARATE SECTION.

~~All women have a right to a safe pregnancy (Freedman et al., 2005), including women living with HIV. There are proven strategies that improve the health of the mother during pregnancy and reduce the risk of mother-to-child transmission of HIV. The most important strategy is for the woman to access health care services where she can be evaluated for the use of antiretroviral drugs. "Antenatal care must include 'fast-tracking' [women living with HIV] into programmes providing holistic care, including treatment with HAART…[with] HIV care to be integrated into routine antenatal care, and not [maintained] as a separate programme" (Sebitloane and Mhlanga, 2008: 496 and 498).~~

~~Antiretroviral treatment is vital to ensuring safe motherhood and reducing vertical transmission. Even in historical contexts where mono or duo therapy was used, dramatic reductions were seen in vertical transmission. For example, a retrospective study analyzed demographic data for 13,583 infants born between 2000 and 2006 from birth until age two in South Africa found that when PMTCT programs became available in 2001, mortality of infants under age two declined 36% and after antiretrovirals became available in 2004, declined another 20% (Ndirangu et al., 2010). While the risk of vertical transmission is dramatically reduced to 2% (Fowler et al., 2010) through the use of triple therapy for the mother, vertical transmission can still occur (Read, 2010).~~

~~Some scientists have argued "universal maternal HAART could largely eliminate the overall MTCT risk" (Becquet et al., 2009a: 1942). Women who are on a HAART regimen [for their own health] have the least risk of perinatal transmission, estimated at~~

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1% (Stek, 2008). "Tritherapy, which has mainly been aimed at protecting the mother's health, has proven very profitable to the child as well" (Kouanda et al., 2010a: 848). In addition, women on HAART [for their own health] have a much greater likelihood of an expanded lifespan, which results in a better quality of life for the woman herself and reduces the likelihood of an intergenerational effect for orphans and vulnerable children.

However, not all pregnant women access treatment. Globally, nearly two-thirds of pregnant women do not even know their HIV status (WHO et al., 2011b). In 2007, only 12% of pregnant women identified as HIV-positive during antenatal care were assessed to determine whether they were eligible to receive antiretroviral therapy for their own health, and only 9% of those HIV-positive women who received PMTCT services received HAART (UNAIDS, 2009e). In 2008, 24% of HIV-positive pregnant women were assessed with a CD4 cell count for ART eligibility for their own health (Zolfo et al., 2010). In 2010, among 99 low- and middle-income countries reporting data, an estimated 45% of pregnant women who were known to be HIV-positive were assessed, either through clinical staging or CD4 count, for their eligibility to receive antiretroviral therapy (UNAIDS, 2011a). The WHO notes that, in 2010, among an estimated 571,000 pregnant women who were eligible for treatment due to their CD4 count, only 25% or 197,000 women received HAART (WHO et al., 2011b). "Data on numbers of women who have had clinical staging and CD4 cell count testing and who require and receive antiretroviral treatments, as well as the antiretroviral prophylaxis regimens that are given to women not receiving treatment, are needed" (Mofenson, 2010b: S144). Studies have also found that pregnant women who qualified for HAART did not access HAART due to "competing life priorities, such as …seeking food and shelter, as major barriers to accessing HIV care" (Muchedzi et al., 2010). *[See also Treatment: Provision and Access* and *Care and Support: Orphans and Vulnerable Children]*

Because TB is a risk factor for increased vertical transmission (Gupta et al., 2011), HIV-positive women are pregnant should be considered for routine TB preventive therapy (Marais, 2011). "…Prevention of TB among HIV-infected mothers should be considered as part of a well-functioning HIV MTCT program. The exceptionally high TB and transmission risk provides additional motivation to carefully monitor all HIV-infected women for TB during and after pregnancy" (Marais, 2011: 305). *[See Preventing, Detecting and Treating Critical Co-Infections]*

Lifelong ARV Treatment Is Recommended for Women Living with HIV

Women living with HIV who have access to triple therapy can expect a close-to-normal life span and a reduction in the risk of vertical transmission. "The best way to ensure that infants are not born with HIV or acquire it during breastfeeding is to provide HIV-positive women the care they need for

"…Each new pediatric HIV infection is considered a missed opportunity for prevention" (Abrams, 2007: 705).

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their own disease" (International Treatment Preparedness Coalition, 2009: 11). The 900-1,200 new cases of HIV in babies in developing countries every day could be prevented (International Treatment Preparedness Coalition, 2009; UNAIDS, 2009d).

The development of ARV regimens to treat pregnant women and prevent vertical transmission is evolving and implementation varies around the world. For instance, in Western Europe, the initiation of ARV therapy in pregnant women proceeds according to the same CD4 count measurements as are used to initiate therapy within the general population, with the goal of full suppression of HIV by the third trimester of pregnancy (European AIDS Clinical Society, 2009). By contrast, in the United States, ARV therapy is now recommended for all pregnant women, regardless of their CD4 counts (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2009).

In 2010, the WHO released new recommendations for the use of ARVs in pregnant women. The new guidelines represent the current consensus on best international practice for the use of ARVs in pregnant women in developing country settings for both the maintenance of the woman's own health and the prevention of mother-to-child transmission of HIV (WHO, 2010i). These guidelines recommend *lifelong* antiretroviral drug regimens for women who need ARVs to protect their own health (based on severe or advanced clinical disease or with the CD4 count at or below 350 cells/cubic mm, regardless of symptoms) and *short-term* prophylactic regimens to decrease the risk of HIV transmission to the baby during pregnancy, labor and delivery and throughout the breastfeeding period (based on CD4 cell counts above 350 or for women who do not require ARVs for their own health). Short-term prophylactic regimens delivered to the baby during delivery and the breastfeeding period (should the mother choose to breastfeed) are also recommended and are discussed in the Delivery and Postpartum sections. Of note, the recommendation for initiating ARV treatment for pregnant women has been raised from a CD4 count of <200 cells/cubic mm to a CD4 count of <350 cells/cubic mm, regardless of clinical staging of disease (WHO, 2010i).

Not all countries provide lifelong triple therapy and WHO has recommended eligibility criteria based on both scientific and economic considerations. For women who do not meet a country's eligibility criteria for ARV treatment for her own health, initiation of short-term treatment to prevent vertical transmission is now recommended at 14 weeks gestation instead of 28 weeks gestation (WHO, 2010i). Some governments continue to use single dose nevirapine to reduce vertical transmission with the rationale that this reduces costs. It should also be noted that an analysis of the cost-effectiveness of the 2009 WHO guidelines compared to the standard of care in Nigeria for prevention of vertical transmission found that triple antiretroviral therapy may be more cost-effective than the standard short-course antiretroviral therapy (Shah et al., 2011).

"The intervention that would have the most substantial impact on HIV-related maternal deaths and perinatal infections throughout the world is the initiation of lifelong

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antiretroviral therapy in pregnant and lactating women infected with HIV-1 who meet the treatment criteria" (Mofenson, 2010a: 2316). Recent PEPFAR guidance has endorsed antiretroviral therapy for pregnant women "for their own health as medically indicated" (PEPFAR, 2011a). UNICEF has recently promoted gender equality within UNICEF programs (UNICEF, 2010b).

There Are Unknown Effects to Discontinuing Treatment Postpartum

As noted, the recent WHO guidelines (WHO, 2010i), state that women with CD4 counts below 350 should receive HAART for their own treatment needs; however, "poor ability to assess clinical stage and limited or no access to CD4 cell counts, particularly in resource-poor settings, continue to represent major hurdles" to implementation of the new WHO guidelines (Zolfo et al., 2010: 288). Nonetheless, when a woman is on HAART with CD4 counts below 350, HAART will improve her own health and drastically reduce vertical transmission. Studies have found that starting HAART at CD4 counts up to 500 increases survival (Cohen et al., 2011b). *[See also Treatment]* When a woman has CD4 counts *above* 350, current recommendations are to have the woman go on ARVs during pregnancy, at labor and delivery or postpartum for the duration of breastfeeding. It is unknown at this time whether women who have CD4 counts above 350 and who go on HAART to prevent perinatal transmission should continue with HAART following pregnancy or breastfeeding or should stop and resume HAART when their CD4 counts go below 350. While it is clear that those who go on ARV therapy for their own treatment needs should not interrupt treatment (Fauci, 2009a, SMART Study Group, 2006), treatment interruption for women who are on HAART simply to prevent perinatal transmission rather than for their own health needs has never been evaluated." The risk for maternal health of stopping …maternal triple ARV prophylaxis after breastfeeding cessation is unknown" (WHO, 2010i: 47) – especially if an HIV-positive woman has multiple pregnancies. These unknown short- and long-term effects have also been noted by the US Department of Health and Human Services and the Panel on Antiretroviral Guidelines for Adults and Adolescents (US HHS, 2011: 46; Panel on Antiretroviral Guidelines for Adults and Adolescents, 2009).

A study funded by NIH (www.clinicaltrials.gov), begun in January 2010 with results expected in 2015 should answer this vital question. The PROMISE Study (Promoting Maternal-Infant Survival Everywhere) is a multi-national clinical trial in 18 countries that is being conducted by the International Maternal Pediatric Adolescent AIDS Clinical Trials Group. It will examine the long-term effects on the health of women who initiate ARV therapy as prophylaxis to prevent vertical transmission and then stop treatment in addition to comparing the effectiveness of different drug combinations for the treatment of PMTCT (NIAID Web Bulletin, January 21, 2010; McIntyre, 2011).

For women and their providers, this remains a critical issue: "The difficult question here is whether HAART should or should not be stopped postpartum in women who were not

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eligible for HAART" (Chama et al., 2010: 365). [Stopping] could be risky, increasing the risk of mortality and "will need to be tailored to the evolving knowledge in this field" (Becquet et al., 2009a: 1939). Currently, US guidelines recommend that pregnant HIV-positive women with CD4 counts under 500 be initiated on lifelong antiretroviral therapy (US HHS, 2011). In addition, HIV-positive women having second pregnancies and stopping and starting triple ARVs leads one researcher to note that "…initiation of life-long ART at first pregnancy for all women may be beneficial" (French, 2012, Abstract). Pregnant women who stop triple ARVs and then restart at the end of breastfeeding may have high viral rebounds and thus be at higher risk of vertical transmission in a second pregnancy (Zolfo et al., 2010). "Pregnant women who stop triple ARVs and then restart at the end of breastfeeding may have high viral rebounds and thus be at higher risk of vertical transmission in a second pregnancy." (Cavallo et al., 2010: 112).

Others have argued that since clinical staging performs poorly in identifying pregnant women for ART and there are still many barriers to obtaining CD4 cell counts that "universal ART initiation among HIV-positive pregnant women, irrespective of CD4 cell count or clinical staging is a potentially superior strategy for the prevention of vertical transmission and the improvement of mothers health" (Zolfo et al., 2010: 287). "Universal start of combination ART during pregnancy is standard of care in resource-rich settings; why not implement it in countries where HIV/AIDS is the leading cause of mortality among women in reproductive age and an important contributor to infant mortality?...Life-long continuation of combination ART beyond the breastfeeding period would certainly facilitate implementation and avoid seemingly contradictory messages around ART, 'ART is lifelong' and PMTCT 'ART may be stopped" (Zolfo et al., 2010: 288).

In addition, given the recent study showing that treatment may reduce transmission, treating pregnant women with triple ART and keeping them on ART may also reduce transmission to their male sex partners (Cohen et al., 2011b). *[See also Prevention for Women: Treatment as Prevention]* In an article from July 2011, the Minister of Health of Malawi stated that because access to CD4 cell count is minimal, and because the total fertility rate is 5.6 births per woman – making repeat pregnancies highly likely, because stopping and starting triple therapy could lead to viral rebounds, because HAART reduced the risk of TB, because of concerns that stopping and starting ARVs will lead to drug resistance, and due to the reduced risk of transmission by people living with HIV who are on HAART, "the message that triple therapy must be taken for life and on a daily basis from the start is simple" (Schouten et al., 2011: 282), Malawi has proposed to "offer all HIV-infected pregnant women lifelong ART" (Schouten et al., 2011: 282).

In April 2012, WHO released a programmatic update providing countries with the option of "providing the same triple ARV drugs to all HIV-infected pregnant women beginning in the antenatal clinic setting but continuing this therapy for all of these women for life"

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(WHO, 2012b: 1). Until April 2012, WHO recommended that pregnant women who accessed HAART with CD4 counts above 350 (i.e., for PMTCT prophylaxis) should continue "through the end of the breastfeeding period" (WHO, 2010i: 19); implying that women can stop HAART at the end of breastfeeding if their CD4 count remains above 350. Until the results from the PROMISE study are available, the question about what this might mean for the woman's future treatment options remains.

Providers Should Consult the Most Recent Guidelines Regarding Medications' Effect in Pregnancy

Health care providers should evaluate the most recent evidence when considering which ARVs to use for pregnant women. Currently, there is no evidence of a significant increased risk of birth defects associated with the appropriate antiretroviral treatment before conception or during the first trimester (Antiretroviral Pregnancy Registry Steering Committee, 2007 cited in Coll et al., 2008). A review of treatment options found that prophylaxis with the antibiotic co-trimoxazole is still advisable for persons with CD4 counts under 200, even if they are on HAART. Experts advise that once viral load is undetectable, co-trimoxazole is no longer required. While co-trimoxazole is potentially teratogenic, WHO recommends its use throughout pregnancy because the risk of life-threatening infection among women with low CD4 counts or symptomatic HIV infection may outweigh other risks (Watts and Mofenson, 2006). However, co-trimoxazole "should not be used as a substitute for the availability of HAART regimens for pregnant women with advanced disease but rather as an adjunct" (Watts and Mofenson, 2006: 1480). Single-dose nevirapine is no longer recommended for the prevention of vertical transmission and a number of countries have phased out its use. WHO is working with countries to disaggregate data on what regimens are currently being used for prevention of vertical transmission (UNAIDS, 2011a).

Nevirapine Resistance Is a Concern in Future Treatment Options

Nevirapine increases the numbers of infants with HIV-free survival, but may prejudice future treatment for the HIV-positive infant (Lockman et al., 2007; Coffie et al., 2008). For women who have received nevirapine already for PMTCT, and then access HAART, there are some concerns that prior use of nevirapine may hinder treatment. A study with 114 women in the U.S. found resistance rates of up to 43% in women who had pregnancy-limited antiretroviral treatment (Paredes et al., 2010). A study of 872 women in Zambia found that HAART was less effective among women who had been exposed to single dose nevirapine (Kuhn et al., 2009b). The OCTANE trial conducted in seven African counties (South Africa,

> *"What people think does not hinder me because this life is mine. Let them talk. I'm not the first one to have HIV"*
>
> HIV-positive woman in a PMTCT program in Uganda *(Duff et al., 2010: para 24).*

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Kenya, Zimbabwe, Botswana, Zambia, Malawi and Uganda) found that women who had history of single dose nevirapine therapy had an increased risk of virological failure and death when treated with a nevirapine based regimen (Lockman et al., 2010). WHO no longer recommends single dose nevirapine for pregnant women living with HIV (WHO, 2010i). "…Single dose nevirapine prophylaxis is moderately effective but induces viral load resistance in HIV-1 infected mothers and infants" (Becquet et al., 2009a: 1938). The problem of drug resistance can be reduced by combining single dose nevirapine with short courses of lamivudine (with or without zidovudine) for seven days after delivery but "none of these approaches fully eliminate the selection of drug-resistant virus" (Becquet et al., 2009a: 1938). Despite the fact that nevirapine may prejudice treatment options for mothers and transmit nevirapine resistance to their infants (Kiptoo et al., 2008), in 2010, 11% of pregnant women, or 150,000 women in 33 countries received single dose nevirapine (WHO et al., 2011b), prejudicing the mother's HIV treatment options (Bulterys et al., 2010; Gingelmaier et al., 2010).

Questions Remain About ARVs and Infant Exposure

"With the availability of antiretroviral drugs increasing globally, WHO's expanded recommendations will lead to a rapidly growing number of antiretroviral-exposed, HIV uninfected children. Total exposure of these uninfected infants to antiretroviral drugs will start *in utero* and continue until the end of breastfeeding. The exposure period to these drugs could be up to 2 years, yet there are limited data on safety. There is now an urgent need to better understand the consequences of extended exposure to HIV and antiretroviral drugs on HIV-uninfected children to contribute to improved monitoring and management of potential adverse effects" (Heidari et al., 2012a : 290). "The immense benefits of antiretroviral drug use during pregnancy for PMTCT and maternal health far outweigh potential adverse effects identified to date. However, there are limited data on long-term effects of *in utero* antiretroviral exposure on uninfected children, and combination regimens have been in use for only about 10–15 years" (Heidari et al., 2012a: 294). "Continued evaluation of uninfected children with *in utero* ARV exposure for long-term adverse outcomes is important" (Williams et al., 2010a: e250; Cavarelli and Scarlatti, 2011).

Further information about treatment in general can be found in that section. For the most recent WHO treatment guidelines for safe motherhood and prevention of vertical transmission (WHO, 2010i), see:
http://www.who.int/hiv/pub/mtct/antiretroviral2010/en/index.html

Treatment guidelines for the US may also be adaptable to certain country contexts:
http:// www.aidsinfo.nih.gov

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

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1. ~~Triple antiretroviral treatment regimens are efficacious for pregnant women living with HIV to improve the health of the mother when used as *treatment*.~~
2. ~~Triple antiretroviral treatment regimens are efficacious to reduce vertical transmission of HIV when used as *prophylaxis* (though questions remain about the effect of termination on future drug resistance for both mother and infant).~~
3. ~~*Early* initiation of HAART in HIV-positive pregnant women results in reduced vertical transmission.~~
4. ~~For women who are pregnant and cannot access HAART either for their own health or for prevention of vertical transmission, short course duo ARV therapy reduces vertical transmission and can reduce nevirapine resistance for both mothers and infants.~~
5. ~~Extending an HIV-positive woman's life increases the long-term survival of her infant.~~
6. ~~National scale-up of HAART in pregnancy improves maternal and infant outcomes.~~
7. ~~Integrating ARV therapy into antenatal care, rather than referring women separately for HIV treatment, may reduce time to treatment initiation for pregnant women living with HIV.~~
8. ~~Efavirenz may be safe to use for HIV-positive women who become pregnant, with little difference in the incidence of birth defects compared to other ART treatments.~~

~~*Promising Strategies:*~~

9. ~~PMTCT-Plus (family-focused) HIV care can increase the numbers of women and their male partners who access testing and treatment.~~
10. ~~CD4 cell count screening to identify women who will benefit from antiretroviral therapy may be more effective than HIV clinical disease staging.~~

~~9C-2. Evidence~~

1. **~~Triple antiretroviral treatment regimens are efficacious for pregnant women living with HIV to improve the health of the mother when used as *treatment.*~~**

   - ~~A **Cochrane review** concluded that "a regimen combining triple antiretrovirals is most effective for preventing transmission of HIV from mothers to babies" (Siegfried et al., 2011:4). The review covered 25 randomized trials including 18,901 participants (Siegfried et al., 2011). (Gray I) *(treatment, pregnancy)*~~

   - ~~A **Cochrane review** which included three randomized trials and six observational studies found that in women eligible for triple ARV regimens, triple therapy is safe, effective and reduces vertical transmission and has become "the standard of care to prevent MTCT in HIV-~~

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infected pregnant women in resource-rich settings (Sturt et al., 2010: 8). Triple antiretroviral regimens result in lower rates of vertical transmission than short course regimens (Sturt et al., 2010). (Gray I) *(treatment, pregnancy)*

- **A systematic review of the literature** on the relationship between pregnancy and HIV disease progression in the context of HAART with six research studies found that "...the general consensus remains that the potential side effects of HAART use for HIV positive women during pregnancy appear to be minimal, but further research is required" (MacCarthy et al., 2009: S67). However, studies suggest that pregnant HIV-positive women on HAART have the lowest risk of HIV disease progression, compared with pregnant HIV positive women on other forms of treatment (MacCarthy et al., 2009). (Gray I) *(HAART, pregnancy)*

- A 2005-2008 study followed 824 HIV positive pregnant women and their 805 infants, who visited antenatal clinics at five sites in **Burkina Faso, Kenya** and **South Africa,** for 18 months. The study found that at 12 months, infants of mothers receiving triple antiretroviral prophylaxis had a relative risk reduction of 43% compared to infants of mothers receiving standard prophylaxis. The pregnant women (with CD4 cell counts of 200-500) were randomized into two groups: 1) triple antiretroviral prophylaxis (zidovudine, lamivudine and lopinavir + ritonavir twice daily) and 2) standard prophylaxis (zidovudine twice daily and single-dose nevirapine at birth, and, after 2006, one week postpartum). Prophylaxis began between 28 and36 weeks of gestation and continued until 6.5 months (the end of breastfeeding) for the triple ARVs group and through delivery and, after 2006, also one week postpartum for the standard group. All infants received nevirapine at birth and, after 2006, also one week postpartum. Mothers were counseled on feeding options: exclusive formula feeding and provision of six months of free formula or exclusive breastfeeding and weaning at six months. The study found that women who received triple antiretroviral prophylaxis had higher CD4 cell counts at delivery, 6 months and 12 months; twice the number of mothers with undetectable viral load at delivery; lower rates of postpartum HIV infection (2.2% v 4.7%); and lower infant mortality at 12 months compared to mothers who received the standard prophylaxis (6.2% v 9.8%) (Kesho Bora Study Group et al., 2011). (Gray I) *(treatment, pregnancy, Burkina Faso, Kenya, South Africa)*

- A study from the **United States** that analyzed data from 2,543 HIV positive women attending clinics at various sites correlating HAART use during pregnancy with maternal and pregnancy outcomes found that the benefits of antiretroviral treatment outweighed the risks. Maternal outcomes assessed included hematologic, gastrointestinal, neurologic, renal and dermatologic complications; gestational diabetes; lactic acidosis; and death. Logistic regression analyses controlling for multiple covariates revealed HAART to be independently associated with few maternal complications (Tuomala et al., 2005). (Gray I) *(treatment, HAART, PMTCT, United States)*

- A study conducted in **sub-Saharan Africa** and **Thailand** (the PMTCT-Plus initiative) found decreased mortality and higher retention for all patients initiating ART and a better CD4 count response for pregnant women. A total of 6,421 adults were enrolled in to the MTCT-Plus initiative from 2003 to 2006. Of those, 1,083(76%) were women including 605(36%) pregnant at ART initiation. A total of 1,794 patients had baseline CD4 count and at least one after initiating ART for CD4 count analysis. The mean baseline CD4 count at initiation of ART was 149 cells. Pregnant women had a mean CD4 count of 328, 370, 397, 441 and 451 at 6, 12, 18, 24, and 30 months, respectively, after initiation of ART. The CD4 response in non-pregnant women was similar to pregnant women but with a more gradual increase. By 2007, 85% of patients initiated on ART remained on follow-up. The mortality rate was 1.8 per 100

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person-years and the loss to follow-up was 4.6 per 100 person-years for all patients initiated on ART. The mortality rate for pregnant women was 1.4 per 100 person years and for non-pregnant 1.7 per 100 person years and for men was 2.4 per 100person years (Toro et al., 2010). (Gray IIIa) *(treatment, pregnancy, CD4 counts, sub-Saharan Africa, Thailand)*

- A prospective observational study done in **Botswana** found that HAART was associated with substantial reduction in mother to child transmission of HIV compared to zidovudine with or without single dose nevirapine. A total of 439 mothers living with HIV between 2009 and 2010 participated in the study. Two hundred and fifty eight (60.3%) infants were born to mothers taking HAART and 170(39.7%) to mothers taking zidovudine of whom 18 received additional single dose nevirapine. Most mothers in both groups opted to formula feeding. Final HIV status was determined for 415(97%) infants. Ten (2.5%) babies became HIV positive during the follow up of whom 9 were from the zidovudine group and 1 baby was from the HAART group. At 6 months of age 95.7% of the babies born from mothers who were on HAART and 90.4% of the babies born from mothers who took zidovudine were HIV negative. Maternal HAART was associated with a substantial decrease in the rate of mother to child HIV transmission compared with zidovudine. Mothers who took antenatal HAART had considerably lower CD4 counts but were still less likely to transmit HIV. Infants born to mothers receiving HAART were more likely to be HIV negative at six months than infants whose mothers took zidovudine (Dryden-Peterson et al., 2011). (Gray IIIb) *(treatment, pregnancy, HAART, Botswana)*

2. Triple antiretroviral treatment regimens are efficacious to reduce vertical transmission of HIV when used as *prophylaxis* (though questions remain about the effect of termination on future drug resistance for both mother and infant). *[See also Postpartum]*

- **A 2007 Cochrane review** on antiretrovirals used to prevent perinatal transmission of HIV found that antiretroviral treatment during the perinatal period (antenatal and peripartum) significantly reduced the risk of vertical transmission in comparison with placebo. For zidovudine, the length of treatment was significantly associated with risk of HIV transmission. Longer treatments during the antenatal period appear to significantly lower infant risk of HIV acquisition. Moreover, for mothers, a short-course of zidovudine and lamivudine during pregnancy, labor, and postpartum along with a single dose of nevirapine during labor is especially effective in reducing perinatal transmission. For infants of HIV-positive mothers who have not received antiretroviral prophylaxis, treatment with a single dose of nevirapine along with one week of zidovudine reduced the risk of HIV acquisition. No significant adverse events were identified for either mothers or their infants after antiretroviral use to prevent perinatal transmission (Siegfried et al., 2011). (Gray I) *(PMTCT, treatment)*

- A 2011 study combined the results from five randomized controlled trials of daily antiretroviral prophylaxis for 5,396 infants breastfed by HIV-positive mothers included in the SWEN trials in **Ethiopia, India** and **Uganda,** and the PEPI and BAN trials in **Malawi** (Leach-Lemens, 2011). The study found that nevirapine (and in one trial combined with zidovudine) substantially reduced the rate of transmission to infants by 71% and the rate of infant death by 58%. These results were obtained after adjusting for differences in study location, baseline maternal CD4 count and infant weight at birth. The authors also found a trend in greater reduction in risk of infection with longer infant prophylaxis, up to 28 weeks.

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The trials compared the following daily treatments for infants who were HIV-negative at birth: nevirapine for 6 weeks, 14 weeks or 28 weeks, or nevirapine plus zidovudine for 14 weeks. Infant HIV transmission risk was 1.6% compared to 3.4% among controls after six weeks of nevirapine, 1.9% versus 7.3% among controls after 14 weeks of nevirapine and 2.3% versus 7.3% among controls after 14 weeks of nevirapine and zidovudine. Cumulative risk of infection at 28 weeks was 5.8% after six weeks of nevirapine, 3.7% after 14 weeks of nevirapine, 4.8% after 14 weeks of nevirapine and zidovudine, and 1.8% after 28 weeks of nevirapine. The comparison groups included infants who were HIV-negative at birth and breastfed by HIV-positive mothers (Leach-Lemens 2011, Hudgens et al., 2011). (Gray I) *(treatment, infant testing, Ethiopia, India, Uganda, Malawi)*

- A 2006-2008 study in **Botswana** randomized 560 HIV-positive pregnant women (with CD4 counts above 200) and found that all HAART regimens administered from pregnancy through six months resulted in high rates of viral suppression and resulted in an overall vertical transmission rate of 1.1%. The median duration of HAART before delivery was 11 weeks in the intervention groups and 13 weeks in the observational group. About 97% of infants were breastfed (71% for at least five months). For the observational group, results were similar (77% at delivery and 84% during breastfeeding). Women received treatment from 26 to 34 weeks gestation through six months postpartum when they were counseled to end exclusive breastfeeding. In addition, the study also observed 170 HIV-positive pregnant women with CD4 counts below 200, who received HAART. All infants received single-dose nevirapine at delivery and daily zidovudine for one month. Free formula and replacement foods were provided for infants from the time of weaning until 12 months. Intention to breastfeed exclusively was an inclusion criterion for study enrollment. Mother-infant pairs were evaluated monthly until six months postpartum (Shapiro et al., 2010). (Gray II) *(pregnancy, HAART, treatment, Botswana)*

- A meta-analysis of studies done in **Europe**, **USA**, **Latin America**, the **Caribbean**, **Brazil**, **Botswana** and **Côte D'Ivoire** between 1996 and 2008 found that the benefit of HAART in terms of increased survival for the mother and decreased HIV transmission to her baby outweighed the potential risks to the baby. A prospective data on 4,329 babies found no increase in birth defects following ART exposure in utero until 2008. An overall increase in congenital abnormalities was seen with didanosine. However, no particular abnormality has been reported. A prospective study of mothers who initiated mostly on NRTIs and PIs (implicated in mitochondrial toxicity) found no significant difference in the lymphocyte mitochondrial DNA to nuclear DNA ratio compared with HIV-negative mothers. A significant rise in mitochondrial DNA was seen in all women over time. Data of the infants exposed to HAART showed increased levels of mitochondrial DNA in their blood when compared with HIV-unexposed infants. "Thus, mitochondrial toxicity appears to be a feature of HIV infection *per se* that may be exacerbated by zidovudine monotherapy" (Martin and Taylor, 2009: 896). An increased rate of pre-term delivery (before 37 weeks of pregnancy) associated with HAART was found in a number of European studies. Data of 5,462 patients in the UK showed that compared with Pre-HAART era, HAART was associated with up to two-fold increase in pre-term delivery with majority born before 32 completed weeks (severe). An analysis of 419 births in Italy showed increased pre-term deliveries with PI-based HAART initiated in the second and third trimester. However, studies from North and South America did not show association between HAART and increased pre-term delivery. Data from seven clinical studies between 1990 and 1998 found no difference in rate of pre-term delivery between 1,143 mothers who received no treatment and 1590 women who were treated with zidovudine monotherapy (17% and 16%, respectively). Furthermore, no increased risk was observed between mothers who took monotherapy and HAART. The Women and Infants

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Transmission Study (WITS) conducted between 1990 and 1998 did not find an association between HAART and pre-term delivery. Data from Latin America and the Caribbean on 681 HIV-positive pregnant women found no correlation between PI-based HAART and preterm delivery or small for gestation age. A study in Brazil that analyzed data from 1996 to 2006 found no association between adverse pregnancy outcomes and zidovudine monotherapy in 179 pregnant women. In Bangkok, with NNRTIs, pre-term delivery occurred in 18.5% of mothers treated with nevirapine. An increased risk of small for gestational age and stillbirth by 1.8 to 2.8 was reported from Southern Africa with continuation or initiation of HAART during pregnancy. A recent study from Botswana found increased pre-mature delivery with HIV infection, neonatal death and lower birth weight. "Careful examination of pre-term delivery rates and any associated morbidity or mortality is necessary as HAART is increasingly prescribed to pregnant women who do not have access to neonatal intensive care"(Martin and Taylor, 2009: 898). HAART increased survival of mothers and greatly reduced transmission of HIV to the newborn and this outweighed the risk of adverse pregnancy outcomes as a result of treatment (Martin and Taylor, 2009). (Gray II) *(pregnancy, treatment, HAART, Europe, USA, Latin America, the Caribbean, Brazil, Botswana and Côte D'Ivoire)*

- A 2007-2009 retrospective study followed 2,831 HIV-positive pregnant women who sought antenatal care and delivered their infants at a hospital in **Uganda**. The study found that at three months postpartum, 2,337 infants had been tested for HIV. Those whose mothers received HAART during pregnancy achieved a lower early infection rate (1.7%) compared to infants whose mothers received other antiretroviral regimens during pregnancy (4.6%-4.9%). Infants whose mothers received only single-dose nevirapine during labor (11.2%) or no antiretroviral intervention (36.4%) experienced higher transmission rates. The study observed the following antiretroviral regimens: 1) 1,269 mothers received zidovudine twice daily starting at 28 weeks gestation plus single dose nevirapine at birth; 2) 1,045 mothers received zidovudine plus lamivudine twice daily from 33 weeks gestation plus single-dose nevirapine at birth; 3) 1,420 mothers received HAART if their CD4 count was less than 350; 4) 1,042 mothers received single dose nevirapine at birth; or 5) 31 mothers received no antiretroviral treatment. Excluding women on HAART, all women received zidovudine and lamivudine daily for one week postpartum and all infants received single-dose nevirapine and one week of zidovudine. The overall early infection rate was 5%. Early infection was defined as infants who were identified as HIV-positive at three months of age or less. More than 90% of women in this study breastfed their infants. Only 60% of the total HIV-positive women who presented for antenatal care returned to the hospital for delivery and less than 50% of mothers returned with their infants for postnatal care (Namukwaya et al., 2011). (Gray IIIa) *(pregnancy, HAART, treatment, Uganda)*

- A 2007-2008 study in **Nigeria** followed 446 HIV-positive pregnant women treated with HAART and found a transmission rate of 1.1% among their infants after six months. All enrolled women received HAART during pregnancy, 62% for at least six months prior to delivery, regardless of disease stage. After delivery, mothers ineligible for HAART according to Nigerian national guidelines (asymptomatic and CD4>200), discontinued treatment unless they chose to breastfeed, which allowed continued treatment through six months. All infants received single dose nevirapine at birth and zidovudine for six weeks (Chama et al., 2010). (Gray IIIb) *(pregnancy, HAART, treatment, Nigeria)*

- A 2003-2006 study followed 416 HIV-positive mothers, who sought antenatal care and were given triple antiretroviral therapy to prevent vertical transmission, and their 400 infants in **Kenya**. At 24 months, the study found that cumulative HIV transmission rate from mother to

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child was 7%; cumulative mortality rate was 10.4%; and that infant HIV-free survival was 84.3%. The Kisumu Breastfeeding Study enrolled HIV positive pregnant women, with intention to breastfeed, and provided HAART from 34 weeks gestation through six months postpartum, while counseling mothers to breastfeed exclusively and wean by six months when HAART would be discontinued (except for mothers with CD4 counts below 200). Triple antiretroviral therapy consisted of zidovudine, lamivudine and either nevirapine or nelfinavir (310 and 212 pregnant women, respectively). Infants also received single dose nevirapine at birth. Mothers were evaluated weekly prior to birth, at delivery, monthly until three months and then quarterly until 24 months. Twelve maternal deaths were attributed to opportunistic infections (9) and preexisting cardiac disease (3). No maternal deaths were linked to ARVs. By 24 months, 10% (49 of 487) of infants had died, 86% in the first year of life, due to diarrhea (35%), pneumonia (16%) and respiratory failure (12%). No child deaths or adverse events were clearly attributed to maternal or child ARVs. Before five months, the study observed that 22% of mothers practiced mixed feeding. Of HIV negative infants at six months, 87% reportedly stopped breastfeeding. Nine of these infants became HIV positive, after which only two mothers stated they had breastfed after six months. Of the 310 women initially given nevirapine, 13.5% had to substitute an ARV and of the 212 women initially given nelfinavir, 5% had to substitute an ARV (Thomas et al., 2011a). (Gray IIIb) *(pregnancy, HAART, treatment, Kenya)*

- Secondary data analysis from a completed randomized trial assessing nevirapine versus zidovudine in reducing PMTCT in **Uganda** found that maternal viral load was the best predictor of both early and late perinatal transmission. Treatment with HAART lowers maternal viral load. Of 610 infants who were evaluated for HIV acquisition, 99 were infected in the early transmission period (first positive HIV RNA PCR obtained before 56 days of age) and 23 were infected in the late transmission period (after 56 days of age). In the six to eight weeks postpartum period, an increase of log10 Viral RNA increased the risk of mother-to-child HIV transmission by 3.66-fold. The risk of early transmission was 2 times more for every log10 viral load increase in the pre entry period (Mmiro et al., 2009). (Gray IIIb) *(treatment, HAART, PMTCT, Uganda)*

- A 2004-2007 study in **South Africa** followed 302 women, who initiated HAART at an antenatal ARV clinic, and found a perinatal transmission rate of 5%. Women who received more than seven weeks of HAART during pregnancy had a perinatal transmission rate of 0.3%. The study analyzed 689 women who had not previously received treatment for HIV and began treatment with HAART while pregnant. These women were followed weekly for eight weeks until stable. HIV status was determined by HIV-1 DNA testing. The study also routinely screened for syphilis. Women were excluded if they conceived while initiating HAART. About 300 women were diagnosed with HIV during the current pregnancy. The study also found that 23% of women were aware of their HIV status before conception and did not seek medical care until the third trimester. Of 455 women providing data on delivery, 56.9% delivered vaginally, 25.7% underwent cesarean sections for reasons not related to HIV and 17.4% had emergency cesarean sections. Of 244 women who provided follow up data, 80% experienced an increase in CD4 cell count and of 211 women who provided data on viral load, 80.5% experienced a decrease in viral load over 15 weeks. All infants born HIV positive were born to women who received seven or fewer weeks of HAART. "Recent data suggest that pregnancy is associated with a lower risk of HIV disease progression, and experience with the ANC ARV cohort supports this finding" (Tai et al., 2007 as cited in Black et al., 2008: 279). This study was constrained by a national policy restricting viral load testing to twice a year. Among women who did have viral load testing, 75.6% had an undetectable viral load (Black et al., 2008). (Gray IIIb) *(treatment, HAART, pregnancy, South Africa)*

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- A study from 1999 to 2005 of 551 infants born to HIV positive women seen at GHESKIO, **Haiti,** found that prior to HAART availability in 2003, infant mortality was 23 per 100 live births per year. Following the introduction of HAART for HIV positive women, infant mortality fell to 7 per 100 live births in 2005. In the cohort of 399 women given exclusively single drug prophylaxis, the perinatal transmission rate was 10%. In the 60 women who received HAART the perinatal transmission rate was 1.9% (Noel et al., 2008). (Gray IIIb) *(HAART, PMTCT, Haiti)*

- A prospective cohort study from 2002 to 2006 enrolling HIV positive pregnant women in **Latin America and Caribbean countries** found that MTCT rates were very low, most women had viral loads below 1000 copies/mL, almost all women were receiving antiretroviral treatment either for prophylaxis or for the mother's health, and many women chose elective cesarean section to further reduce the risk of MTCT. Of 770 mother-infant pairs included, 87 percent of women had viral loads below 1000 copies/mL, 99 percent of women received one or more antiretrovirals during pregnancy, and 41 percent delivered through elective cesarean section. Less than one percent of infants were diagnosed as HIV positive at the end of the study period (Read et al., 2007). (Gray IIIb) *(treatment, cesarean section, PMTCT, Latin America, Caribbean)*

- A study from **Côte d'Ivoire** that enrolled HIV positive pregnant women between 2003 and 2005 in an MTCT-Plus program found that antiretroviral treatment for pregnant women, both indicated for the mother's health as well as solely for PMTCT purposes, was effective and safe. Women with CD4 counts below 200 were considered eligible for HAART for their own health and received a treatment combination of mainly zidovudine (ZDV), lamivudine (3TC), and nevirapine (NVP). Women not eligible for HAART for their own health received a short course of ARVs, mainly ZDV and 3TC from 32 weeks of pregnancy until 3 days postpartum and a single dose of NVP during labor; ZDV from 28 weeks of pregnancy; single dose NVP; or ZDV and single dose NVP. All infants in the sample received ZDV syrup for 7 days after birth and a single dose of NVP 3 days after birth regardless of mother's ARV regimen. Of the 261 HIV-infected women identified and enrolled in the study, 57% (143) received short-course ARVs and 43% (107) received HAART. Overall, the HIV status of 97.4% (225) children was determined with 12 confirmed HIV infections. The probability of peripartum HIV infection was 2.2% for children born to mothers using HAART and 3.1% for children born to mothers using short-course ARVs. The only factor found to be significant in peripartum HIV acquisition was low birth weight, while infant feeding practice, gender, maternal ARV regimen, CD4 count and age were not significant (Tonwe-Gold et al., 2007). (Gray IIIb) *(PMTCT-Plus, HAART, PMTCT, Côte d'Ivoire)*

- A 2002 study in **Nigeria** found that among the 32 women who were given HAART, transmission of HIV to infants was 9.1%. Among the 22 women who had single dose nevirapine in labor there was a transmission rate of over 33%. The best outcome was among those that had HAART, an elective C-section and did not breastfeed; none of the babies were HIV-positive at 18 months. "It is recommended that the single dose nevirapine be abandoned in favour of combination treatment… The single dose nevirapine ….may lead to the spread of a nevirapine-resistant strain" (Chama et al., 2007: 134 and 136). (Gray IIIb) *(HAART, PMTCT, treatment, Nigeria)*

- A study in **Mozambique** from 2002 to 2005 of 985 HIV-positive pregnant women found that HAART was more widely accepted than single-dose nevirapine in earlier studies, with 80%

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completing a treatment protocol of HAART until six months postpartum and beyond. Maternal mortality was 0.8%, with vertical transmission rates of 1.4% at six months, equivalent to those developed countries (Marazzi et al., 2007). (Gray IIIb) *(HAART, treatment, Mozambique)*

- A sub-study (year unspecified) of the HIVNET 024 trial analyzed data on 1,317 infants born to HIV positive women in **Malawi, Tanzania** and **Zambia** who were followed for 12 months. Previously reported, the 2001-2003 HIVNET 024 trial results showed significant association between late postnatal transmissions and both low maternal CD4 count (below 200) and high maternal viral load (more than 50,000 copies). This sub-study found that among infants at risk for late postnatal transmission, 15.6% (206 in 1,317) were exposed to low maternal CD4 count, 25.2% (332 in 1,317) were exposed to high maternal viral load and 6.2% (82 in 1,317) were exposed to both low maternal CD4 count and high maternal viral load. The proportional reduction in mother to child transmission that would occur if the above exposures were removed (the population attributable fraction) was 26%, 37% and 16%, respectively for the three exposure groups. The World Health Organization defines a population attributable fraction as the proportional reduction in population disease or mortality that would occur if exposure to a risk factor were reduced or removed (WHO). If the maternal exposures were reduced in highest risk infants (exposed to both low maternal CD4 count and high maternal viral load), an estimated 16% of late postnatal transmissions could be prevented. These percentages also imply that "a large proportion of late postnatal transmissions are contributed by those women with less advanced HIV disease [63%, either low CD4 count or high viral load] (p. 315)." Late postnatal transmission was defined as infants who acquired HIV between 4-6 weeks and 12 months of age (Chen et al., 2010). (Gray IIIb) *(pregnancy, treatment, Malawi, Tanzania, Zambia)*

- A retrospective study gathered routine data from 2003-2006 of 454 HIV-positive mothers and their infants at two medical centers in **Burkina Faso**. The study found that after 18 months, infants born to mothers treated with HAART had a 0% (0/195) transmission rate compared to infants born to mothers treated with short-course antiretroviral therapy who had a 4.6% (12/259) transmission rate. Of the mothers in the first group, 59% began treatment before and 41% during pregnancy and continued to receive HAART through 18 months of follow-up. Mothers in the short-course antiretroviral group were diagnosed during pregnancy or birth and received either single-dose nevirapine (93%) or single dose zidovudine (7%). At birth, most infants received single-dose nevirapine (83%) and the rest either received zidovudine daily for one week (13%) or did not receive any treatment (4%). Follow-up data included postnatal check-ups and infant HIV testing at 2-6, 9 and 18 months, some through PCR and others through rapid testing. The majority of women in both groups chose formula feeding: 76% in the short-course antiretroviral therapy group and 89% in the HAART group. Among infants of mothers treated with short-course antiretroviral therapy, the transmission rates for formula fed infants was 3.6% (7/195) as compared to breastfed infants 7.8% (5/64) (Kouanda et al., 2010a). (Gray IV) *(pregnancy, treatment, HAART, Burkina Faso)*

- A study in **South Africa** that compared vertical transmission rates found that following the implementation of revised 2010 guidelines that initiated pregnant women on triple ART, vertical transmission was reduced from 3.4% to 1.5%. A cohort of 1,995 mother-infant pairs was included, with 57% of mothers attending PMTCT services prior to the 2010 guidelines and 42.5% attending PMTCT services following the implementation of the 2010 guidelines (Rundare et al., 2012). (Abstract) *(pregnancy, treatment, South Africa)*

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3. *Early* initiation of HAART in HIV-positive pregnant women results in reduced vertical transmission. *[See also Pre-Conception]*

- 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 assess 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 with infant HIV infection by 12 weeks (Chibwesha et al., 2011). (Gray IIIa) *(pregnancy, treatment, CD4 counts, Zambia)*

- A 2005-2009 study followed 218 HIV-positive mothers and their infants recruited from maternal and child health clinics in **China** for 12 to 18 months after delivery. The study found that since 2005, there was a statistically significant improvement in early enrollment resulting in an average increase of time on HAART before delivery by nine days each year (1.1 weeks), for a total of 35 days (5.5 weeks). This study also found that early initiation of HAART for the mother during pregnancy resulted in a transmission rate of 1.04% (2/193) and a one year infant survival rate of 96.3%. A total of 218 mothers received treatment and delivered 223 infants: seven who died (due to diarrhea (2), respiratory illness (2), malnutrition (1), encephalitis (1) and sepsis (1)), 26 who had not yet reached 12 weeks of age (when PCR testing occurs) and four who remained untested (three who were lost to follow up). Mothers began HAART between 14-28 weeks gestation (in 2005: average of 28.5 weeks gestation and by 2009: average of 23 weeks gestation). At delivery, women with CD4>350 discontinued HAART, while mothers with CD4<350 were referred to other programs to continue treatment. Infants received single dose nevirapine at birth and zidovudine for one to four weeks depending on the mother's treatment regimen. Parents were counseled to exclusively formula feed and provided with 12 months of formula. Early enrollment resulted from improved implementation of PMTCT programs, earlier detection of HIV in pregnant women and increased confidence in the effectiveness of the programs by staff (Zhou et al., 2010). (Gray IIIa) *(pregnancy, treatment, HAART, China)*

- A retrospective study in 2005-2009 pooled data of 3071 HIV-positive mothers and their infants from DREAM clinics in **Malawi** and **Mozambique** and found that the longer mothers had received HAART during pregnancy, the lower the infant HIV transmission and infant mortality rates. Mothers were included if they intended to breastfeed. HAART was given to mothers at 14 weeks gestation, if they had CD4 counts under 350, or at 25 weeks for prevention of mother-to-child transmission and terminated at six months postpartum. Mothers were counseled to breastfeed exclusively and wean at six months. At 12 months, 2% of infants were HIV positive, the infant mortality rate was 6.7% and the HIV free survival rate was 92.5%. Transmission and/or death rates at 12 months were higher for infants of women

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who received more than 30 days of HAART before delivery compared to women who received at least 90 days of HAART before delivery (14% versus 6.9%). At 12 months, infants whose mothers received no antiretroviral treatment before delivery had a statistically significant risk of HIV transmission and/or death (relative risk 1.5) (Marazzi et al., 2010). (Gray IIIb) *(pregnancy, treatment, CD4 counts, Malawi, Mozambique)*

- A prospective cohort study (DREAM) done in **Mozambique** found significant reduction in maternal and infant mortality with early initiation of HAART to HIV-positive pregnant mothers. HIV-1 positive mothers were followed at centers for prenatal care and their live-born infants. A total of 341 one month old infants and their mothers were followed from 2005 to 2007 to determine HIV-1 free survival at 12 months among the HIV exposed infants. The mothers received prenatal and postnatal HAART for at least six months after delivery. Out of the total mother infant pairs, 92% completed six months and 83% completed 12 months of follow up. There were 8 cases of HIV transmission over the 12 months of follow up. Eleven of the 341 infants died during the study period. Only one of the infants who died had documented HIV infection at 1 month of age. HIV diagnosis was ascertained for 84% of the infants including the 4 infants who died before the age of 6 months (out of the 11 deaths). The observed risk reduction in infant mortality for the children in the study was 67% and the observed risk reduction for maternal mortality was 41%. A total of 55(16%) women who had CD4 counts less than 350 continued HAART for their own health. There was no further mother to child transmissions in this group of women beyond 6 months. Only 8 patients of the original 341 mothers had prior history of antiretroviral exposure for their own health and none of these infants acquired HIV. Of the 50 women who had repeat pregnancies, none of infants acquired HIV. Undetectable HIV RNA (below 400 copies) was achieved in 232(79%) women. Six of the 8 transmissions were in women with a viral load above 4 log at baseline. Six of the 8 transmissions also occurred in women who took less than 3 months of antepartum HAART. In this study, postnatal HAART provided with adequate clinical and lab infrastructure led to an infant HIV-free survival rate of 94% at 12 months of age (Marazzi et al., 2009). (Gray IIIb) *(pregnancy, treatment, CD4 counts, Mozambique)*

- 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. Among mothers who received antiretroviral treatment prior to birth (HAART or short course ART), the early vertical transmission rate was 6.6% (22 in 335). Among the 418 mothers, 17.5% received HAART, 62.5% received short course ART, and 20% received single dose nevirapine at birth. Type of ARV treatment was determined by number of weeks pregnant and CD4 count. Infants received single-dose nevirapine at birth plus seven days of ART, or 30 days of ART if mothers had not received any antenatal antiretroviral treatment (Tchendjou et al., 2010). (Gray IIIb) *(pregnancy, treatment, HAART, Cameroon)*

- A 2004-2008 prospective cohort study reported on 873 HIV-positive women in **South Africa** who received HAART (either before or during pregnancy) and found that longer duration of HAART before birth was associated with reduced mother-to-child transmission of HIV. Among the 730 women who began HAART during pregnancy, each additional week of treatment reduced odds of vertical transmission by 8%, after adjusting for baseline CD4 cell count and type of HAART regimen. The overall mother-to-child transmission rate for women receiving HAART (before and during pregnancy) was 4.9% (43 in 873). The same clinics reported a 7.9% (121 in 1,534) transmission rate among mothers who received single dose nevirapine during labor, which was recommended for women with CD4 cell counts above

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250. No transmissions occurred in women who received HAART for more than 32 weeks prior to delivery. Women were observed at combined antenatal and antiretroviral clinics at two hospitals in Johannesburg. Mothers and infants were followed until infant HIV testing at 4-6 weeks postpartum. Seventy-six percent of women had a CD4 cell count below 200 in this cohort. About 97% of infants received replacement feeding. According to studies published in 2007 and 2008, the national prevalence of HIV among pregnant women was 29.3% in South Africa (Hoffman et al., 2010a). (Gray IIIb) *(pregnancy, treatment, HAART, South Africa)*

- A retrospective analysis of an observational cohort of 367 treatment naïve HIV-positive pregnant women in **South Africa** found that each additional week on ART reduced transmission by 20%. There was no HIV transmission to infants among women who received more than eight weeks of ARVs. 265 women (72%) commenced ART before giving birth and 20% were referred for PMTCT and 8% received no intervention. Among ART eligible women, 13% were lost to follow up. Of those starting ART, median duration of therapy prior to birth was 7.6 weeks (Fitzgerald et al., 2010). (Gray IIIb) *(treatment, pregnancy, PMTCT, South Africa)*

4. For women who are pregnant and cannot access HAART either for their own health or for prevention of vertical transmission, short-course duo ARV therapy reduces the risk of vertical transmission and can reduce nevirapine resistance for both mothers and infants.

- A 2009 study from **Thailand** found that one month of zidovudine (ZDV 300 mg twice daily) and didanosine (ddI400 mg once daily) following a single dose of nevirapine (NVP) during labor prevented almost all NNRTI resistance. Two hundred and twenty ARV näive HIV-positive pregnant women with CD4 counts greater than 250 cells/mm^3 receiving postpartum ZDV treatment during the third trimester, single dose NVP during labor, and 1 month of ZDV/ddI were matched with women (with similar CD4 counts) receiving ZDV treatment during the third trimester and single dose NVP during labor (but no postpartum treatment). Resistance mutations were found in 1.8% of women who received the 1 month postpartum ZDV/ddI and in 20.7% of the women who did not receive postpartum treatment (Lallemant et al., 2009). (Gray IIIa) *(PMTCT, treatment, Thailand)*

- A study from **Thailand** that enrolled 169 HIV-positive pregnant women (28 to 38 weeks gestation) from 2006 to 2008 found that postpartum antiretroviral treatment for at least 7 days after a single dose of intrapartum nevirapine (NVP) significantly reduced the development of NVP resistance. Women included in the study had CD4 counts of greater than 250 cells/mm^3, may or may not have received zidovudine (ZDV) during their current pregnancy or a past pregnancy, and were not intending to receive ART within 8 weeks postpartum. Overall, 169 women received either ZDV, didanosine (ddI), and lopinavir/ritonavir (LPR/r) for 7 days postpartum; ZDV and ddI for 30 days postpartum; or ZDV, ddI, and LPV/r for 30 days postpartum (after receiving intrapartum single dose NVP). These 3 treatment groups were compared to a historic control group from a 2001 to 2003 study of 119 women who had received prenatal ZDV treatment and intrapartum single dose NVP, but no postpartum treatment regimen. In comparison to the control group, women receiving any of the three postpartum treatments had a significantly lower risk of developing NVP resistance (Van Dyke et al., 2012). (Gray IIIa) *(PMTCT, pregnancy, treatment, Thailand)*

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- A cross sectional study of PMTCT programs in Busia, **Kenya** from 2006 to 2008 found that the odds of having an HIV positive baby was 4.6 times higher among women receiving a partial protocol (WHO's recommendations prior to 2009: mother: HAART or AZT four weeks plus single dose nevirapine plus AZT+3TC; and child: Single dose nevirapine plus AZT for seven days) than the complete protocol. Exclusive breastfeeding until six months was promoted. The odds of having an HIV positive baby was 43 times higher among those pregnant women receiving no intervention. Babies were tested using DNA PCR at six weeks of age and six weeks following the cessation of breastfeeding. During the two years, 22,566 women accepted testing; 1,688 women tested HIV-positive; and 1,036 were registered in the PMTCT program, with 38% of those who tested HIV positive not registering with the PMTCT program. Program coverage was 40.4%. An estimated 15.86% of infants acquired HIV by the cessation of breastfeeding. "Although more sophisticated ARV regimen has shown more efficacy to reduce HIV transmission, the main problem is those women and babies who do not access to the services and do not receive any treatment" (Azcoaga-Lorenzo et al., 2011: 278). (Gray IIIb) *(treatment, pregnancy, HAART, Kenya)*

- A study enrolling HIV-positive pregnant women not requiring HAART for their own health in **Côte d'Ivoire, Cambodia** and **South Africa** from 2006 to 2007 found that a combination of tenofovir disoproxil fumarate and emtricitabine taken along with single dose nevirapine at delivery and for 7 days postpartum was effective in preventing nevirapine resistance and was well tolerated. All study participants also received antenatal zidovudine. Of 38 women included in the study no resistance mutations for any antiretroviral were detected one month after delivery and no cases of MTCT were found. Nine serious adverse events were documented in women and eleven in infants, including four infant deaths, although these were determined unlikely to be related to antiretroviral exposure (TEmAA ANRS 12109 Study Group et al., 2009). (Gray IIIb) *(PMTCT, HAART, treatment, Côte d'Ivoire, Cambodia, South Africa)*

- A study in **South Africa** between 2005 and 2007 showed that prevention of perinatal transmission of HIV through combined use of ZDV from 34 weeks of pregnancy and a single dose of NVP during delivery reduced NVP resistance rates reported by previous studies. Seventy-six pregnant women not yet qualified for antiretroviral treatment (CD4 count above 200/µl and no AIDS defining illness) were included in this study, with 13 (17.1%) presenting NVP resistance mutations approximately 6 weeks after delivery (van Zyl et al., 2008). (Gray IIIb) *(PMTCT, treatment, South Africa)*

5. Extending an HIV-positive woman's life increases the long-term survival of her infant. *[See also Care and Support: Orphans and Vulnerable Children]*

- A review of seven randomized MTCT intervention trials looked at the effect of maternal health, infant HIV infection, feeding practices and age at acquisition of infection on the rate of child mortality among 3,468 African children born to HIV positive women. Child mortality was associated with maternal death, CD4 cell counts <200 and infant infection and varied by region (east, west and southern Africa), with overall rate of more than 50% of vertically infected children dying by age 2 (Newell et al., 2004). (Gray II) *(PMTCT, child mortality, feeding practices)*

- A retrospective cohort study with more than ten years of follow-up in **Malawi** found that mortality in children less than five years was much higher in children born to HIV positive mothers than in those born to HIV negative mothers. Among those with HIV positive

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mothers, mortality was 27% as infants, 46% for those under five years, and 49% for those under ten years of age. For those with HIV-negative mothers, mortality was 11% as infants, 16% under the age of five, and 17% under the age of ten (Crampin et al., 2003). (Gray IIIa) *(PMTCT, child mortality, Malawi)*

- Children left motherless are 3 to 10 times more likely to die within two years than children who live with both parents (UNFPA, 2000a). (Gray IV) *(orphans, child mortality)*

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

- A retrospective review of clinical records of 571 HIV-positive pregnant women in antenatal care in **Jamaica** between 2002 and 2006 found that national scale-up of HAART improved maternal and infant outcomes. Acceptance of HAART increased: from 2002-2004, HAART was used by 2 to 3% of pregnant women; by 2006, 62% of HIV-positive women accessed HAART during pregnancy. From 2002 to 2005, zidovudine and/or nevirapine were used. For all four years, 24 maternal deaths occurred. Of these, 23 or 96% occurred in those who took zidovudine/nevirapine, with only one death or 4% occurring in those who accessed HAART. By bringing viral load to an undetectable level, HAART has minimized the "chance of perinatal transmission to under 2% in Kingston and under 5% islandwide" (Johnson et al., 2008: 221). Between 2002 and 2005, only 1% received HAART despite 8% of patients having been clinically assessed as warranting HAART. In 2008, "we offer four-drug HAART…. to all HIV infected women who are diagnosed early in pregnancy, with island-wide uptake consistently approaching 90% regardless of the woman's individual disease stage" (Johnson et al., 2008: 221). Recent island-wide upgrade of lab facilities allowing wide availability of CD4 counts and viral loads has "already minimized peripartum deaths in pregnant women with HIV infection" (Johnson et al., 2008:220). (Gray IIIb) *(HAART, treatment, PMTCT, Jamaica)*

- A review of PMTCT programs in **Ukraine** found substantial improvements in MTCT on a national level. MTCT rates decreased from 15.2% in 2001 to 7% in 2006. By January 2008, 3,356 mother-child pairs had received PMTCT services. Among women receiving no ARV prophylaxis, the PPT rate was 26.7%, decreasing to 15.7% for women who received single dose nevirapine, 7% for women receiving zidovudine; 9.2% for women who received both zidovudine and single dose nevirapine and 3.9% among women who accessed HAART. Maternal HIV clinical disease stage (WHO clinical stages 1 and 2) as compared to WHO clinical stages 3 and 4 were not significantly associated with PMTCT. PMTCT rates more than halved between 2001 and 2006, with a PMTCT rate of one in 14 in 2006. Use of HAART is planned for all HIV-positive women in Ukraine's next PMTCT program. Most women received their first HIV diagnosis in pregnancy (Thorne et al., 2009). (Gray IIIb) *(PMTCT, treatment, HAART, Ukraine)*

- A retrospective study in Addis Ababa, **Ethiopia** using PMTCT monthly reports from 2004 to 2009 found that HIV-positive women were 18 times more likely to be referred for treatment, care and support in 2009 than in 2004. The cumulative probability of HIV infection among babies was 15% in 2007 and only 8.2% in 2009. Between 2004 and 2009, 663,603 pregnant women attended antenatal care; of these 135,986 had HIV testing; of these 6.2% were HIV-positive. Among HIV-positive women, 52.4% received ARV prophylaxis and 41% were referred for treatment, care and support. However, only 10.6% of HIV-positive women

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completed follow-up of infant HIV testing (Mirkuzie et al., 2010). (Gray IIIb) *(pregnancy, treatment, Ethiopia)*

- A study of PMTCT uptake introduced into 38 sites in **Zambia** starting in 2005 increased significantly the percent of HIV-positive pregnant women referred for clinical care from 62% in 2005 to 89% in 2008. In 2005, 9,7723 pregnant women were counseled on PMTCT; 4,630 (45%) were tested for HIV and received their results; 890 tested HIV positive, and 549 HIV-positive women were referred for clinical care post partum. By 2008, 9,410 women were counseled about PMTCT; 9,274 received their HIV test results; 1,361 were HIV positive; and 1,212 were referred for clinical care postpartum. Costs per mother ranged from US$113 to US$126, including labor, drugs, supplies, labs, and other operating costs. With a 14.3% HIV prevalence, the Ministry of Health estimates that over one million people are HIV positive, half a million infants are born every year and 40,000 infants acquire HIV through vertical transmission. Baseline and service data were collected on a monthly basis. Acceptance of counseling and HIV testing increased from 45% in 2005 to 99% in 2008. Use of ARV prophylaxis increased from 29% in 2005 to 97% in 2008. PMTCT was integrated at all levels of health care, including hospitals and all health care settings. Entry into PMTCT was also obtained through antenatal care, labor and delivery, maternal and child health clinics, family planning clinics and STI services. In Zambia, about 90% of pregnant women attend antenatal care at least once, but less than 50% deliver at a facility. Health workers provided antenatal care in communities that were far from health facilities. Lay counselors were engaged in motivating women to test and to provide support to people living with HIV, including making referrals and assist in adherence. Community education on PMTCT was provided and traditional and religious leaders were engaged. Facilities were improved to provide privacy and blood draws for CD4 were shipped, rather than having patients travel. Postnatal follow up was conducted through the "mother baby tracking tool." Commodities were managed to reduce stock outs (Torpey et al., 2010a). (Gray IIIb) *(PMTCT, testing, treatment, Zambia)*

- A study in **Cuba** of all 314 HIV-positive mothers and their 32 children who acquired HIV vertically between 1986 and 2007 found that the rate of vertical transmission was reduced from 50% in 1986 to 2.2% in 2007. In 1986, infant formula was provided; by 1989, HIV-positive women delivered by cesarean section; by 1999, AZT was given; by 2001, HAART was given to pregnant women with CD4 counts under 350; by 2004, HIV tests were given once per trimester; and in 2005, AZT was given in addition to HAART (Gonzalez et al., 2010) (Gray IIIb) *(pregnancy, treatment, HAART, Cuba)*

7. Integrating ARV therapy into antenatal care, rather than referring women separately for HIV treatment, may reduce time to treatment initiation for pregnant women living with HIV. *[See also Structuring Health Services to Meet Women's Needs]*

- An evaluation in **Zambia** that compared integration of antiretroviral therapy in antenatal care to referral to ART care found that where antiretroviral therapy was integrated with antenatal care, women were more than twice as likely to be enrolled while pregnant and within 60 days of HIV diagnosis and to have initiated ART while pregnant. Between 2007 and 2008, 13,917 women started antenatal care more than 60 days before the intervention rollout and constituted the control cohort; 17,619 women started antenatal care after ART was integrated into ANC and constituted the intervention cohort. Of the 1,566 patients found eligible for

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ART, 376 out of 846 (44.4%) enrolled while pregnant and within 60 days of HIV diagnosis as compared with 181 of 716 (25.3%) who were referred for ART. 278 out of 846 (32.9%) of women who accessed ART in integrated services in ANC initiated ART while pregnant compared to 103 of 716 (14.4%) of those who were referred for ART. Women found to be HIV-positive through antenatal testing had a specimen routinely sent for a CD4 cell count. Separate ART facilities were located on the same premises but physically separate and separately staffed. However, although 38% of eligible pregnant women (CD4 counts under 250), 62% of HIV-positive pregnant women did not initiate triple therapy during pregnancy (Killam et al., 2010). (Gray IIIa) *(treatment, PMTCT, antenatal care, Zambia)*

- A study in **Mozambique** found that integration of HIV/AIDS services into ANC services reduced loss to follow-up of HIV-positive women 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 HIV-positive pregnant women attended either standard PMTCT sites (where pregnant women were referred to ART clinics that were off-site) *or* integrated sites, where all services for HIV-positive pregnant women 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 mothers 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 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)*

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- A study of 872 women in **Zambia** found that HAART was less effective among women who had been exposed to single dose nevirapine. HIV-positive women who had received single dose nevirapine between 2001 and 2005 who could be contacted were evaluated for eligibility for HAART if they had CD4 counts under 200 or viral counts under 35 and evidence of WHO clinical disease stage 3" (Kuhn et al., 2009b). . Mortality in women who met ART eligibility criteria was high with 23.7% mortality by 24 months in the era before ART became available. Of 161 single dose nevirapine exposed women who were still on HAART after six months, 70.8% achieved a viral load less than 400 copies per milliliter and 40.4% achieved a viral load less than 50 copies per milliliter. Of eight women exposed to single dose nevirapine within six months of starting HAART, only three achieved a viral load of less than 400 copies per milliliter by six months after therapy compared with 59.1% of 22 women who started HAART within six to 12 months after single dose nevirapine and, 72.1% of 61 who started HAART within 12 to 24 months, and 77.1% of 70 who started more than 24 months after exposure. "With HIV treatment programs now in place, women should be screened for ART during pregnancy" (Kuhn et al., 2009b: 135). "If ART is available, pregnant women should be prioritized and started on therapy if eligible as a matter of urgency… These results emphasize the importance of establishing appropriate referrals and coordination between services so that pregnant HIV infected women can be triaged for ART if appropriate" (Kuhn et al., 2009b: 136). (Gray IIIb) *(HAART, PMTCT, Zambia)*

- Training a key obstetrician on antiretroviral treatment at a medical center in **Tanzania** resulted in 25 women needing HAART gaining timely access to treatment (Ginsburg et al., 2007). (Gray V) *(providers, training programs, HAART, Tanzania)*

- In a study at Coronation Women and Children Hospital, **South Africa**, data were gathered from HIV-positive women attending antenatal care from June 2004 to July 2005 to evaluate linking antenatal with antiretroviral treatment (ARV) services. After a patient record review, interventions were implemented to strengthen service linkages and integrate ARV treatment within antenatal care. Laboratory investigations were streamlined, including CD4 cell count testing at the first antenatal visit. MTCT risk for women initiating ARV treatment was compared with that of women infant pairs receiving single dose nevirapine (sd NVP). In total, 164 pregnant women initiated ARV treatment and 863 received sd NVP. After changes to service delivery, time-to-treatment initiation was reduced from a median of 56 days to 37 days. The risk of MTCT for women receiving ARV treatment was lower than for those given sd NVP (van der Merwe et al., 2006). (Gray V) *(PMTCT, treatment, antenatal care, South Africa)*

8. Efavirenz may be safe to use for HIV-positive women who become pregnant, with little difference in the incidence of birth defects compared to other ART treatments.

- A retrospective study analyzed data on 344 HIV-positive women who became pregnant while receiving efavirenz-based (213) or nevirapine-based (131) antiretroviral therapy between 2003 and 2009 in **Côte d'Ivoire**. The study found no difference in pregnancy outcomes of mothers receiving efavirenz based or nevirapine based ART, with the exception of abortion (14.3% versus 7.3%). Of 326 mothers with known pregnancy outcomes, 11.7% sought an abortion, 5.2% miscarried, 6.7% delivered a stillborn, 10.8% delivered preterm and 20.2% delivered an infant of low birth weight. No external congenital abnormalities were reported in the charts of 249 infants born to mothers exposed to either efavirenz based or nevirapine-based ART. The women were recruited from four HIV care centers participating in the IeDEA

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project and two ANRS trials. In accordance with previous findings that efavirenz may cause birth abnormalities, women were advised of the potential risks and offered free contraception before initiating treatment with efavirenz. Congenital abnormalities were defined as all visible and external abnormalities observed or diagnosed in the first six weeks postpartum. Of women enrolled in the study, 56% presented at WHO clinical stage 3 or 4. During pregnancy, 5.2% of women were lost to follow up and 55.6% switched their initial treatment, including 89% (190 in 213) of women initially receiving efavirenz based ART. After conception, the median length of exposure was 52 days for women receiving efavirenz based ART and 264 days for women receiving nevirapine-based ART. These exposure lengths include the critical period of fetal development (Ekouevi et al., 2011). (Gray IIIb) *(treatment, pregnancy, Côte d'Ivoire)*

- A 2006-2008 study followed 195 HIV-positive women who unintentionally became pregnant while receiving efavirenz based antiretroviral therapy in **South Africa** and, dependent on the gestational age, continued on efavirenz based therapy or received a substitute. The study found that birth defects occurred in five of 184 live births (3.3%) compared to population estimates in South Africa of 2.6%-8%. In addition, the authors compared first and second/third trimester efavirenz exposure, and did not detect a significant difference in birth defects. The study also found that more women who continued on efavirenz based treatment reached levels of undetectable viral load at birth 83% (75 out of 90 HIV positive pregnant women) compared to women who switched treatment [68% (28 out of 41 HIV positive pregnant women)]. This result provides support for the continued use of efavirenz in areas where it is regularly prescribed. For example, "in South Africa, EFV is prescribed more often than NVP for the treatment of HIV 1 infected adults, because it is safer, easier to monitor, superior on time to viral load suppression, and may be associated with improved survival rates compared with NVP" (Nachega et al., 2008 cited in Bera et al 2010: 284). Furthermore, "with increasing numbers of reproductive aged women accessing ART services, it is anticipated that an increasing number of them will conceive on EFV based ART…[especially] in resource-poor countries where ART options are limited, coupled with the high burden of TB, it is likely that EFV will remain an important component of ART" (Bera et al 2010: 284, 288). In this study, one hundred and thirty four women who presented in the second or third trimester (14 weeks gestation or later) remained on efavirenz. Conversely, women who presented during the first trimester (0-13 weeks gestation) switched to nevirapine (55 women with CD4 count below 250) or lopinavir boosted ritonavir (8 women with CD4 count above 250). Women were followed throughout pregnancy until six weeks postpartum. Infants were examined by ultrasound at 18-23 weeks gestation and were monitored by a physician for six weeks. Birth defects noted included Trisomy 18, arthrogryposis multiplex congenita, oesophageal atresia with tracheo oesophageal fistula, postaxial polydactyly, and lower central incisor tooth (Bera et al., 2010). (Gray IIIb) *(treatment, pregnancy, South Africa)*

- A 2011 updated meta-analysis reported on the safety of efavirenz use in the first trimester of pregnancy for infants born to HIV-positive women. Among 21 studies, including studies in **Asia, Africa, Latin America, US and Europe**, the meta-analysis found birth defects in 2% of live births (39 of 1,437) and a relative risk of birth defects of 0.85 when comparing women on efavirenz-based versus non-efavirenz-based regimens. This means that infants of mothers receiving efavirenz-based regimens were at a 15% lower risk of birth defects compared to infants of mothers receiving non-efavirenz-based regimens. Previously reported, the 2010 meta-analysis showed "no increase in overall birth defects comparing first trimester receipt of efavirenz and non-efavirenz based regimens, although the limited number of reports prevented a definitive conclusion regarding the risk of rare outcomes such as neural tube defects" (Ford et al., 2010a cited in Ford et al., 2011). The meta-analysis included 21 studies

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where the primary endpoint was any kind of birth defect. Birth defect prevalence ranged from 0% to 22%, with a pooled prevalence of 2%. Analyses observed no difference in birth defects depending on publication status, study design or length of exposure to efavirenz, though noted higher prevalence of birth defects in developed versus developing countries. The relative risk of 0.85 was calculated based on data from 11 studies reporting birth defects among infants born to woman receiving efavirenz based and non-efavirenz based antiretroviral treatment (38 in 1289 versus 316 in 8122). Studies included were mostly prospective cohorts, with the quality of studies low For comparison, in 2006 the Antiretroviral Pregnancy Registry reported a prevalence of 2.9% for birth defects among women treated with non-efavirenz-based antiretrovirals and the March of Dimes Global Report also in 2006, reported a prevalence of 6% among the general population (p. 2: Joao et al., 2006 and Global Report on Birth Defects, 2006 cited in Ford et al., 2011). Efavirenz is one of the antiretrovirals of choice for patients co-infected with TB and it is well tolerated. (Ford et al., 2010a; Ford et al., 2011). (Gray IIIb) *(pregnancy, treatment, Asia, Africa, Latin America, United States, Europe)*

- A longitudinal cohort study done in the **United States** found that efavirenz increased survival as first line ARV. Data from the Women's Interagency HIV Study (WIHS) was used for a computer simulation model. Women who were non pregnant and ART naïve were enrolled between 1994 and 1995 and followed until 2002. ART was initiated at CD4 counts under 350 and an HIV RNA level above 100,000 copies. Estimation of survival in HIV positive women was done based on two first-line treatment option 1) efavirenz based ART regimen 2) non-efavirenz based regimen in which efavirenz use was delayed because of concerns of pregnancy. Reported rates of pregnancy, live birth and teratogenicity were then incorporated to estimate the potential risk events on the fetus per 100,000 women exposed to efavirenz compared to women who were unexposed. Efavirenz teratogenicity prevalence of 2.72% among HIV positive women with no exposure history to efavirenz and 2.9% among HIV positive women exposed to efavirenz was used in the simulation. The mean projected life expectancy for women on efavirenz based regimen was 28.91 life years versus 28.02 years for women who were on alternative regimens; a net gain of 0.89 years. When the initial recommended efavirenz based regimen was substituted by a nevirapine based regimen and ART was initiated at CD4 counts under 250, the estimated survival decreased from 27.08 years to 25.49 years. Mean projected life expectancy for women receiving an efavirenz based first-line ART regimen starting at CD4 counts under 500 cells was 30.45 life years, while mean life expectancy for women who delayed efavirenz use and were treated with an alternative initial ART regimen which did not contain efavirenz was 29.53 life years. The life expectancy gain attributable to using an efavirenz based initial antiretroviral regimen was 0.92 years. For women who did not have history of efavirenz exposure the rate of teratogenic events was 72.46 per 100,000 women. With efavirenz exposure, the rate was 77.26 per 100,000 women. A higher rate of teratogenicity (11.72 excess events per 100,000 women) was observed in younger women between the ages of 15 to 24 attributable to increased rate of pregnancy in younger women (Hsu et al., 2011). (Gray IIIb) *(pregnancy, treatment, United States)*

Promising Strategies:

9. PMTCT-Plus (family-focused) HIV care can increase the numbers of women and their male partners who access testing and treatment.

- 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)*

- Follow up data from 2003 to 2008 of 9,718 adults and 6,739 children enrolled in the MTCT-Plus Initiatives in **Cameroon, Côte d'Ivoire, Kenya, Mozambique, Rwanda, South Africa, Uganda, Zambia and Thailand** found that 4,275 (45%) of women enrolled during pregnancy; 3,611 (37%) enrolled during postpartum, 1,569 HIV-positive male partners accessed treatment, along with 449 older children. More than 6,000 women chose to enroll their newborn, with more than 70% of exposed infants tested (Betancourt et al., 2011). (Gray IIIb) *(PMTCT-Plus, treatment, Cameroon, Côte d'Ivoire, Kenya, Mozambique, Rwanda, South Africa, Zambia, Thailand)*

10. CD4 cell count screening to identify women who will benefit from antiretroviral therapy may be more effective than HIV clinical disease staging. However, lack of available CD4 screening should not be used to deny women needed treatment.

- A study assessed performance of World Health Organization criteria for antiretroviral treatment among 6,036 HIV-positive women who enrolled in the MTCT-Plus Initiative from 2003 to 2008 in **Cameroon, Côte d'Ivoire, Kenya, Mozambique, Rwanda, South Africa, Thailand, Uganda** and **Zambia**. The study found that CD4 cell count was more effective than HIV disease clinical staging in identifying pregnant and postpartum HIV-positive women who could benefit from antiretroviral therapy. WHO clinical disease stages III/IV identified 23% of all women who could benefit from antiretroviral therapy compared to 94% identified by CD4 cell count below 350. In the MTCT Plus Initiative, revisions to WHO criteria in 2009 (increasing CD4 cell count threshold from 200 to 350) would have increased the proportion of all HIV-positive mothers eligible to receive ART from 21% to 45%. Women were classified as HIV disease stage I (71%), stage II (18%), stage III (10%) or stage IV (1.2%). Only 11% of women were eligible based on HIV clinical disease stage III or IV compared to 45% who had a CD4 cell count below 350. The study found no difference between clinical disease staging among pregnant and postpartum women, however pregnant women had significantly lower median CD4 cell counts compared to postpartum women with pregnant women 50% more likely to be eligible for antiretroviral treatment than postpartum women. This finding may be due to a natural decrease in CD4 cell count associated with pregnancy (Ekouevi et al., 2007; Tuomala et al., 1997; and Lebon et al., 2007 cited in Carter et al., 2010: 409). The results of this study "are consistent with evaluations of public PMTCT programs and large PMTCT clinical trials conducted in sub-Saharan Africa, which show low rates of symptomatic disease (1%-9% WHO stage III/IV) among pregnant women, but a high prevalence of immunosuppression (24%-45% CD4 cell count below 350)" (Ekouevi et al., 2007; Kilewo et al., 2008 cited in Carter et al., 2010: 408). The MTCT Plus Initiative supported 13 clinics across 9 countries to deliver family-focused HIV care and treatment. All women underwent CD4 cell count screening and HIV disease clinical staging at entry. At time of enrollment,

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62% were pregnant and 38% were up-to-six-months postpartum. Prior to participating in the MTCT-Plus Initiative, 91% of these women had received only single-dose nevirapine or no antiretroviral treatment. Mothers were excluded from this analysis if they had received ART or short-course ART before baseline data were measured (Carter et al., 2010). (Gray IIIb) *(pregnancy, CD4 counts, treatment, Cameroon, Côte d'Ivoire, Kenya, Mozambique, Rwanda, South Africa, Thailand, Uganda and Zambia)*

- A study assessed the impact of revised 2009 World Health Organization criteria for eligibility to receive treatment among 1,025 HIV-positive women and infants in a breastfeeding trial, which took place in **Zambia** between 2001 and 2004. The study found that under the new criteria 68% of women would be eligible for treatment (54% by CD4 cell count and 14% by HIV disease clinical staging) and, if effectively treated, 92% of maternal deaths could be prevented (88% identified by CD4 cell count and 4% by clinical staging). In addition, the higher coverage levels could prevent 88% of perinatal and postnatal transmissions (mostly among women identified by CD4 cell count: 76% of perinatal transmissions and 83% of postnatal transmissions). HIV clinical stage IV disease was not identified in any women. Using lower CD4 cell count thresholds of 200 only prevented 59% of maternal deaths, using CD4 counts of 250 only prevented 72% of maternal deaths and using CD4 counts of 300 for initiation of antiretroviral treatment only prevented 79% of maternal death. Improving detection of HIV in these settings is a high priority because these "programs to prevent mother-to-child HIV transmission are now one of the major sites where HIV-infected adults are identified and treated" (Kuhn et al 2010b: 1374). The 2009 WHO criteria recommend initiating antiretroviral therapy in adults with HIV clinical stage III or IV (regardless of CD4 cell count), or CD4 cell count below 350 (regardless of clinical staging). WHO criteria for initiation of antiretroviral therapy prior to 2009 required CD4 cell counts below 200 or if CD4 cell counts were between 200 and 350, HIV clinical stage III or IV. The trial was conducted from 2001 to 2004 before widespread availability of antiretroviral treatment. Mothers were recruited during pregnancy and followed for 24 months postpartum along with their infants (Kuhn et al., 2010b). (Gray IIIb) *(pregnancy, treatment, CD4 counts, Zambia)*

- A 2011 study with 232 pregnant women who were attending antenatal care in **South Africa** found that a point-of-care CD4 measurement accurately identified pregnant women who were eligible for ART initiation. Capillary specimen was collected for determining CD4 count for the point-of-care (PIMA analyzer) testing. Blood samples were also collected for the lab-based CD4 count which was done within 24 hours. The median CD4 count using PIMA was 350 cells compared to 362 cells using lab based testing. Ninety four percent of women tested with PIMA were correctly identified as ART eligible (lab CD4 count of below 350 cells). The positive and negative predictive values for the PIMA test were 89% and 94% respectively (Mnyani et al., 2012). (Abstract) *(pregnancy, treatment, CD4 counts, South Africa)*

9C-2. Gaps in Programming – Treatment

1. Interventions are needed to increase knowledge of PMTCT-Plus programs among women and the community and to reduce stigma and discrimination directed toward HIV-positive mothers.
2. Interventions are needed to inform both providers and women injection drug users of the benefits of harm reduction early in pregnancy and to provide women who use drugs with

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proven effective interventions for safe motherhood and prevention of vertical transmission.

3. Pregnant women living with HIV need timely CD4 count testing, with results, to access HAART.
4. Prospective surveillance systems of pregnant women on ARVs who give birth in developing countries are needed to inform the assessment of rare birth defects.
5. Additional efforts are needed so that pregnant women who qualify receive HAART, both for their own health and to prevent transmission to partners and infants.
6. Nutritional supplements in addition to ARVs may be needed to avert adverse outcomes for mothers and babies.
7. Further research is needed to assess the long-term health impacts and possible drug resistance for pregnant women living with HIV who initiate ART solely for the prevention of vertical transmission and then stop.
8. Interventions are needed to address gender inequity related to uptake and adherence of ART and ARV prophylaxis.

1. **Interventions are needed to increase community knowledge of PMTCT-Plus programs and to reduce stigma and discrimination directed toward HIV-positive mothers.** *[See also Strengthening the Enabling Environment: Reducing Stigma and Discrimination]* Studies found that single-dose nevirapine for HIV-positive mothers to prevent vertical transmission which is currently contraindicated by WHO is still widely used. Studies found that providers do not expect pregnant women living with HIV to be sexually active and do not have adequate training or counseling skills. Providers and community members blamed women for being HIV-positive and for becoming pregnant. A study also found that pregnant women believed that HAART is only required after clinical signs of HIV are manifested.

    - Gap noted, for example, in **Uganda** (Duff et al., 2010); **South Africa** (Sprague, 2009; Sprague et al., 2011), **Botswana** (Kebaabetswe, 2007) and **Zimbabwe** (Feldman and Masophere, 2003).

2. **Interventions are needed to inform both providers and women injection drug users of the benefits of harm reduction early in pregnancy and to provide women who use drugs with proven effective interventions for safe motherhood and prevention of vertical transmission.** *[See also Prevention for Key Affected Populations: Women Who Use Drugs and Female Partners of Men Who Use Drugs]* A study of PMTCT programs found that women who use drugs were the least likely to receive treatment and only to be tested for HIV during labor. No linkages were found between PMTCT programs and harm reduction programs. Women who use drugs fear accessing health services for fear of losing custody of their children. Another study found that continuous methadone treatment for female drug users during pregnancy is associated with earlier antenatal care

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and improved neonatal outcomes. However, a study found that medical providers caring for pregnant women did not understand opioid agonist treatment or the safety of opioid agonist treatment during pregnancy. Another study found that fewer pregnant HIV-positive drug users had access to proven effective interventions for safe motherhood and prevention of vertical transmission compared to other pregnant women.

- Gap noted, for example, in **Ukraine** (Finnerty et al., 2010; Thorne et al., 2011; Thorne et al., 2009); Australia (Burns et al., 2006); and for FWID in **numerous countries** (Pinkham and Malinowska Sempruch, 2008; HRW, 2005 cited in Pinkham and Malinowska Sempruch, 2008).

3. **Pregnant women living with HIV need timely CD4 count testing, with results, to access HAART.** A study found that of 14,815 HIV-positive pregnant women, only 17.1% had their CD4 cells counted and of those only 66.5% had their CD4 counts available; of these, only 581 were initiated on HAART.

    - Gap noted, for example in **Zambia** (Mandala et al., 2009) **Zimbabwe** (Muchedzi et al., 2010) and globally in resource-limited settings (Wilfert et al., 2011).

4. **Prospective surveillance systems of pregnant women on ARVs who give birth in developing countries are needed to inform the assessment of rare birth defects.** Randomized controlled trials would be unethical but meta-analysis shows the need for more data to assess birth defects for pregnant women who give birth while on ARVs.

    - Gap noted generally in **Côte d'Ivoire, South Africa, Thailan**d and other countries (Ford et al., 2011).

5. **Additional efforts are needed so that pregnant women who qualify to receive HAART, both for their own health and to prevent transmission to partners and infants.** A study found that pregnant women who were eligible for HAART did not access HAART.

    - Gap noted, for example, in **South Africa** (Stinson et al., 2010); **Uganda** (Ahoua et al., 2010) and **Brazil** (Fernandes et al., 2010).

6. **Nutritional supplements in addition to ARVs may be needed to avert adverse outcomes for mothers and babies.** A study found high rates of anemia as well as adverse infant outcomes due to maternal malnutrition. Globally, women in developing countries suffer high rates of anemia in pregnancy (Hardee et al., 2012).

    - Gap noted globally (Mirochnick et al., 2010); in **Uganda** (Cohan et al., 2012) and **Tanzania** (Mehta et al., 2010)

7. **Further research is needed to assess the long-term health impacts and possible drug resistance for pregnant women living with HIV who initiate ART solely for the prevention of vertical transmission and then stop.** A study showed that changes in CD4 counts and viral levels over a period of one year were similar between women who

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~~continued ART and stopped ART after delivery, however increased immune activation among women stopping ART requires further study. The ongoing NIH-funded PROMISE study is designed to answer this question with results anticipated in 2015.~~

- ~~Gap noted, for example, in the **United States** (Watts et al., 2009); and **South Africa** (Parboosing et al., 2011).~~

8. ~~**Interventions are needed to address gender inequality related to uptake and adherence of ART and ARV prophylaxis.** *[See Treatment]*~~

   - ~~Gap noted for **Uganda** (Duff et al., 2010).~~

9D. *Safe Motherhood and Prevention of Vertical Transmission:* Delivery

For women with HIV, there is little evaluated evidence available regarding delivery options, though research has shown that by substantially lowering viral load, HAART can diminish the advantage of a cesarean section in reducing perinatal transmission (Sharma and Spearman, 2008; Rongkavilit and Asmar, 2011; Coovadia and Newell, 2012). Cesarean sections are not always available or safe in many developing country settings. In situations where a safe cesarean section can be provided however, further research is needed to determine whether women with HIV suffer more adverse events due to the procedure. Further research is also needed on whether elective cesarean sections provide PMTCT benefits for HIV-positive pregnant women who have viral loads lower than 1,000 copies/mL (Anderson and Cu-Uvin, 2009; US HHS, 2011). While cesarean sections may not be the best option for the delivery for HIV-positive women in resource poor settings, they remain necessary surgical procedures in some cases to reduce the maternal mortality associated with difficult deliveries.

> *"I felt extremely bad …when I was writhing with labour pains in the corridor…when a nurse shouted at me on top of her voice, 'have you swallowed your tablet.' Everyone looked at me and instantly knew I have HIV" –HIV-positive woman in Uganda (cited in Were and Hasunira, 2010:24)*

In vaginal deliveries, routine episiotomies have been shown to be particularly risky for HIV-positive women. A study in South Africa of 241 HIV-positive women compared to 427 HIV-negative women who gave birth and were evaluated at four intervals (within 72 hours post delivery, and at one, two, and six weeks) for clinical signs of postpartum infection, found that episiotomy was associated with a two-fold increased risk of postpartum infections among the HIV-positive women. Among HIV-positive women with low CD4 counts, the risk of postpartum infection associated with episiotomy was even higher. Because the majority of postpartum infections were detected

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at the one-week review, it is important to have a skilled attendant examine the woman postpartum within the week following delivery (Sebitloane et al., 2009).

The mode of delivery does not seem to affect HIV disease progression. A study from 1990 to 2004 in the United States found no difference in HIV-related disease progression after delivery for HIV-1-positive women delivering through elective cesarean section (before membrane rupture), non-elective cesarean section (after membrane rupture), or vaginally. Of the 1,491 births where mode of delivery was documented, 1,087 were vaginal, 183 were elective cesarean, and 221 were non-elective cesarean and the mode of delivery was not associated with viral load increase or CD4 count decrease within 18 months after delivery or progression to AIDS or death within an average of 2.7 years after delivery (Navas-Nacher et al., 2006).

Globally many HIV-positive women experience violations of human rights, as well as stigma and discrimination during labor and delivery. Women living with HIV have faced coerced and forced sterilization (Mthembu et al., 2011) and FIGO has issued guidance that "consent to sterilization must not be made a condition of receipt of any other medical care, such as HIV/AIDS treatment…" (FIGO, 2011). Health care providers need training to reduce this stigma and discrimination against HIV-positive women in the delivery setting. They also need access to appropriate personal protective equipment (PPE) such as gloves, gowns, needleless systems and eye shields so that they can protect their own health as they care for their patients (WHO, 2009f). *[See Structuring Health Services to Meet Women's Needs]* Health care providers must ensure HIV-positive women's confidentiality regarding HIV serostatus. …" HIV-positive women, as all women, need support and information about their choices in childbirth.

In settings where many women do not present for antenatal care, HIV testing to establish serostatus has been offered during labor and delivery (Bello et al., 2011b). However, …most women with unknown HIV status in labour represent a particularly vulnerable group in a particularly vulnerable situation" (Bello et al., 2011b: 30) and voluntary consent is called into question if women are first offered testing during labor and delivery (Center for Reproductive Rights, 2005). HIV testing at the time of labor should be treated as the last resort for prevention of MTCT, because the women then miss the opportunity to receive the full prophylactic regime as well as other PMTCT services. Moreover, being confronted with a positive HIV result is associated with great distress and labor is not the optimal time for conveying such information" (Hahn et al., 2011: para 30).

As previously mentioned in the introduction to the treatment section above, the WHO released new guidelines in 2010, with a newer update in 2012, for the use of ARVs in pregnant women that expands treatment to women with CD4 counts below 350 cells/cubic mm, rather than below 200 cells/cubic mm and provides for earlier ARV prophylaxis at 14 weeks gestation, rather than 28 weeks gestation (WHO 2010i).

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9D. What Works—*Safe Motherhood and Prevention of Vertical Transmission:* Delivery

Promising Strategies:

1. In addition to the use of antiretroviral drug regimens for either treatment of the mother's health or prophylaxis to prevent mother-to-child transmission of HIV, elective cesareans (if safely available) may further reduce the risk of vertical transmission.

9D. Evidence

Promising Strategies:

1. **In addition to the use of antiretroviral drug regimens for either treatment of the mother's health or prophylaxis to prevent mother-to-child transmission of HIV, elective cesareans (if safely available) may further reduce the risk of vertical transmission.**

   - A study of a cohort of 453 pregnant women living with HIV in **Brazil** found that HAART and elective Cesarean section reduced the risk of vertical transmission. Data from 401 infants born between 2000 and 2009 was analyzed, of whom 15 acquired HIV and 386 infants remained HIV-negative. Use of HAART for longer periods and elective Cesarean section were associated with a lower risk of vertical transmission. The rate of vertical transmission was 3.74% and the mean CD4 cell count of HIV pregnant women was 474 cells/mm3, with 70.3% having an undetectable viral load in the third trimester. For women with CD4 cells below 350, the risk of vertical transmission was increased 12-fold. HAART use for less than 15 days prior to delivery increased the risk of vertical transmission 15 fold. Vaginal delivery after the onset of labor increased the risk of vertical transmission five-fold (Delicio et al., 2011). (Gray IIIb) *(PMTCT, cesarean section, delivery, HAART, Brazil)*

   - Because the risk of perinatal transmission of HIV is directly proportional to maternal viral loads, for women who have either very low or undetectable viral loads, there may be no additional benefit to cesarean section delivery. "For those [women] on highly active antiretroviral therapy who have undetectable or low viral loads, the added benefit of cesarean delivery is not established and is probably negligible" (Sharma and Spearman, 2008: 414). (Gray V) *(PMTCT, cesarean section, delivery, HAART)*

9D. Gaps in Programming—Delivery

1. Efforts are needed to ensure HIV-positive women have information on birthing options and the right to make choices based on that information.
2. Interventions are needed to ensure that stigma from health care workers does not

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discourage HIV-positive women from giving birth in safer settings.

3. Efforts are needed to ensure that health care workers protect the confidentiality of HIV-positive women's serostatus.
4. Interventions are needed to provide HIV testing and counseling during labor and delivery that respects informed consent.
5. Health care providers must have access to personal protective equipment such as gowns, gloves, needle-less systems and eye protection to decrease the risk of occupational exposure.

1. **Efforts are needed to ensure HIV-positive women have information on birthing options and the right to make choices based on that information.** Studies found that HIV-positive women were not given information on birthing options.

    - Gap noted, for example, in **Ukraine** and **Brazil** (Yaremenko et al., 2004).

2. **Interventions are needed to ensure that stigma from health care workers does not discourage HIV-positive women from giving birth in safer settings.** *[See also Strengthening the Enabling Environment: Reducing Stigma and Discrimination]* Studies found that HIV-positive women experienced discrimination by providers in ANC services or did not attend ANC services due to fear of mistreatment by health providers.

    - Gap noted, for example, in **Uganda** (Were and Haunira, 2010): **Thailand** (Teeraratkul et al., 2005), **Cote d'Ivoire** (Painter et al., 2004) and **Vietnam** (Hong et al., 2004).

3. **Efforts are needed to ensure that health care workers protect the confidentiality of HIV-positive women's serostatus.** A study found that health workers violated women's confidentiality.

    - Gap noted, for example, in **Ukraine** (Yaremenko et al., 2004).

4. **Interventions are needed to provide HIV testing and counseling during labor and delivery that respects informed consent.** *[See HIV Testing and Counseling for Women and Antenatal Care: Testing and Counseling]*

5. **Health care providers must have access to gowns, gloves, needle-less systems and eye protection to decrease the risk of occupational exposure to HIV.** *[See Structuring Health Services to Meet Women's Needs]*

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9E. *Safe Motherhood and Prevention of Vertical Transmission:* Postpartum

Postpartum care is the most neglected aspect of maternal health, yet a time of high risk for maternal mortality. "The majority of maternal deaths occur during or immediately after childbirth; …up to half of all newborn deaths occur within the first 24 hours of life" (WHO et al., 2011c). While many women access antenatal care, much fewer women globally have access to postnatal care. For example, in Uganda, 75% of women who have had a live birth received no postnatal care. Only one in five mothers received postnatal care within the critical first two days after delivery (DHS Uganda 2006 cited in Were and Hasunira, 2010). For HIV-positive women, even fewer access postnatal care (Nassali et al., 2009).

It is critical that women living with HIV are retained in care for their own health following the birth of their child. "…Many pregnant women, even those found to be living with HIV and provided with antiretroviral drugs to prevent the vertical transmission of HIV, are not retained in care for their own health" (WHO et al., 2011a: 22). *[See Treatment and Antenatal Care: Treatment]* Postpartum interventions to prevent vertical transmission of HIV include protecting the health of the mother with triple therapy treatment for her own health and providing ARV treatment during pregnancy or during both pregnancy and breastfeeding to the mother solely for the purpose of reducing HIV transmission from mother to infant. Contraception counseling for women in order to space their next pregnancy or prevent an unintended pregnancy is also a critical – though often overlooked – component of postpartum intervention planning in PMTCT for HIV-positive women (Wilcher et al., 2008).

The benefits of ARV treatment for women living with HIV are clear. *[See Treatment and Antenatal Care: Treatment]* "Additionally, the systematic use of tritherapy could contribute to a reduction in expenditures for breast-milk substitutes (formula)" (Kouanda et al., 2010a: 848). ARV treatment for infants and children can also provide excellent prospects for survival into adulthood. However, without antiretroviral treatment, approximately half of children with perinatal infection die before two years of age (Newell et al., 2004, cited in Abrams, 2007). "International approaches for preventing MTCT of HIV now focus on child survival, not just HIV transmission, as the appropriate outcome to measure success of PMTCT programs. Ultimately, the goal is a live and healthy, HIV-negative child and an alive and healthy mother to care for that child" (Jackson et al., 2009: 226).

Mothers Need to Know the HIV Status of Their Infants

In order to appropriately assess what course of action to take, health providers and parents need to know the HIV status of infants, with the express permission of the mother. Yet in 54 reporting countries, only 15% of children both to mothers living with HIV were tested for HIV in the first two months of life (Zachariah et al., 2011a). Among

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65 reporting countries, only 28% of infants born to mothers living with HIV received an HIV test within the first two months of life. Only 23% of HIV-exposed children in 87 reporting countries received co-trimoxazole within two months of birth in 2010 (WHO et al., 2011b). "In children younger than 18 months, … the lack of appropriate laboratory facilities for PCR testing, the cost of assays, and the need to repeat PCRs in infants who are exposed to infected breast milk, makes it difficult to implement infant diagnosis programs…" (Kellerman and Essajee, 2010: para 9). A potentially promising diagnostic is being developed and tested by PATH to detect HIV status in infants in less than 30 minutes (Boyle et al., 2012). In addition, testing the infant reveals the mother's HIV status which could expose her to stigma and discrimination. *[See Strengthening the Enabling Environment: Reducing Stigma and Discrimination and HIV Testing and Counseling]* Infant serostatus can currently be reliably confirmed via PCR within 14 weeks (Havens and Mofenson, 2009). Without diagnosis and effective treatment, one-third of infants living with HIV die before the age of one and almost half die during their second year of life (WHO et al., 2011b).

Four Interventions to Reduce Postnatal Transmission

What works best to prevent postnatal transmission via breastfeeding has been the subject of much scrutiny. "Identified risk factors for transmission during breastfeeding include increased severity of maternal disease, mastitis and breast abscess, mixed infant feeding, maternal seroconversion during lactation, lower maternal CD4 cell count, and higher maternal HIV viral load" (Mmiro et al., 2009: 32).

Formula Feeding May Increase Infant Mortality Where There is No Access To Clean Water

Infant formula feeding may avert transmission of HIV via breastfeeding. However, there are more than one billion people globally without adequate access to clean water, leading to over 1.8 million child deaths from diarrhea and other diseases caused by unclean water and poor sanitation. Some have argued that advanced biomedical approaches to preventing vertical transmission "should not detract from the need for … greater access to clean drinking water and safe environment to support formula feeding" (Saloojee and Cooper, 2010: 342).

In settings prevalent in most of the developing world where there is no access to safe, clean drinking water, HIV-positive women who use infant formula may see their baby, who was born HIV-negative, die from diarrheal diseases if fed formula. "Several studies confirm that the benefits of shortening breastfeeding are offset by adverse outcomes in those infants who escape infection" (Kuhn et al., 2009a: 83). Globally, breastfeeding leads to about 300,000 HIV-positive infants every year, while at the same time, UNICEF estimates that not breastfeeding and having infants formula fed with contaminated water leads to approximately one and a half million child deaths per year (Fletcher et al., 2008). Additionally, concerns have been raised that promoting infant formula as a best practice to prevent vertical transmission may have negative consequences by decreasing

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breastfeeding of infants. Even in countries such as Botswana, where "almost the entire population has access to piped water…" (Creek et al., 2010: 14) and where no-cost infant formula is provided and 64% of HIV-positive women received formula following delivery, flooding in 2006 led to an outbreak of diarrheal disease, resulting in 35,046 cases and 532 deaths, 97% of these in children under the age of 2 and 64% with mothers living with HIV. "Many factors that influence the safety of replacement feeding are external to the individual household, a reality that is difficult to account for during infant feeding counseling" (Creek et al., 2010: 19). Even in higher income countries such as Botswana and South Africa, the supply of infant formula through public health facilities is unreliable (Goga et al., 2009 cited in Doherty et al., 2010).

For women who do not have access to ARVs for either treatment or MTCT prophylaxis and who do not have access to clean water to make formula feeding safe, health providers have been advising breastfeeding. Many studies have shown that mixed feeding increases the risk of HIV transmission from the HIV-positive mother to her infant. Experts thus advise that it is better for an HIV-positive mother to exclusively breastfeed than to breastfeed and add any additional nutrition in the way of food or water prior to six months (Kuhn et al., 2009a). After six months, for HIV-positive mothers who do not have access to clean water, infant survival is increased by continued breastfeeding and adding additional nutrients for the child. Breastfeeding beyond six months, however, may increase the risk of HIV infection of the infant to 9.68% by the time the infant is two years old (Taha et al., 2007). Experts advise that infants who are HIV-positive should be breastfed. However, in most cases, the choice of feeding is often decided before the mother knows her infant's serostatus. Feeding choices can be laden with stigma as well. HIV-positive women may face heavy stigma from partners, families and communities if they formula feed their infants, yet if they do not formula feed, they may fear HIV transmission to their infants.

WHO Breastfeeding Recommendations:

For HIV-negative mothers*:* exclusive breastfeeding for six months and then breastfeeding for 24 months while adding other solid foods;

For HIV-positive mothers*:* exclusive breastfeeding for six months and then breastfeeding for twelve months while adding solid foods.

(WHO, 2010j)

New Guidelines About Infant Feeding Still Leave Unanswered Questions

The WHO rolled out a new policy on infant feeding (WHO, 2010j: http://whqlibdoc.who.int/publications/2010/9789241599535_eng.pdf), which now recommends that "mothers known to be HIV-infected (and whose infants are HIV-uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first six months

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of life, introducing appropriate complimentary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breastfeeding can be provided" (WHO, 2010j: 6). HIV-positive women should also know that breastfeeding does not harm their own health (Taha et al., 2006, Allen et al., 2007a, Lockman et al., 2009, Wilfert and Fowler, 2007).

The 2010 WHO guidelines state that if infant formula is given to prevent perinatal transmission, the following conditions are needed: safe water and sanitation assured at the household level and in the community; the mother or other caregiver can reliably provide sufficient infant formula milk to support normal growth and development of the infant; the mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhea and malnutrition; the mother can, in the first six months, exclusively give infant formula milk; and the family is supportive of this practice; and the mother or caregiver can access health care that offers comprehensive child health services (WHO, 2010j: 7). In 2010, these WHO guidelines represented the best available evidence that was informed by a risk/benefit analysis of economic and other factors specific to resource-limited settings: (Annexes 5 and 6, WHO, 2010j: http://www.who.int/maternal_child_adolescent/documents/9789241599535/en/).
However, this is a rapidly changing scientific landscape and it is realistic to expect best practices to change based on new evidence. In addition, WHO 2010j recommendations will need to be tailored by countries to their specific contexts.

The WHO also recommends that infants be given daily AZT or NVP from birth until six weeks of age (WHO, 2010j). However, the impact on future treatment options should an infant become HIV-positive while on this regimen are unclear and the infant may develop drug resistance (Zeh et al., 2011). Studies show that infant prophylaxis can decrease infant acquisition of HIV when breastfed.

Infant Feeding Research Offers Complex and Contradictory Advice

> *"It is confusing to us, today breastfeed, tomorrow don't." -HIV-positive mother (cited in Chisenga et al., 2011:155)*

In the absence of HAART or safe conditions for infant feeding, questions remain on how long HIV-positive women should breastfeed to minimize the risk of HIV transmission but reduce the risk of their infant dying from diarrheal disease. "How to protect the infant from complications related to non-exclusive breastfeeding and keep the child HIV free is a dilemma in the settings where replacement feeding is not safe" (Taha et al., 2011: 393). "Scientific messages…need to be clarified. Women are told both that 'Breastfeeding is a mode of HIV transmission' and 'Exclusive breastfeeding is a mode of prevention'" (Desclaux and Alfieri, 2009: 825).

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WHO now recommends that women living with HIV either receive HAART while breastfeeding and beyond or to use infant formula. However, infant feeding studies have offered complex and sometimes contradictory advice on the best feeding practices and the optimal time to wean for both averting HIV transmission and reducing infant mortality (Palombi et al., 2007; Kagaayi et al., 2008; Kuhn et al., 2009c; Kuhn et al., 2010c; Taha et al., 2007; Becquet et al., 2008; Kuhn et al., 2008; Thior et al., 2006; Leroy et al., 2008 cited in Gray and Saloojee, 2008; Becquet et al., 2007; Rollins et al., 2008). However, it is clear that for women who lack access to ARVs, the CD4 count is important in the likelihood of HIV transmission to the infant (Kuhn et al., 2009c, Kuhn et al., 2010c). Ultimately, HAART for the mothers improves the likelihood that infants will not acquire HIV via breastfeeding (Kuhn et al., 2009c).

Studies show that mixed feeding (when a mother both breastfeeds and provides any other food, in addition to breast milk), particularly prior to the infant being four to six months of age, can put the infant at a higher risk of acquiring HIV. Studies describe the increased statistical risk of the infant acquiring HIV when mixed feeding is used, but do not describe the mechanism. It may be that the immature gut mucosa in an infant can be damaged by the introduction of other foods and nonhuman milk, thus leading to increased permeability enabling HIV viral entry (Charurat et al., 2009) or it may be that when a mother does not breastfeed regularly she can develop mastitis, a painful inflammation of the breast. Mastitis may not always be severe enough to compel a woman to receive medical care, however, studies have shown that HIV-positive women with even subclinical cases of mastitis have a higher viral load in the breast milk of the affected breast (Nussenblatt et al., 2006, Kasonka et al., 2006, Kantarci et al., 2007). Further research is needed.

Women Face Difficult Decisions in Infant Feeding

Mothers report that they struggle to stop breastfeeding at 12 months, which goes against cultural norms and could reveal their HIV-positive serostatus as well as the status of their infants, referred to pejoratively by others as "nevirapine babies." Many mothers also struggle to purchase nutritious food for their infants starting at six months (Ostergaard and Bula, 2010). Mothers living with HIV in resource-limited settings are faced with a terrible dilemma at the time of infant feeding, forced to choose between "two competing risks: exposure to malnutrition or exposure to HIV infection" (Cames et al., 2010b: 784). With infants more likely to die from malnutrition than HIV, WHO has recommended breastfeeding. Yet, HIV-positive mothers in resource-poor settings may be so motivated to protect their infant from vertical transmission, that they may stop breastfeeding early even when lacking adequate replacement foods (Lumney et al., 2008 cited in Cames et al., 2010b). In sub-Saharan Africa, breastfeeding is universal and continued until age 24 months in most settings (DHS, 2007 cited in Taha, 2011).

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Women who follow WHO's current advice to breastfeed were made to feel in earlier years that if they breastfed their infants they were failing to ensure their infants survival, or worse, providers accused women of killing their infants with their breastmilk (Chisenga et al., 2011; Ostergaard and Bula, 2010). One HIV-positive mother of five in Cameroon said that she was told: "'Your child is going to die if you breastfeed. You'll contaminate him' (cited in Desclaux and Alfieri, 2009: 824). Women reported that when they breastfed, "I felt like I was giving poison to my child" (Woman living with HIV in Malawi, cited in Ostergaard and Bula, 2010: 217). WHO's current advice presents a huge advantage as the recommendation to exclusively breastfeed for six months and then partially breastfeed for the infants' first 12 months more closely mirrors the usual infant feeding practices and will not "advertise the woman's HIV-positive status, thus reducing stigma" (Chisenga et al., 2011: 157). But women still struggle with the knowledge that breastmilk can increase the risk of HIV transmission and "are aware of the fact that the child could be given infant formula exclusively (instead of mother's milk) but as the financial cost is high, they feel too poor to buy it" (Ostergaard and Bula, 2010: 217). And some women living with HIV cannot breastfeed for the same reasons as for HIV-negative women, or as one woman living with HIV put it: "I had to leave breastfeeding because I wanted to go and look for a job" (Woman cited in Morgan et al., 2010: 869). "To maximize HIV-free survival among HIV-negative infants born to HIV-positive women, infant feeding recommendations must balance the risks of HIV acquisition through breast-feeding with the setting specific risks of diarrhea, pneumonia, malnutrition and death associated with replacement feeding" (Ciaranello et al., 2012, Abstract). Women living with HIV also face pressures from their partners, families and communities to breastfeed for more than 12 months and to provide mixed feeding prior to the recommended six months of exclusive breastfeeding (Msellati, 2009; Gewa et al., 2011; Wachira et al., 2009; Tomasoni et al., 2011).

In many countries, formula feeding is associated with HIV and women who formula feed face stigma. For example, in Botswana, free ARVs and infant formula are widely available, as is safe drinking water; yet, more than half of women in a study did not formula feed their babies due to stigma (Shapiro et al., 2003). PMTCT programs may also inadvertently increase stigma against women living with HIV by having separate HIV facilities, home visits for HIV-positive women, or providing infant formula (Thorsen et al., 2008). For women living with HIV who have infants who are HIV-positive, breastfeeding is best, but women are often unable to know their infant's serostatus prior to deciding whether to breastfeed or not. Since the infant feeding advice that women get is contradictory, it is not surprising to find studies where "the majorities of the mothers …seemed confused about how HIV-infected mothers should feed their infants" (Falnes et al., 2011: para 39). Other studies found that mothers understood the dangers of HIV transmission but that exclusive breastfeeding and exclusive replacement feeding were difficult to maintain because of the stigma of going against cultural norms and the fear that disclosing their HIV positive serostatus would lead to abandonment by

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their husbands, with dire economic consequences for them and their children (Chisenga et al., 2011; Fadnes et al., 2010; Ostergaard and Bula, 2010). *[See Strengthening the Enabling Environment: Reducing Stigma and Discrimination]*

Prevention of Vertical Transmission in the Postpartum Period Remains Challenging
Further research is urgently needed to clarify what works best in infant feeding in settings where infant diarrheal deaths are common to prevent perinatal transmission. "Prevention of mother-to-child HIV transmission during breastfeeding remains one of the greatest challenges facing scientists, clinicians and women in the developing world… While awaiting further studies… promoting exclusive breastfeeding with safer weaning and assuring ART for pregnant and postpartum women with advanced HIV will likely prevent the majority of needless maternal and infant deaths" (Kuhn et al., 2009a: 90-91).

Although only about half of infected infants survive their first two years without antiretroviral treatment, about a quarter will live ten years or more. As these perinatally infected HIV-positive children become adolescents will need testing, treatment and sexual and reproductive health services (Ferrand et al., 2011). *[See Prevention for Young People]*

"It is easy to get overwhelmed by the enormity of the world-wide perinatal HIV epidemic and the extent of resource and infrastructure needs; however, this cannot be an excuse for inaction. Implementation will be challenging. However, the cost of indecision and delay in program implementation is high, because every pediatric HIV infection that is not prevented increases the ultimate economic and social cost to each family, community, and country" (Mofenson, 2010b: S144).

9E. What Works—*Safe Motherhood and Prevention of Vertical Transmission:* Postpartum

1. Triple therapy, when used for treatment or prophylaxis through the postpartum period reduces mother-to-child HIV transmission.
2. Early postpartum visits, especially with on-site contraceptive services, can result in increased condom use, contraceptive use, HIV testing and treatment.
3. Exclusive breastfeeding for the first six months of the infant's life with a gradual decrease in breastfeeding results in lower rates of HIV transmission to the infant, reduced infant mortality, and improved infant growth compared to mixed feeding or abrupt weaning. Where clean accessible water is not available, breastfeeding after six months reduces infant mortality.

Promising Strategies:

4. Postnatal home visits by trained lay counselors may reduce mixed feeding.

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5. Conducting HIV testing and counseling for women who bring their children for immunization can increase the number of women accessing testing and treatment services.
6. Early HIV diagnosis and early HAART for HIV positive infants can drastically reduced infant mortality in resource-limited settings.
7. Community support groups can be highly beneficial for HIV-positive pregnant women and mothers.

9E. Evidence

1. **Triple therapy, when used for treatment or prophylaxis through the postpartum period reduces mother-to-child HIV transmission.** *[See also Antenatal Care: Treatment]*.

   - A randomized controlled trial from 2005-2008 in **Burkina Faso**, **Kenya** and **South Africa** assessed both mothers' health and mother-to-child transmission among HIV-positive women whose CD4 count was between 200 and 500. The study found that triple-antiretroviral treatment initiated during pregnancy and continued until six months postpartum reduced the risk of transmission to infants and improved HIV-free survival of infants compared to standard short-course antiretroviral therapy. At 12 months, 6.7% of the 402 infants whose mothers received triple-course antiretroviral treatment had died compared to 10.2% of the 403 infants whose mothers received short-course antiretroviral treatment. This effect was especially strong in women with CD4 counts between 200 and 350. At 12 months, the rate of transmission from mother to infant for triple-antiretroviral therapy was 5.5% compared to 9.5% for those who received short-course antiretroviral treatment. The infants whose mothers received triple-course antiretroviral therapy experienced a 42% risk reduction in HIV infections and a 37% risk reduction of death at 12 months, for a combined 36% risk reduction of either HIV infection or death. The study also found that triple-antiretroviral therapy had low toxicity for mothers and infants. All infants received single-dose nevirapine plus zidovudine in the first 72 hours and all mothers received counseling on replacement feeding or exclusive breastfeeding with weaning by six months. Formula was provided free of cost (Kesho-Bora Study Group, 2009). (Gray I) *(treatment, PMTCT, Burkina Faso, Kenya, South Africa)*

   - A study in **Botswana** (no date given) found a positive association between maternal viral load (in both plasma and breast milk) and mother-to-child transmission after one month in breastfed infants. 1,200 HIV-positive women at 4 sites were enrolled in the study and randomized to either exclusively breastfeed for 6 months in combination with infant zidovudine treatment or to exclusively formula feed. Mothers received antenatal zidovudine starting at 34 weeks of pregnancy along with intrapartum zidovudine and either single-dose nevirapine or a placebo at delivery. During the study HAART became available and women with CD4 counts below 200 cells/mm^3 or AIDS defining illnesses were eligible for treatment either antenatally or postnatally. Infants received single-dose of nevirapine or a placebo at birth along with one month of zidovudine prophylaxis for formula fed infants and six months for breastfed infants. After 17 months the study protocol was changed so that all infants received single-dose nevirapine at birth. Of 1,116 infants alive and HIV-negative at birth,

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1.1% of formula fed and 1.3% of breastfed infants tested HIV-positive after one month. Of 547 breastfed infants HIV-negative at one month, 4.4% tested HIV-positive before 2 years of age. Only 4 formula-fed infants tested HIV-positive after one month but before 2 years of age. For breastfed infants, the only predictors of mother-to-child transmission after one month of age were high maternal viral load and low maternal CD4 count. Infant prophylaxis with zidovudine was not a significant predictor of transmission. No transmission was observed in breastfeeding mothers who had started treatment with HAART before delivery. Similarly, no transmission was observed in breastfeeding mothers who had viral loads of less than 3,500 copies/mL. Maternal treatment with single-dose nevirapine at delivery did not predict mother-to-child transmission (Shapiro et al., 2009). (Gray II) *(PMTCT, breastfeeding, formula feeding, treatment, Botswana)*

- The Post-Exposure Prophylaxis of Infants (PEPI) trial in **Malawi** found that extended infant prophylaxis with nevirapine or with nevirapine and zidovudine for the first 14 weeks of life significantly reduced breast-feeding acquired HIV-1 infection in 9-month-old infants. Between 2004 and 2007, 3016 breastfeeding infants were randomly assigned to one of three different drug regimens. The control group received single-dose nevirapine plus one week of zidovudine, the second group received the control regimen plus daily extended prophylaxis with nevirapine (extended nevirapine group) and the third group received the control regime plus nevirapine and zidovudine (extended dual prophylaxis group). At nine months (the primary end point in the study), the estimated rate of HIV-1 infection in the control group was 10.6%. The extended nevirapine group had an infection rate of 5.2% and the extended dual prophylaxis group had a rate of 6.4%. There were no significant differences between the two extended prophylaxis groups although the extended dual prophylaxis group had a significant increase in the number of adverse events which were thought related to a study drug. This study demonstrated a protective efficacy of more than 60% for the two extended prophylaxis groups at 14 weeks. Cumulative risk of postnatal infection between birth and 14 weeks was 8.4% in the control group and 2.8% in the extended prophylaxis groups. This net difference of approximately 5% continued at 24 months. (Kumwenda et al., 2008) (Gray II) *(breastfeeding, treatment, PMTCT, Malawi)*

- The Six Week Extended-Dose Nevirapine (SWEN) study combined study data from sites in **Ethiopia**, **India** and **Uganda** to assess whether daily nevirapine given to breastfed infants through six weeks of age would decrease HIV transmission from breastfeeding. HIV-positive women who were breastfeeding their infants were randomized to receive either single-dose nevirapine (during labor for the mother and after birth for the baby), or six week extended dose nevirapine (during labor for the mother and after birth for the baby) plus daily nevirapine doses for the baby from day 8 to 42. The primary goal of the study was to assess HIV-infection rates at six months of age for infants who were HIV PCR negative at birth. The study concluded that a six week regimen of daily nevirapine might be associated with a reduction in the risk of HIV transmission at six weeks of age but the lack of a significant reduction of HIV transmission at the study end point of six months of age suggests that a longer course of daily infant nevirapine to prevent HIV transmission via breast milk might be more effective.[3] (Six Week Extended-Dose Nevirapine (SWEN) Study Team, 2008) (Gray II) *(breastfeeding, treatment, PMTCT, Ethiopia, India, Uganda)*

[3] Note: The three co-principal investigators of this study from India published a critique of this study write up in Lancet in the same publication issue. These investigators disagree with the statistical analyses used in this study, express concern about the 40% of infants who experienced grade III or IV side effects during treatment and conclude that the recommendation to continue nevirapine beyond six weeks is "inappropriate." The investigators suggest that a more prudent strategy is to "follow WHO/UNICEF

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- A study in **Ethiopia**, **India** and **Uganda** found that at 12 months of age infants who were on extended-dose nevirapine had reduced mortality and HIV transmission compared to infants who received single-dose nevirapine. Two thousand and seventeen HIV-positive pregnant women were recruited for the study from 2001 to 2004 in the three countries. A total of 1,890 infants were randomized in to single-dose nevirapine (given at birth once) and extended-dose nevirapine (given at birth and for 6 weeks daily) group. At the end of the 12 months follow-up period in 2007, data was available for 902 infants in the single-dose nevirapine group and 803 infants in the extended-dose group. The number of infants who received HAART during infancy was similar between the groups. HIV transmission was 8.9% in the extended-dose group compared to 10.4% in the single-dose nevirapine group. At 12 months, the overall mortality was 5% in the single-dose group compared to 1.9% in the extended-dose group. The impact of extended-dose nevirapine was highest in mothers whose CD4 counts were above 350 at birth (HIV transmission 8.4%; death 7.8%) compared to infants born to mothers whose CD4 counts were under 200 (HIV transmission 15.4%; death 27.6%). The extended-dose group had significantly fewer deaths (62% reduction) compared to the single-dose group among the uninfected infants (Hudgens et al., 2011). (Gray II) *(breastfeeding, treatment, PMTCT, Ethiopia, India, Uganda)*

- A follow-up study of the PEPI trial conducted from 2004 to 2007 in **Malawi** assessed the impact of maternal HAART on vertical transmission from 14 weeks until 24 months postpartum among 2,188 HIV-negative and breastfed infants, who had received 14 weeks of extended antiretroviral prophylaxis. Among eligible mothers (CD4 cell count below 250), HAART provided an 82% reduced risk of vertical transmission compared to those who did not receive HAART, after adjusting for infant antiretroviral prophylaxis. In other words, mothers who were eligible for HAART and did not receive treatment were at 5.89 times increased risk of transmitting HIV to their infants compared to mothers who were eligible and received treatment. Per maternal treatment category, the rate of HIV transmission to infants for the eligible but untreated mothers was 10.56 per 100 person-years, for the eligible and treated mothers was 1.79 per 100 person-years and for the ineligible mothers was 3.66 per 100 person-years. In the PEPI trial, infants were randomized into 3 arms with varying lengths of infant antiretroviral prophylaxis (single-dose nevirapine and one week of zidovudine, nevirapine for 14 weeks or nevirapine plus zidovudine for 14 weeks) and followed for 24 months. The trial initially reported 5.6% (130 in 2,318) mother-to-child-transmission from birth to week 14. Mothers were counseled to exclusively breastfeed for 6 months and then wean. About 80% of infants were weaned between 6 and 9 months. Infants were provided with antibiotics from age 6 weeks until 3 months after weaning. At the start of the study, maternal HAART was not available in Malawi. Once the government program introduced HAART in 2006, most mothers enrolled in the study began treatment at 14 weeks postpartum, after infants in the intervention arm had finished their treatment. Maternal HAART status was categorized as eligible but untreated, eligible and treated or ineligible, based on a CD4 cell count threshold of 250 and HAART treatment status determined by records (Taha et al., 2009). (Gray IIIa) *(breastfeeding, PMTCT, treatment, Malawi)*

- A 2001-2003 study in **Tanzania** assessing 398 infants of HIV-positive women intending to breastfeed who were treated with zidovudine and lamivudine at antenatal clinics, found a

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guidelines for developed countries and to make formula feeding safe, sustainable, acceptable, and affordable for mothers in developing countries."(Six Week Extended-Dose Nevirapine (SWEN) Study Team, 2008: 287).

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3.8% transmission rate of HIV from mother-to-child at week six and a 4.9% transmission rate after six months. The cumulative rate of HIV infection or death for infants was 8.5% at six months. Women were treated with zidovudine or lamivudine from 36 weeks gestation to one week post-delivery. Infants were treated with zidovudine and lamivudine for the first week of life and then lamivudine throughout six months of breastfeeding. Follow-up appointments included infant feeding counseling and occurred at weeks 1, 3 and 6 and months 3, 6, 9, 12, 15, 18, 21 and 24. Women were counseled to breastfeed exclusively and wean by six months. The infants were breastfed for a median of 18 weeks. Mothers reported 95% breastfeeding at six weeks, 86% after 12 weeks and 18% after 26 weeks. A total of 19 children became HIV-positive, 15 were considered early transmissions and 4 were considered late transmissions. CD4 count and viral load were significantly associated with mother-to-child transmission. No infants suffered serious adverse outcomes due to antiretroviral treatment. The comparison group for this study was a historical study of the same cohort where mothers received the same antiretroviral regimen but infants were not treated throughout breastfeeding. In this earlier study, mothers reported 85% breastfeeding at six weeks, 77% at 12 weeks and 64% at 26 weeks. This study revealed a 5.4% transmission rate at six weeks and 11.9% transmission rate at six months. The cumulative risk for HIV acquisition or death was 8.7% at six weeks and 15.5% at six months, about 50% higher than the current study (Kilewo et al., 2008). (Gray IIIa) *(treatment, PMTCT, breastfeeding, Tanzania)*

- "A recent analysis undertaken for WHO for southern African countries found that the cost per 10,000 HIV-positive mothers would be US$522,542 with the option of breastfeeding plus maternal HAART for women with a CD4 count under 350. In comparison, it would cost US $2,063,100 per 10,000 HIV-positive mothers provided with maternal HAART and six months of formula milk for women with a CD4 count under 350. The study concluded 'any feeding strategy that includes free provision of infant formula to HIV-infected mothers, even for a limited six months, is between two and six times more costly than a strategy that provides ARVs as prophylaxis to reduce postnatal transmission.'" (WHO, 2010 cited in Doherty et al., 2010). (Gray IIIb) *(breastfeeding, treatment, Southern Africa)*

- A study (Breastfeeding, Antiretrovirals and Nutrition i.e. BAN) in **Malawi** randomized 2,369 mother-infant pairs. HIV-positive pregnant women and their infants were randomized to three groups: 1) HAART for the mother (849); 2) twenty-eight weeks of nevirapine for the infant (852); and 3) neither (668). Enrollment to the control group, which received neither of the interventions, was halted by the Data and Safety Monitoring Board by NIH's Division of AIDS in 2008 and ethically could not be conducted today. All mothers received single dose nevirapine, which WHO no longer recommends. All women were counseled to wean rapidly between 24 and 28 weeks (also no longer recommended by WHO). By twenty-eight weeks, complete cessation of breastfeeding was reported by 67% to 68% of mothers in each study group. Among infants who were HIV-negative at two weeks, the estimated risk of HIV-1 infection by 28 weeks for infants was 10.9% in the control group, 8.2% in the maternal regimen group and 6% in the infant regimen group. All mothers and infants received perinatal prophylaxis with single-dose nevirapine and 1 week of zidovudine plus lamivudine (Chasela et al., 2010). (Gray IIIb) *(breastfeeding, treatment, PMTCT, Malawi)*

- A nonrandomized interventional cohort study from four public health centers in **Rwanda** from 2005 to 2007 found that maternal HAART while breastfeeding resulted in a minimal risk of postnatal transmission. Women could choose to feed their infants either formula (305 infants) or breastfeeding (227 infants) while on HAART. All women regardless of CD4 count, were given HAART. Only one infant who was breastfed became HIV-positive while the mother was on HAART; none of the infants fed by formula became HIV-positive, with this

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difference not being statistically significant. Adherence to HAART by the HIV-positive mother whose infant acquired HIV was uncertain, due to vomiting from gastritis. Among breastfeeding mothers on HAART, the cumulative probability of vertical transmission by nine months was 1.8%. Formula was provided at no cost. After birth, prophylactic HAART to prevent vertical transmission rather than treatment for the mother, was stopped among those women who chose to formula feed their infants. For women who choose to breastfeed, prophylactic HAART was given until the infant was 7 months, i.e. one month after weaning. Following WHO recommendations, all newborn infants exposed to HIV received nevirapine at birth and ZDV twice daily for 7 days. Follow up visits were scheduled at 15 days, 6 weeks and 3,6,7, and 9 months postpartum where adherence to HAART was assessed through pill counts and mothers received feeding counseling (Peltier et al., 2009). (Gray IIIb) *(HAART, treatment, breastfeeding, Rwanda)*

- A pooled analysis of data from **Kenya, Burkina Faso, Côte d'Ivoire, Rwanda, Mozambique and Tanzania** found that "HAART in breastfeeding women results in transmission rates generally under 5%" (Becquet et al., 2009a: 1942). (Gray IIIb) *(HAART, breastfeeding, treatment, Kenya, Burkina Faso, Côte d'Ivoire, Rwanda)*

- A study in **Mozambique** from 2005-2007 followed 313 HIV-positive mothers on HAART, who were counseled to breastfeed exclusively for six months and found that HAART reduced the risk of mother-to-child transmission by 93%. There were a total of 8 cases of HIV transmission, 4 of which were considered late postnatal transmission. Women with repeat pregnancies, who had previously received antenatal care and HAART through six months of breastfeeding, did not transmit HIV to their infants. HIV testing of infants was performed at 1, 6 and 12 months. Antiretroviral treatment began at 15 weeks of gestation and continued until six months after delivery. HAART was continued beyond six months if the mothers had CD4 cell counts that remained below 350. In combination with HAART, nutritional supplements to mother and infant, patient counseling to increase adherence to breastfeeding and a strong network of support within the community led to the marked reduction of maternal and infant deaths (Marazzi et al., 2009). (Gray IV) *(HAART, treatment, PMTCT, breastfeeding, Mozambique)*

- A study enrolling HIV-positive pregnant women receiving a single dose of nevirapine for preventing perinatal transmission of HIV during labor from 2003-2004 in **Uganda** found that nevirapine was detectable in breast milk, maternal plasma, and infant plasma for 2-3 weeks after a single dose of maternal nevirapine. Overall, 62 women were included in the study. Sixty-one women received a single dose of nevirapine at least 1.5 hours before delivery, and 53 women chose to breastfeed. All infants received a single dose of nevirapine syrup within 72 hours of birth. Samples of breast milk and plasma from both mothers and infants were taken 1, 2, and 6 weeks after maternal nevirapine treatment. Infant plasma levels of nevirapine at delivery were correlated with the timing of maternal nevirapine intake. Infant nevirapine levels were the highest approximately 4 hours after maternal nevirapine intake, after which infant treatment with nevirapine only slightly increased infant nevirapine plasma concentrations. Furthermore, nevirapine transferred from maternal plasma to breast milk rapidly, and nevirapine in breast milk was detectable before infants initiated breastfeeding. The long-term duration of nevirapine in breast milk was determined to be protective against postnatal transmission due to the effective suppression of HIV in breast milk for up to 3 weeks after maternal single dose nevirapine intake. However, the long-term duration of nevirapine also increases the risk for nevirapine resistance mutation development, and the acquisition of a resistant virus for infants. Because the risk of nevirapine resistance decreases over time, infants are most at risk for acquiring a resistant virus during the initial

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breastfeeding period. Extended antiretroviral treatment with zidovudine/lamivudine should therefore be considered to reduce the risk of nevirapine resistance (Kunz et al., 2009). (Gray IV) *(PMTCT, treatment, breastfeeding, Uganda) [See introduction of Antenatal Care: Treatment for discussion of nevirapine resistance]*

- Lower maternal CD4 count was associated with a significantly higher risk of transmission through breastfeeding (Mofeson et al., 1999 cited in Abrams et al., 2007), therefore HAART, by increasing CD4 counts, can reduce transmission of HIV during breastfeeding (Abrams et al., 2007). (Gray V) *(CD4 counts, breastfeeding, HAART, PMTCT)*

2. Early postpartum visits, especially with on-site contraceptive services, can result in increased condom use, contraceptive use, HIV testing and treatment.

- A prospective study of 354 HIV-positive pregnant women who attended two urban clinics in **Rwanda** found that providing long-acting reversible contraceptives (Implants and IUDs) on site increased the number of women starting hormonal implants in the postpartum period. In Rwanda in 2009, among women currently not using contraceptives but intending to use a modern method in the future one in five would prefer a long-acting reversible contraceptive or sterilization (Ministry of Health, Rwanda, 2009 cited in Dhont et al., 2009). However, access to long acting reversible contraceptives has been limited. Between 2005 and 2007, HIV-positive pregnant women entering the PMTCT program from 28 weeks of gestation were invited to a non-randomized prospective cohort study where 179 women at one site were referred for public health family planning services and at the other site, 175 women were offered hormonal implants free of charge (Norplant or Jadelle) and IUDs on site and were referred to the adjacent public family planning services for short-acting contraceptives. At the public family planning services, long acting reversible contraceptives were only available occasionally due to stockouts, lack of qualified staff, and women were charged a small fee. The overall postpartum uptake of modern contraception, measured at the nine month visit, was 84% at both sites, significantly higher than that in a routine PMTCT setting where the rate was 45%. Only three out of 242 women without desire for future children were not using contraception. Uptake of implants among the women at the site where implants were offered on site was 38%, significantly higher than the 6% at the site where women were referred for public family planning services. When adjusting for maternal age and having at least one living child at enrolment, women with onsite access to implants were 11.8 times more likely to use implants than women referred for public family planning services (Dhont et al., 2009). (Gray IIIa) *(contraception, Rwanda)*

- A cross-sectional analysis from 2007 to 2009 derived from baseline visits of 435 HIV-positive women in St. Petersburg, **Russia**, of whom 120 were postpartum, who were counseled by clinicians on a range of contraceptive options for which they were eligible based on medical criteria found that 35% used a highly effective method of oral contraceptives together with condoms and 51.7% used DMPA along with condoms as their preferred choice. Family planning services were integrated into HIV clinical care. DPMA could be started immediately postpartum, while oral contraceptives could not be started until 21 days after delivery (Whiteman et al., 2009). (Gray (IIIb) *(contraception, DMPA, Russia)*

- A quasi-experimental pre-post test study conducted from 2006 through 2007 of maternal health care interventions in **Swaziland** that provided care for all pregnant women, including HIV-positive women at several intervals (within the first six hours after delivery; an exam

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once per day postpartum while the woman was in the health facility; providing assessment, care and counseling, along with a specific appointment for the first postnatal visit upon being discharged from the facility and providing a postnatal visit at one week postpartum and a second visit at four to six weeks postpartum) increased contraceptive use and counseling on condom use. Over 60% of maternal deaths occur within 48 hours after childbirth (Lewis, 2004 cited in Mazia et al., 2009), yet in Swaziland, mothers are usually discharged within 12 hours of delivery. The conventional recommendation for the first postnatal visit is at four to six weeks, by which time most of the postpartum deaths have already taken place. The study collected data on 114 HIV-positive women at the start of the study and from 136 HIV-positive women to evaluate the impact a year later. The intervention increased early postnatal visits by twenty-fold. Providers increased counseling of HIV-positive women on the need to regularly monitor CD4 counts for the mother from 41% to 74%. Following the intervention, 93% of mothers were assured of privacy. While at baseline, the provider asked the woman her preferred family planning only 32% of the time, by the end of the intervention, 82% did so. While at baseline, only 28% of clients received their preferred family planning method, at the end of the intervention, 70% did so. While at baseline, providers only counseled on condom use 16% of the time, by the end of the intervention, 25% did so. The percent of women on HAART increased from 4% to 15% and the mother tested for her CD4 count since giving birth increased from 4% to 26%. There was also a statistically significant increase in the proportion of postpartum women (88 to 98%) and their partners (from 28% to 56%) getting tested for HIV. Since the postnatal visit within one week of delivery did not exist anywhere in the country at the pre-intervention phase, conclusions following the introduction of the new timing of postnatal care could be assessed. Actual condom use was not measured (Mazia et al., 2009). (Gray IIIb) *(PMTCT, family planning, counseling, HIV testing, Swaziland)*

- A study in **Côte d'Ivoire** with 546 HIV-positive women and 393 HIV-negative women who were tested for HIV prenatally and followed up for two years following delivery and were provided contraception as desired at each postpartum visit, resulting in high rates of contraception use after delivery and low pregnancy incidence. HIV-positive women had fewer unwanted pregnancies than HIV-negative women. At each postpartum visit, women received family planning counseling and free contraception. Between 6 and 24 months, proportion of women using modern contraception varied from 52 to 65% among HIV-positive women. Among HIV-positive women, pregnancy incidence for 100 women years at risk was 5.70 and unwanted pregnancy incidence was 1.07 (Brou et al., 2009). (Gray IIIb) *(pregnancy, contraception, Côte d'Ivoire)*

- A pre-post test design with 356 postpartum women and 53 health care workers that instituted a one week post-delivery postpartum visit along with provider training in **Swaziland** from 2006 to 2007 found that the proportion of HIV-positive postpartum women not wanting another child increased from 77% to 83%. Provider training increased the woman being asked about her preferred contraceptive method, from 32% to 82% and receiving her preferred method, from 28% to 70%. Male partners who tested for HIV increased from 28% to 56% (Warren et al., 2008). (Gray IIIb) *(contraception, HIV testing, Swaziland)*

- A study of 319 HIV-positive pregnant women who were followed postpartum for one year in a perinatal HIV transmission study in **Kenya** and were referred to local clinics for contraceptive counseling and management resulted in high rates of contraceptive use and dual method use, with 72% initiating hormonal contraceptive use and 61% of 231 hormonal contraceptive users reporting condom use in additional to hormonal contraceptives. Prior to this project, which had linked antenatal care with family planning, only 50% of the currently using 231 hormonal contraceptive users had a history of previous hormonal contraceptive use.

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Prior to this project, only 6 or 3% had used condoms. Of those using contraception, 44% used DMPA, 31% used oral contraception and 25% switching methods at follow up. Women were counseled antenatally to initiate contraception postpartum and dual contraception was encouraged. No particular method of contraception was given priority. Hormonal methods were the most popular contraceptive method, possibly because they are female controlled and available. Women who opted of formula feed their infants were counseled to initiate contraception four weeks after delivery, whereas those who opted to breastfeed were counseled to initiate contraception six weeks after delivery. Breastfeeding women who wanted oral contraception received progesterone only pills and non-breastfeeding women received combined oral contraceptive pills. DPMA was available for both breastfeeding and non-breastfeeding women. Median time to initiation of sexual activity was two months following delivery, ranging between one and 11 months, with 77% of women resuming sexual activity within three months of delivery. Partner notification and condom use were similar between those using and not using other forms of contraception besides condoms. (Balkus et al., 2007). Other studies that did not provide contraceptive counseling in antenatal care found much lower rates of contraceptive use post partum (Nebie et al., 2001; Desgrées-Du-Loû et al., 2002 cited in Balkus et al., 2007). (Gray IIIb) *(pregnancy, contraception, condom use, Kenya)*

3. **Exclusive breastfeeding for the first six months of the infant's life with a gradual decrease in breastfeeding results in lower rates of HIV transmission to the infant, reduced infant mortality, and improved infant growth compared to mixed feeding or abrupt weaning. Where clean accessible water is not available, breastfeeding after six months reduces infant mortality.**

- A study in **Zimbabwe** from 1997 to 2000 of 2,060 infants born to HIV-positive mothers found that solid foods or animal milks given to infants prior to three months of age was associated with a fourfold greater risk of postnatal transmission of HIV at six months compared with exclusive breastfeeding. The protective effects of early exclusive breastfeeding were still significant at 18 months with a 61% reduction in postnatal transmission compared with mixed breastfeeding. Thus, the more strictly HIV-positive mothers are able to breastfeed exclusively, the lower the risks of HIV or death for their infants. More than two-thirds of all postnatal transmission of HIV occurred after six months. This is consistent with other studies from West Africa, South Africa and Tanzania and supports early cessation of breastfeeding among HIV-positive women. Lastly, women with CD4 counts less than 200 cells/ul were five times more likely to transmit HIV during breastfeeding compared with women with CD4 cell counts over 500 cells/ul, confirming the findings of other studies that postnatal transmission of HIV is highly correlated with immune suppression in the mother (Iliff et al., 2005). (Gray II) *(breastfeeding, PMTCT, infant feeding, Zimbabwe)*

- A 2001-2004 study in **Zambia** followed 958 HIV-positive mothers, who intended to breastfeed their infants, for 24 months and found that weaning by five months was associated with a 2-fold increase in infant mortality and weaning by five to 18 months was associated with a 4-fold increase when compared to weaning after 18 months. The mothers were recruited from antenatal clinics, offered voluntary counseling and testing and single-dose nevirapine at birth. All mothers were counseled to breastfeed exclusively. Mothers were randomized into two groups: the first to abruptly wean at four months, and the second to continue breastfeeding and wean whenever they chose. For infants in the early weaning

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group, the study offered three-months supply of formula and fortified cereal. For 24 months, mothers and infants were followed every two weeks by either home visits or site visits. Among 749 uninfected infants who were breastfed for 18 months, mortality was 9.7% compared to 17.4% for infants who were weaned by 5 months. Infants weaned by 4-5 months experienced a 2-fold increase in mortality, by 6-11 months experienced a 3.54-fold increase in mortality, by 12-18 months experienced a 4.22-fold increase in mortality compared to infants who were weaned after 18 months. The leading causes of infant death were diarrhea (among infants aged 6-24 months) and pneumonia (all ages) (Kuhn et al., 2010a). (Gray II) *(breastfeeding, PMTCT, Zambia)*

- A retrospective study (year unspecified) analyzed data from two randomized trials (HIVNET 012 1997-2001 and HIVIGLOB/NVP 2004-2007) conducted at the same hospital in **Uganda** and found that early cessation of breastfeeding was associated with increased risk of serious gastroenteritis among HIV-exposed uninfected infants when compared to later breastfeeding cessation. Infants in the HIVIGLOB/NVP trial were weaned at a median age of four months, with complete cessation of breastfeeding by six months. Infants in the HIVNET trial were weaned at a median age of 9.3 months, with some infants continuing to breastfeed after 12 months. Study analyses included a total of 623 infants from the HIVNET trial and 698 infants from the HIVIGLOB/NVP trial. The rates of serious gastroenteritis events were higher among infants in the HIVIGLOB/NVP trial compared to the HIVNET trial reaching statistical significance at 3-4 months (16.2 events per 1000 child-months versus 0 events per 1000 child-months). The overall rates of serious gastroenteritis events were highest in the HIVIGLOB/NVP trial at 8 events per 1000 child-months compared to 3.1 events per child-months in the HIVNET trial, which was also statistically significant. Both trials weaned infants at much earlier ages than the national median age of 19.9 months according to the Uganda Demographic Health Survey in 2000. The HIVNET trial counseled mothers to exclusively breastfeed for at least six months and then to wean, though no specific time was indicated. The HIVIGLOB/NVP trial counseled to exclusively breastfeed for 3-6 months and then abruptly wean before six months. All infants in this trial received co-trimoxazole from six weeks until HIV-negative following cessation of breastfeeding. HIV-positive children continued to receive co-trimoxazole indefinitely. Gastroenteritis was defined as an episode of diarrhea (3 or more loose or watery stools within 24 hours), regardless of vomiting. Serious gastroenteritis was defined as diarrheal events that resulted in hospitalization or death of the infant (Onyango-Makumbi et al., 2009). (Gray IIIa) *(infant feeding, breastfeeding, PMTCT, Uganda)*

- A study from **Zambia** (2001 to 2004) enrolling HIV-positive pregnant women from PMTCT programs, found that infants born to HIV-positive mothers who were exclusively breastfed up until at least 4 months were at least 50 percent less likely to acquire HIV through breastfeeding than infants fed any non-breast milk substances in addition to breast milk. Furthermore, the study found no difference in the rates of HIV transmission between infants weaned at 4 months and those who continued breastfeeding past 6 months. Overall, 734 infants who tested HIV-negative at 6 weeks of age and were still breastfeeding at 6 months of age were included in the study. Mothers were randomized into an intervention group in which women were counseled to exclusively breastfeed for 4 months and then wean abruptly, and a control group in which women were counseled to breastfeed for at least 6 months and then introduce complimentary foods while maintaining breastfeeding. At 4 months, 83.5 percent of mothers reported exclusively breastfeeding. The risk of acquiring HIV before 4 months of age was over 3 times higher for infants who were non-exclusively breastfed compared to those who received only breast milk. A maternal CD4 count of below 350 was a strong predictor of HIV transmission before 4 months of age, but a significant reduction in HIV transmission

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related to exclusive breastfeeding remained after controlling for CD4 count. For exclusively breastfed infants, the risk of acquiring HIV was greatest in the first 4 months and then declined thereafter. The rate of HIV transmission for non-exclusively breastfed infants was 2.4 percent per month compared to less than 1 percent per month for exclusively breastfed infants (Kuhn et al., 2007). (Gray IIIa) *(PMTCT, breastfeeding, infant feeding, Zambia)*

- A sub-study followed 118 infants born to 102 HIV-positive women receiving HAART for their own health from 2003-2007 in **Uganda**. After adjusting for maternal CD4 count, maternal marital status or maternal death, the study found that infants who were breastfed for less than six months had a 6-fold increased risk of death compared to infants who were breastfed longer than six months. Infants were followed for a median of 18 months and mothers received HAART prior to delivery for a median of 20 months. By six months of age, 25% (29 in 118) of infants were exclusively breastfed, 20% (23 in 118) received mixed feeding and 48% (57 in 118) had been weaned. No infants in this study were confirmed as HIV-positive at the end of follow-up or death, though only 86% had a final HIV test. About 19% (23 in 118) of infants died during follow-up and these infants were breastfed (exclusively or mixed) for a median of three months. Of infant deaths, about 65% were preceded by severe diarrhea and vomiting, possibly caused by gastroenteritis as a result from weaning. The infants included in this sub-study were part of a randomized clinical trial aimed to evaluate monitoring strategies for 1,100 HIV-positive adults (aged 18-49 with CD4 cell counts below 250 or WHO stage III/IV) receiving HAART in two rural districts in Uganda. All women who gave birth to a live infant during this trial were recruited into the sub-study. Mothers were given single-dose nevirapine at labor and, after 2005 infants were given daily zidovudine treatment for one week in addition to maternal treatment. All mothers were counseled to exclusively breastfeed for six months, then wean and begin replacement feeding. Health workers determined breastfeeding status at weekly home visits. HIV and CD4 tests were collected at 3-month intervals (Homsy et al., 2010). (Gray IIIb) *(breastfeeding, PMTCT, Uganda)*

- A sub-analysis (year unspecified) reported on gastroenteritis-related morbidity and mortality among infants from two randomized trials (one trial from 2003 to 2003 and another trial from 2004 to 2009) on prevention of mother-to-child transmission of HIV in **Malawi**. The analysis found that after age six months, hospitalization and mortality related to gastroenteritis were significantly higher among infants who were weaned early (PEPI) compared to infants who were breastfed long-term (NVAZ). Frequency of hospitalization related to gastroenteritis was consistently higher among infants in infants weaned before six months compared to infants breastfed for longer than six months: 2.9% versus 0.1% at 7-9 months and 1.6% versus 0.2% at 10-12 months. Gastroenteritis-related deaths were also consistently higher among infants in weaned before six months (PEPI) compared to infants breastfed for longer than six months (NVAZ): 19 versus 7 per 1,000 infants at nine months and 24 versus 12 per 1,000 infants at twelve months. The study included 2,035 mother-infant pairs in the PEPI trial from 2004-2007, when women were encouraged to breastfeed exclusively for six months and then wean, and 1,810 mother-infant pairs in the NVAZ trial from 2000-2003, when breastfeeding lasted as long as desired. Among women who weaned their infants before six months, only 23.3% had running water at home; among those who breastfed longer than six months, 26.2% had running water at home. "…Mothers …had poor access to safe water" (Kafulafula et al., 2010: 12). However, only 3.5% of infants who were weaned before six months were HIV-positive compared to 5.7% of HIV-positive infants who were breastfed longer than six months. In the PEPI trial, infants were randomized into 3 arms with varying lengths of infant antiretroviral prophylaxis (single-dose nevirapine and one week of zidovudine, nevirapine for 14 weeks or nevirapine plus zidovudine for 14 weeks) and followed for 24 months. Mothers were

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counseled to exclusively breastfeed for 6 months and then wean. Infants were provided with antibiotics from age 6 weeks until 3 months after weaning. About 80% of infants were weaned between 6 and 9 months. In the NVAZ trial, infants were randomized to receive single-dose nevirapine or single-dose nevirapine plus one week of twice daily zidovudine. Mothers received single-dose nevirapine if they presented early during labor. Infants were followed for 24 months. About 89% were still breastfeeding at 9 months and 60% by 24 months (Kafulafula et al., 2010). (Gray IIIb) *(breastfeeding, treatment, Malawi)*

- A sub-study (year unspecified) analyzed 1,761 infants born to HIV-positive women, who participated in the PEPI trial in **Malawi**, and found that morbidity and mortality were higher among the infants who were weaned prior to 6 months of age regardless of treatment arm compared to infants who continued breastfeeding. At 15 months after adjusting for infant antiretroviral prophylaxis, pneumonia prophylaxis and mother's HIV disease stage, the cumulative mortality for infants who were weaned by 6 months was 6.4% compared to 3.5% among infants who continued breastfeeding. In terms of morbidity, after adjusting for the same factors, infants who were not breastfed had approximately 1.7 times higher rate of illness and/or hospital admission than infants who were breastfed. The PEPI trial was conducted from 2004 to 2009. It was a randomized controlled trial aiming to measure the efficacy of extended infant antiretroviral prophylaxis to prevent mother-to-child HIV transmission. The trial recommended weaning by 6 months. All infants included in this analysis were breastfed for a minimum duration of 14 weeks (through treatment). The treatment arms were composed of the following regimens: 1) single-dose nevirapine given at birth and one week of twice-daily zidovudine (control); 2) control regimen plus daily nevirapine until 14 weeks of age; and 3) control regimen plus daily nevirapine and zidovudine until 14 weeks of age. Infants were followed-up regularly from birth until 24 months of age. All infants were provided with pneumonia prophylaxis from age 6 weeks through 3 months after weaning. Analysis was done by 3-month age intervals: 6-9 months, 9-12 months and 12-15 months (Taha et al., 2011). (Gray IIIb) *(breastfeeding, treatment, Malawi)*

- A retrospective cohort study analyzed data on 1,261 infants of HIV-positive mothers and 1,061 infants born to HIV-negative mothers who attended 9 antenatal clinics in **South Africa** from 2001 to 2004. The study found that infants born to HIV-positive women grew as well as the children born to HIV-negative women, regardless of feeding method though the median duration of exclusive breastfeeding was six months in both groups. In adjusted analysis, the factors most strongly associated with poor growth were maternal mid-upper arm circumference (proxy for BMI or maternal nutrition), CD4 count, infant birth weight and HIV status. All HIV-positive mothers and infants received single-dose nevirapine during labor. HAART was not widely available during the study period. HIV-positive mothers were included in the study if they had known HIV status and CD4 count below 250. Infants of HIV-negative and HIV-positive mothers born between 19-44 weeks gestation with at least one growth measurement were included in the analysis. The study provided counseling support on infant feeding prior to birth, which continued through weekly home visits conducted by lay health workers until infants reached nine months of age to support breastfeeding. At these visits data on infant feeding and morbidity were collected. High rates of exclusive breastfeeding were achieved, with a median duration of 175 days, or a little less than five months. Infants given breast milk had an average weight of .048 higher z-score (standard deviations above or below the mean) compared with children with no breast milk, after allowing for birth weight, maternal mid-upper arm circumference, HIV infection status and maternalCD4 count. Mother-infant pairs also visited the clinic monthly from week 6 to month 9 and then quarterly until 2 years (Patel et al., 2010). (Gray IIIb) *(breastfeeding, CD4 counts, South Africa)*

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- A study in **Nigeria**, which screened pregnant women for HIV-1 between 2004 and 2006, found that risk factors for mother-to-child transmission of HIV-1 differed by infant age. Infants at highest risk of acquiring HIV were those who had mothers with CD4 counts less than 200 and who received mixed feeding. The study analyzed 391 mothers and 371 infants, using follow-up visits 1 week after delivery and 1, 3, 6, and 12 months after delivery. A single-dose of nevirapine was given to each mother during delivery and to her infant within 48 hours of delivery. Women who chose replacement feeding were provided a 6-month supply of formula free of charge, as well as training and counseling on formula preparation, sterilization, and storage processes. Mothers who chose exclusive breastfeeding were provided counseling on the importance of weaning before 4-6 months. Exclusive breastfeeding was defined as only breast milk up until 6 months, with no other liquids or solids; replacement feeding as the use of formula only with no breast milk; and mixed feeding as a combination of breast milk and nonhuman milk or other solids before 6 months of age. For infants who were exclusively breastfed, 8.1% tested HIV-positive by 6-months of age compared to 9.5% of infants exclusively formula fed, and 29.2% of infants who received mixed feeding. After delivery, 71.7% of mothers chose replacement feeding while 28.3% chose to exclusively breastfeed. At 6-month follow-up, 71.1% of mothers who initially chose to breastfeed reported maintaining exclusive breastfeeding, 80.2% of mothers who initially chose formula feeding reported exclusive replacement feeding, and 82 mothers reported using mixed feeding. During the study period, 50 infants became infected with HIV-1, 34% in utero, 30% intrapartum or early postnatally, and 36% postnatally, with an overall transmission rate of 13.5%. For infants infected in utero, risk factors included maternal CD4 count of less than 200 and high maternal viral load. For infants infected during the intrapartum or early postnatal period, risk factors included high maternal viral load, gestational age of less than 37 weeks, and prolonged membrane rupture during delivery. Infants infected during the intrapartum or early postnatal period were at higher risk if they received mixed feeding compared to infants who were exclusively formula or breast-fed (12% compared to 2.2%). For infants infected during the postnatal period, mixed feeding and low birth weight increased the risk of HIV transmission. The risk of transmission for infants who were exclusively breastfed increased from 1.4% during the intrapartum/early postnatal period to 4.2% postnatally. The rate of transmission during all three infant-age periods for infants who were exclusively formula fed was similar. For mothers who initially chose to replacement feed but then switch to mixed feeding, stigma, pressure from family members, and no partner support were reported as reasons for not maintaining exclusive formula feeding (Charurat et al., 2009). (Gray IIIb) *(PMTCT, breastfeeding, infant feeding, mixed feeding, Nigeria)*

- A 2001-2005 **South African** intervention cohort study of 1,372 women and infants which examined the effect of breastfeeding by HIV-positive mothers found that exclusive breastfeeding leads to significantly lower rates of HIV transmission and higher rates of survival than does mixed feeding. "Infants who received formula milk in addition to breast milk, before or after 14 weeks of age, were nearly twice as likely" and "infants who were breastfed but also received solids were nearly 11 times" as likely to become infected than infants who were exclusively breastfed (Coovadia et al., 2007: 1113). HIV-positive women were provided during antenatal care, nevirapine, infant feeding counseling, and no cost commercial infant formula. After delivery, clinic nurses and counselors provided mothers with breastfeeding and replacement feeding support, with infant-feeding counselors visiting mothers three to four times within the first two weeks after birth and once every two weeks until six months after birth. Independent field monitors who visited mothers once a week assessed infant feeding practices. The study defined "exclusive breastfeeding" as feeding a child with breast milk, providing no solid food, and not giving non-human milk or water for

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more than three days total. After delivery, 1,132 mothers began exclusive breastfeeding, and the median duration of breastfeeding of infants for whom HIV test results were available was 159 days. Of the mothers who decided to exclusively breastfeed, 82% exclusively breastfed for at least 6 weeks, 67% exclusively breastfed for at least three months, and 40% exclusively breastfed for 6 months. The study found that 22% of exclusively breastfed infants died or became HIV-infected, resulting in an overall Kaplan-Meier estimated HIV-free survival rate of 75.4% at six months. The risk of HIV transmission was associated with low maternal CD4-cell counts. The study found that the health of mothers was strongly correlated with PMTCT. "Infants exclusively breastfed by women with CD4-cell counts less than 200 μL were twice as likely to become infected and almost four times more likely to die before 6 months of age than were infants exclusively breastfed by women with CD4-cell counts above 500 μL" (Coovadia et al., 2007: 1115). (Gray IIIb) *(breastfeeding, formula feeding, mixed feeding, PMTCT, South Africa)*

- A pooled analysis from 1,115 infants born to women living with HIV in **Côte d'Ivoire** and **South Africa** found that the overall risk of vertical transmission was twice as high among infants who breastfed for more than six months than among children who were breastfed for less than six months (Becquet et al., 2009b cited in Becquet et al., 2009a). (Gray IIIb) *(PMTCT, breastfeeding, Côte d'Ivoire, South Africa)*

- A study done in **Zambia** found that post-weaning breast milk HIV RNA was higher in women who stopped breastfeeding suddenly or used mixed breastfeeding. A total of 958 women living with HIV in the pre-ART era that breastfed were randomized into two groups: half of the women abruptly weaned at 4 months and the other half continued breast-feeding. Breast milk HIV RNA was measured at 1 and 4 months; and 2 weeks after weaning abruptly or at 4 months for those who continued breast-feeding. Seventy seven percent of the 154 women who stopped abruptly had viral RNA above 50 copies versus 40% of 394 women who exclusively breast- feeding at 4 months. The study also found that women who used mixed breast-feeding had significantly higher viral RNA levels. At four and half months 69% of women who used mixed feeding had viral RNA levels above 50 copies (Kuhn et al., 2012). (Abstract) *(breastfeeding PMTCT, Zambia)*

Promising Strategies:

4. Postnatal home visits by trained lay counselors may reduce mixed feeding.

- A 2001-2003 study that followed HIV-positive and HIV-negative pregnant women attending antenatal clinics in **South Africa** found that postnatal home visits offering infant feeding counseling significantly improved adherence to either exclusive breastfeeding or exclusive replacement feeding. The study followed 1,253 HIV-positive and 1,238 HIV-negative pregnant women who attended nine different clinics. Adherence was significantly associated with the number of antenatal feeding counseling home visits for both options. A breastfeeding counselor performed one antenatal home visit for every woman to discuss feeding options and three additional visits were available to those who chose to breastfeed. For women who chose to replacement feed, a specialist visited the home to teach methods of safe replacement feeding. The study also collected data on access to clean water, a refrigerator, fuel for boiling water and regular income for the mother, and found that only 3% of HIV-positive pregnant women had access to all four resources and 32.1% had access to all but regular income. "Of those who intended to replacement feed…few had the necessary resources to prepare infant

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formula safely" (Bland et al., 2007: 292). Infant formula became available in 2002 for HIV-positive pregnant women (Bland et al., 2007). (Gray II) *(breastfeeding, formula feeding, counseling, South Africa)*

5. **Conducting HIV testing and counseling for women who bring their children for immunization can increase the number of women accessing testing and treatment services.** *[See also HIV Testing and Counseling for Women* and *Structuring Health Services to Meet Women's Needs]*

- A study from 1999 to 2000 that provided VCT for women attending maternal and child health clinics for their first postpartum or well-baby visit in **Botswana** found that 937 or 54% of 1,735 postpartum women accepted VCT. 30% of those who accepted VCT were HIV-positive (Thior et al. 2007). (Gray IIIb) *(HIV testing, health facilities, immunization, Botswana)*

- In a project in **South Africa,** maternal CD4 cell count was determined every six months during the infant's immunization visit, with rapid referral for HAART for mothers with CD4 cell counts of less than 200/mm^3 (Barker et al., 2007a). (Gray V) *(treatment, health facilities, immunization, HAART, South Africa)*

- "For women who do not test during antenatal care, parents could be offered HIV testing during infant and child health programs, particularly in high prevalence settings" (Beltman et al., 2010). (Gray V) *(testing, health facilities, Malawi)*

- A randomized, double blind, placebo controlled trial in **South Africa, Tanzania, and Uganda** from 2008 to 2010 found that the use of daily nevirapine for infants for six months of HIV-positive mothers who breastfed, had CD4 counts above 350 and did not receive HAART reduced the risk of vertical transmission by 48%. At the end of twelve months, for the 759 infants who were HIV-negative at randomization, the HIV status of infants at six months was 729 with known HIV status, 30 infants with HIV status not known, 9 infants deaths and 21 infants lost to follow up by the study. For the 763 infants who received placebo, at six months 733 had a known HIV status, 30 infants had unknown HIV status, 9 infants died and 21 infants were lost to follow up by the study. More than 95% of infants in both groups were no longer breastfed by the nine-month study visit. Among infants with 6 months of daily Nevirapine, 1.1% acquired HIV; in the placebo group, 2 to 4% of infants acquired HIV, equating to a 54% reduction in HIV transmission. When stratified by mothers who had HAART prior to randomization, infants did not have different rates of vertical transmission between the two groups. For infants born to mothers with CD4 counts above 350 who did not receive HAART found that the rate of vertical transmission for infants receiving daily nevirapine for six months, infants had a six months HIV infection rate of 0.7% compared to 2.8% in infants of mothers in the placebo group who did not receive daily Nevirapine for six months, a 75% reduction in vertically acquired HIV transmission. For women on HAART, there is no additional benefit to extend daily nevirapine use in infants from six weeks to six months. In addition, infants suffered high rates of adverse events. Loss to follow up by pregnant HIV positive women with CD4 counts above 350 in accessing HAART was not assessed. Infants whose mothers die are at high risk for mortality and infants who seroconvert to HIV positive who have had single dose Nevirapine have had problems with drug resistance. *[See Antenatal Care: Treatment]* A cost analysis of providing clean water as compared to NVP for infants for six months was not included as part of the analysis (Coovadia et al., 2012). (Gray II) *(breastfeeding, treatment, PMTCT, South Africa, Tanzania, Uganda)*

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6. **Early HIV diagnosis and early HAART for HIV positive infants can drastically reduced infant mortality in resource-limited settings.**[4]

   - A study of HIV-positive infants in **South Africa** randomly assigned HIV-positive infants aged six to 12 weeks to HAART when CD4 was reduced to less than 20% (or 25% for infants less than one year of age) or clinical criteria were met or to immediate initiation of HAART until two years of age. At a median age of 74 weeks and a CD4 percentage of 35.2%, 125 infants were randomly assigned to receive deferred therapy and 252 infants were randomly assigned to receive early therapy. After a median follow up of 40 weeks, HAART was initiated in 66% of infants in the deferred therapy group. Twenty infants in the deferred therapy group (16%) died versus 10 infants in the early therapy groups (4%). Early HIV diagnosis and early HAART reduced infant mortality by 76% (Violari et al., 2008). (Gray II) *(treatment, testing, PMTCT, South Africa)*

7. **Community support groups can be highly beneficial for HIV-positive pregnant women and mothers.** *[See Care and Support: Women and Girls]*

9E. Gaps in Programming—Postpartum

1. HIV-positive mothers, fathers, grandmother and the larger community need clear, consistent, non-contradictory and nonjudgmental counseling on infant feeding practices. Health care providers need training based on accurate information.
2. Further research is needed to understand the links between mastitis and vertical transmission.
3. Accurate testing techniques for infants may inform infant feeding.
4. Stigma reduction interventions are needed so that women with HIV can choose replacement feeding, breastfeeding and weaning schedules.
5. Additional efforts are needed to provide postpartum women with contraception information and methods so they may space or prevent their next pregnancy and use condoms to reduce the likelihood of HIV transmission upon resumption of sexual activity.
6. Further efforts are needed to educate families about HIV transmission so that infants are not abandoned.
7. Interventions are needed to scale up CD4 count screening, especially for pregnant women.
8. Interventions are needed to encourage male partners to refrain from sexual activity during the postpartum period of time that women cannot have sex.
9. Increased efforts are needed to retain women on HAART following birth.

[4] While What Works does not cover the vast topic of pediatric HIV treatment, this study, which took place in a resource-limited setting, is of great importance to parents living with HIV, and therefore has been included.

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10. More research is needed to understand the relationship between maternal single-dose nevirapine administered during delivery and postpartum nevirapine resistance found in breastmilk, and its impact on postnatal transmission to infants.
11. Screening for post-partum depression among HIV-positive women may be warranted.
12. Further efforts are needed to assess the feasibility of wet-nursing for HIV-positive mothers.
13. Further efforts are needed to encourage counseling to help HIV-positive mothers with exclusive breastfeeding.

1. **HIV-positive mothers, fathers, grandmothers and the larger community need clear, consistent, non-contradictory and nonjudgmental counseling on infant feeding practices. Health care providers need training based on accurate information.** Studies found that health care providers gave HIV-positive women conflicting information and that simplified structured counseling tools are needed. Studies found that women reported that providers accused them of killing their infants if they breastfed. Women lack access to infant formula but have been told by providers that it is the only way for their infant to survive. Women were told that breastfeeding is a mode of HIV transmission and exclusive breastfeeding is a mode of prevention. Women fear HIV more than diarrheal disease, even though more deaths occur from diarrheal disease. Women were not given choices. Women did not give providers accurate information on how they were feeding their infant for fear of being denied health care. Women were told to feed their infants formula yet did not have adequate food support, most mothers could not do so with few having an income and most with no access to safe drinking water. Women lacked autonomy to decide infant feeding, which was decided by male partners or grandmothers. Despite the current WHO recommendations to use extended infant prophylaxis as long as the infant is breastfed, no data are yet available from a clinical trial to confirm effectiveness and safety of this regimen beyond the first six months postpartum" (Taha, 2011: 919).

    - Gap noted, for example, in **Burkina Faso** (Cames et al 2010a), **Zambia** (Chisenga et al., 2011); **Vietnam** (Sethuraman et al., 2011); **Malawi** (Ostergaard and Bula, 2010; Kerr et al., 2008); **Jamaica** (Cooper et al., 2010); **Burkina Faso**, **Cambodia** and **Cameroon** (Desclaux and Alfieri, 2009), **Malawi**, **Kenya** and **Zambia** (Chopra et al., 2009a), **Lesotho** (Towle and Lende, 2008), **Botswana, Kenya, Malawi and Uganda** (Chopra and Rollins, 2008 and Coutosidis et al., 2002 cited in Chopra and Rollins, 2008), **Cameroon** (Kakute et al., 2005), **South Africa** (Doherty et al., 2006) and **Uganda** (Fadnes et al., 2010).

2. **Further research is needed to understand the links between mastitis and vertical transmission.** Studies found that maternal HIV infection was correlated with mastitis and the potential for vertical transmission.

    - Gap noted, for example, in **Zimbabwe** (Lunney et al., 2010); **Zambia** (Kasonka et al., 2006), **Tanzania** (Kantarci et al., 2007) and **Malawi** (Nussenblatt et al., 2006).

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3. **Accurate testing techniques for infants may inform infant feeding.** Studies note that rapid scale up of early infant diagnosis is needed in low-resource settings in order to access treatment and care as soon as possible. *[For WHO guidance on HIV testing in infants see*: http://www.who.int/hiv/topics/vct/toolkit/additional_resources/children/en/]

    - Gap noted, for example, in **Tanzania** (Finnegan et al., 2009: 216); **Kenya** (Inwani et al., 2009: 492); **South Africa** (Rollins et al., 2009:1855); **Vietnam** (Sohn et al., 2009); **West Africa** (Msellati, 2009) and **globally** in resource-limited settings (Painstil and Andiman, 2009).

4. **Stigma reduction interventions are needed so that women with HIV can choose replacement feeding, breastfeeding and weaning schedules.** Studies found that HIV-positive women feared that if they used infant formula or abruptly weaned, they would be stigmatized for their HIV-positive serostatus.

    - Gap noted, for example, in **Burkina Faso** (Cames et al 2010a), **Kenya** (Morgan et al., 2010); **Burkina Faso, Cambodia and Cameroon** (Desclaux and Alfieri, 2009); **Ethiopia** (Greenblott, 2011); **Tanzania** (Falnes et al., 2011); **Nigeria** (Oladokun et al., 2010b; Maru, 2009); **Zambia** (Chisenga et al., 2011); **Vietnam** (Sethuraman et al., 2011); **Malawi** (Ostergaard and Bula, 2010; Chinkonde et al., 2009; Thorsen et al., 2008), and **South Africa** (Doherty et al., 2006).

5. **Additional efforts are needed to provide postpartum women with contraception information and methods so they may space or prevent their next pregnancy and use condoms to reduce the likelihood of HIV transmission upon resumption of sexual activity.** *[See also Meeting the Sexual and Reproductive Health Needs of Women Living With HIV]* Studies found that women were not given contraceptive counseling or contraceptives postpartum and that transport costs restricted their ability to gain access to their contraceptive method of choice. Studies also found an unmet need for postpartum contraception among women living with HIV. Studies found that sexuality and condom use need to be addressed when sexual activity resumes postpartum. Family planning services are most often not provided postpartum in PMTCT programs. Providers and women did not know that clinically well HIV-positive women can use IUDs. Women lacked the full range of available contraception. No study to date has measured pregnancy intention prospectively in an HIV-discordant couple cohort and measured the effect of desired pregnancy on HIV transmission.

    - Gap noted, for example, in **Ukraine** (Saxton et al., 2010); **Ghana** (Achana et al., 2010); **Kenya** (Brubaker et al., 2010; Chersich et al., 2008b); **Uganda** (Were and Haunira, 2010): **Tanzania** (Keogh et al., 2009); **Kenya, Rwanda, Tanzania, Botswana, South Africa and Zambia** (Heffron et al., 2010); **Malawi** (Makanani et al., 2010); **South Africa** (Crede et al., 2012), **Côte d'Ivoire** (Brou et al., 2008), **Kenya and Zambia** (Thea et al., 2006) and **globally** in resource-limited settings (Baek and Rutenberg, 2010).

6. **Further efforts are needed to educate families about HIV transmission so that infants are not abandoned.** *[See also Care and Support: Orphans and Vulnerable Children]* A study found that families forced HIV-positive women to abandon their infants due to erroneous fears that the infants could transmit HIV.

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- Gap noted, for example, in **Russia** (Zabina et al., 2009).

7. **Interventions are needed to scale up CD4 count screening, especially for pregnant women.** A study found that several barriers limited CD4 cell count screening in rural areas, including "availability of laboratories equipped to perform CD4 cell count enumeration, reagent stockouts, and lack of sample transport systems" (Carter et al., 2010: 408). For mothers with CD4 counts above 500, there may be a low risk of HIV transmission through breastfeeding, though further research is necessary.

   - Gap noted, for example, in **Cameroon, Cote d'Ivoire, Kenya, Mozambique, Rwanda, South Africa, Thailand, Uganda** and **Zambia** (Carter et al., 2010); **Burkina Faso** and **Kenya** (Kesho Bora Study Group, 2010).

8. **Interventions are needed to encourage male partners to refrain from sexual activity during the postpartum period of time that women cannot have sex.** A study found that it is common for men to have multiple sexual partners once their wives have given birth until the women can again engage in sexual activity.

   - Gap noted, for example, in **Ghana** (Achana et al., 2010).

9. **Increased efforts are needed to retain women on HAART following birth.** Studies found that women who initiated ART during pregnancy were more likely to be lost to follow up than non-pregnant women or that pregnant women who were eligible for HAART according to national guidelines were not provided HAART.

   - Gap noted, for example, in **Swaziland** (Bacheno et al., 2010); **Vietnam** (Sethuraman et al., 2011); **Tanzania** (Arreskov et al., 210); **South Africa** (Myer et al., 2012, Abstract; Clouse et al., 2012, Abstract; Westreich et al., 2012, Abstract); **Latin America** (Kreitchmann et al., 2012, Abstract); **Kenya** (Otieno et al., 2010) and **Nigeria** (Rawizza et al., 2012, Abstract).

10. **More research is needed to understand the relationship between maternal single-dose nevirapine administered during delivery and postpartum nevirapine resistance found in breastmilk, and its impact on postnatal transmission to infants.** *[See also Antenatal Care: Treatment]*A study detected nevirapine resistance in 40% of breast milk samples collected from 30 HIV-positive mothers after four weeks of single-dose nevirapine exposure. Breastmilk samples were collected from 19 mothers whose infants tested HIV negative and 11 mothers who infants tested HIV positive by 6 weeks of age.

    - Gap noted, for example, in **Uganda** (Hudelson et al., 2010).

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11. **Screening for post-partum depression among HIV-positive women may be warranted.** *[See also Care and Support: Women and Girls]* A study found high rates of postpartum depression among HIV-positive women.

    - Gap noted, for example, in **Thailand** (Ross et al., 2011) and **Zimbabwe** (Chibanda et al., 2010).

12. **Further efforts are needed to assess the feasibility of wet-nursing for HIV-positive mothers.** A study surveyed 300 women during routine healthcare visits on their knowledge of HIV and breastfeeding, and found that HIV-specific knowledge was poor, but also that the option of using a wet nurse or being a wet nurse was agreeable among 70% and 75% of women, respectively.

    - Gap noted, for example, in **Burkina Faso** (Nacro et al., 2010).

13. **Further efforts are needed to encourage counseling to help HIV-positive mothers with exclusive breastfeeding.** A study followed 61 HIV-positive mothers and their infants and found that after counseling and breastfeeding support, mothers exclusively breastfed for an average of 3.3 months, at which point 96% were exclusively breastfeeding compared to 23.5% in the general population.

    - Gap noted, for example, in **Cameroon** (Nlend and Ekani 2010).

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· *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 for a complete list. If missing or inaccurate there, please contact us.*

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