SECTION 1

Introduction

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2nd Edition, 2018

KEY MESSAGES

- Dissemination and implementation of current recommendations, and retraining of health workers will require funding and coordinated strategies as part of a broad programme in the context of HIV and outside it. However, findings of recent research should give confidence to health workers and policy makers that major improvements in HIV-related child and maternal mortality justify intensified efforts and are attainable.
- In all settings, children with a parent living with HIV should routinely be offered HIV testing.
- HIV testing is usually the entry point for HIV prevention, care and treatment.
- Global, national and community leaders have an opportunity to act in concert to support prevention of horizontal transmission between couples and vertical transmission of HIV to infants.
- Ensuring that patients initiate and continue ART requires interventions at different levels to address and allay their concerns and other barriers.
- Universal HIV treatment, care and support provides the means to scale up prevention of vertical transmission to the next generation, cut new infection rates and save the lives of mothers.

1.1 DEFINITION OF HIV

HIV, the human immunodeficiency virus, and AIDS, the acquired immunodeficiency syndrome caused by HIV, mainly affects sexually active adults. HIV can be vertically transmitted to a baby before, during or after birth, including through breastfeeding especially when women are not receiving ARV. The risks to infant and young child survival posed by artificial feeding create a dilemma for policy-makers and health workers in making recommendations about how HIV-exposed babies should be fed. An expert group describes the transmission risk as "negligible" (Vernazza et al., 2008), when an HIV-infected individual in a serodiscordant (mixed status) relationship has:

- had an undetectable viral load for at least 6 months.
- excellent adherence.
- no other sexually transmitted infections (STIs).

1.2 UNDERSTANDING THE ROUTES OF HIV TRANSMISSION

HIV is a retrovirus, identified in 1983 as the cause of AIDS (CDC, 2017b). There are three routes of transmission: horizontal, bloodborne and vertical.

Horizontal infection

- The most common source of infection is through unprotected sex between men and women, or between men who have sex with men;
- The risk is highest when the infected individual has high levels of virus in the blood during a recent infection or when the immune system has become badly compromised due to active AIDS.

Bloodborne infection

- Individuals can also be infected by transfusion of contaminated blood or blood products, needles, syringes or knives.

Vertical infection

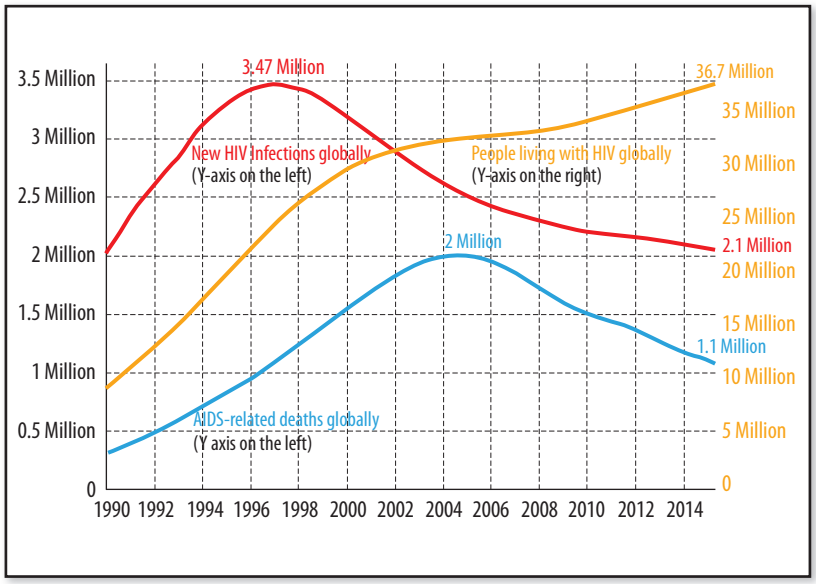
- Babies can be infected by a mother living with HIV during pregnancy, birth or breastfeeding. The risk of vertical transmission is particularly high if a woman acquires a new HIV infection, leading to high viral levels in her blood or milk while she is pregnant or breastfeeding (Dunn et al., 1992). A mother living with HIV is also more infectious when she is not receiving ARVs, and when an untreated HIV infection progresses to AIDS;
- Child-to-mother transmission can occur when an infant infected with HIV transmits the virus to an HIV-uninfected woman through breastfeeding. Transmission is likely to occur as a result of breastfeeding contact when the mother has damaged or abraded nipples and when the baby has inflammation of the mucous lining of any structure in the mouth, which may involve the cheeks, gums, tongue, lips, throat, and roof or floor of the mouth. While infant infection without maternal infection is rare, when it does occur, rates of child-to-mother transmission have been observed to range from 40-60% among mothers reporting breastfeeding after their infants were infected (Little et al., 2012);
- There are benefits of starting ART early in pregnancy, and new data indicates that extended ARV prophylaxis to mothers or infants is effective in substantially decreasing the risk of HIV through breastfeeding (WHO, 2009d; Becquet & Ekouevi, 2011);

- The major obstacles to eliminating vertical transmission globally include low rates of adherence to ART and retention with non-completion of the 'PMTCT care cascade' due to programmatic and structural challenges faced by healthcare systems in low-income countries. This includes antenatal, delivery, and infant follow-up services through 12-24 months of life and provides a way that loss to follow-up or non-adherence to ART can be readily identified.

1.3 GLOBAL PREVALENCE AND STATISTICS

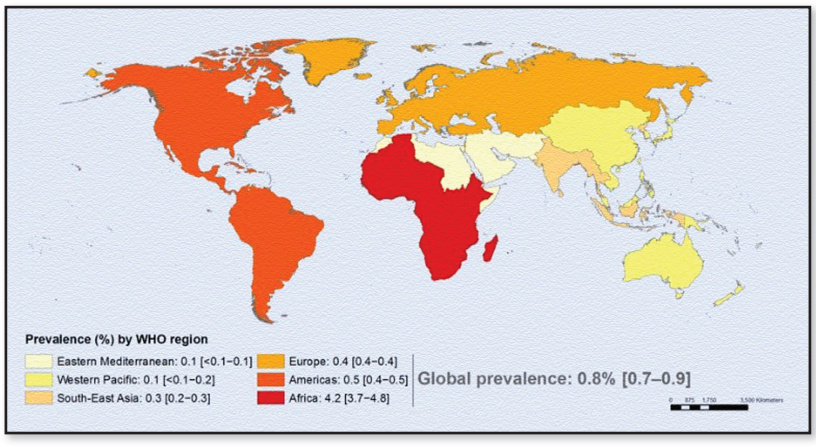
Trends in HIV incidence, prevalence and mortality

FIGURE 1: Global number of AIDS-related deaths, new HIV infections and people living with HIV from 1990 to 2015



Source: Roser (2017)

FIGURE 2: Prevalence of HIV among adults aged 15 to 49, 2016



Source: WHO (2017d)

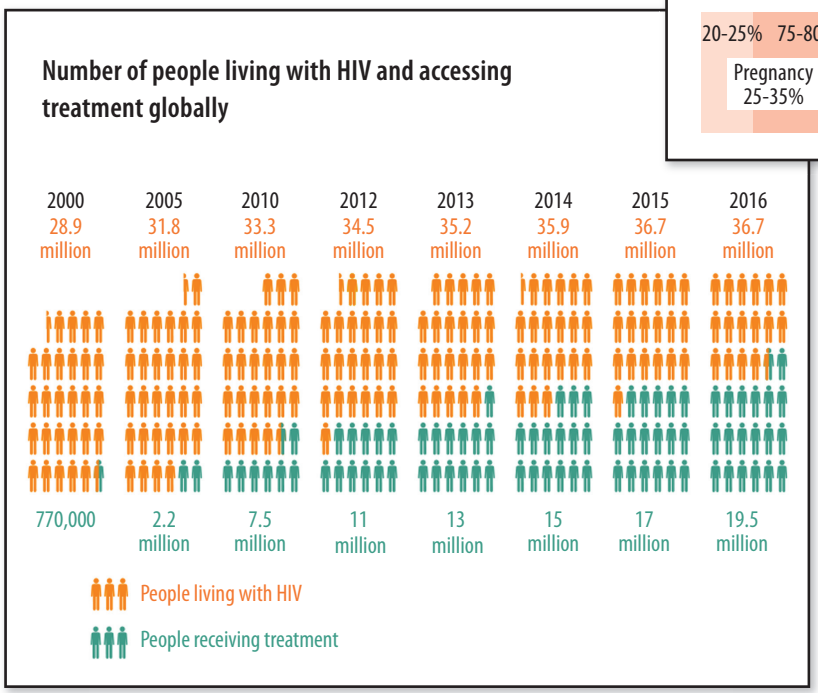
Global HIV facts and figures

- There were 34.5 million adults (17.8 million were women above 15 years old) and 2.1 million of children (<15 years old) living with HIV in 2016 (UNAIDS, 2017a);
- New HIV infections among adults (aged 15 and older) remained static at 1.9 million from 2010 to 2015. However, during the same period the number of new HIV infections among young women aged 15 to 24 years old decreased by 6%, and among women of reproductive age (15 to 49 years) the number of new HIV infections reduced by 2% (UNAIDS, 2017a);
- Globally, 38% of people living with HIV are virally suppressed (UNAIDS, 2016c);
- Most people living with HIV (19.0 million) were in Eastern and Southern Africa (UNAIDS, 2016b). In Sub-Saharan Africa, 25% of new infections were young women and 56% were adult women;
- 19.5 million people living with HIV were on antiretroviral therapy in 2016 (UNAIDS, 2017a)–around 76% of pregnant women living with HIV and 43% of children aged 0-14 years had access to treatment in 2016 (UNAIDS, 2017a). See Figure 3 for details;
- Global coverage of individuals on antiretroviral therapy reached 53% in 2016 (UNAIDS, 2017a);
- According to UNAIDS Report 2016, South Africa (with 3.4 million people in treatment) and Kenya have the largest treatment programmes in Africa (UNAIDS, 2016b);
- In Botswana, Eritrea, Kenya, Malawi, Mozambique, Rwanda, South Africa, Swaziland, Uganda, Tanzania, Zambia and Zimbabwe treatment coverage increased 25% between 2010 and 2015 (UNAIDS, 2016b);
- Sex workers, people who inject drugs, transgender people, prisoners, gay men and men who have sex with men remain the key population with higher risk of HIV infection (UNAIDS, 2017a). Compared to the general population, sex workers have a 10-fold risk of acquiring HIV

while injecting drugs, gay men, and men who have sex with men have a 24-fold risk of becoming infected with HIV;

- Ignorance and misunderstanding continue to undermine efforts to end AIDS (UNAIDS, 2016b). For instance, stigma, discrimination and violation of other human rights block people, including the general population, from seeking HIV testing and treatment, which significantly compromises adherence to available ART. Consequently, lack of adherence to ARV treatment results in disruptions in viral suppression of those on treatment, putting at risk previous treatment gains;
- Gender inequalities, for instance, gender based violence contribute systematically to the vulnerability of women and girls to acquiring HIV and accessing treatment (UNAIDS, 2016b);
- Discrimination and stigmatisation of the population with higher risk of acquiring HIV result in increased barriers for access to HIV prevention, testing and treatment (UNAIDS, 2016b);
- A reinvigoration of prevention efforts are "needed to hasten the decline in adult infections" and "the job is still only half done" (UNAIDS, 2016b).

FIGURE 3: Number of people receiving antiretroviral therapy from 2000 to 2016

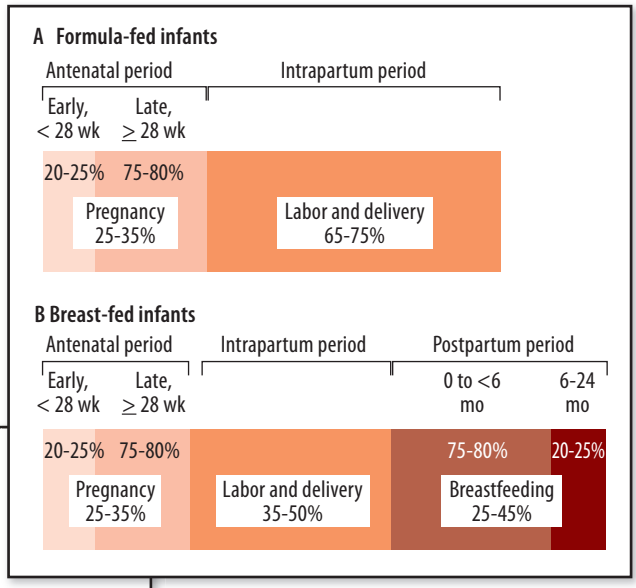


Source: AVERT (2017a)

Paediatric HIV and recommendations for prevention

- In low income settings where women are unable to access effective treatments for their own health, postnatal transmission remains unacceptably high, at 20-45% (De Cock et al., 2000);
- In the absence of effective interventions including ARV regimens, the absolute risk of transmission is 15%-25% in formula-fed infants and 25%-40% in breast-fed infants (Luzuriaga & Mofenson, 2016). See figure 4 for details.

FIGURE 4: Relative proportion of HIV-1 transmission from an untreated mother to her infant, according to gestational period and mode of infant

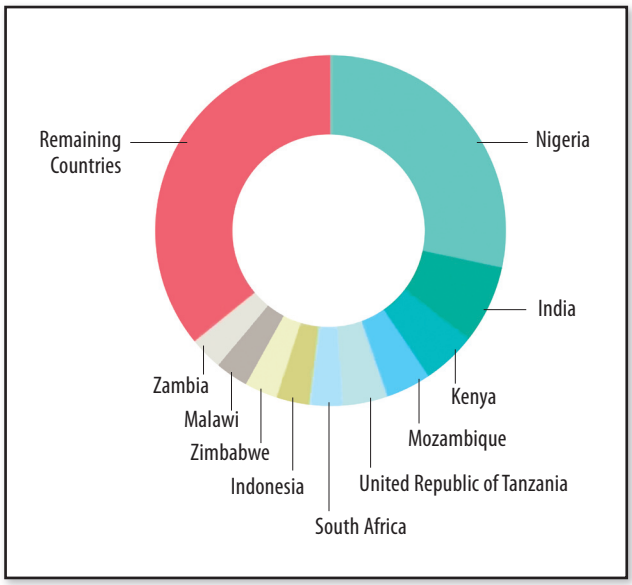


Source: Luzuriaga & Mofenson (2016)

- An unknown percentage of postnatally acquired paediatric HIV may be caused by premastication of food for infants and young children, commonly practised by HIV-positive mothers and other care-givers in both developed and developing countries (CDC, 2011b; Maritz et al., 2011; Ivy III et al., 2012; Gaur et al., 2013). This route of transmission may be facilitated by adult/infant oral thrush, bleeding gums, or infant teething (Drake et al., 2014) and is often indistinguishable from, and may be wrongly attributed to, postnatal transmission through breastfeeding;

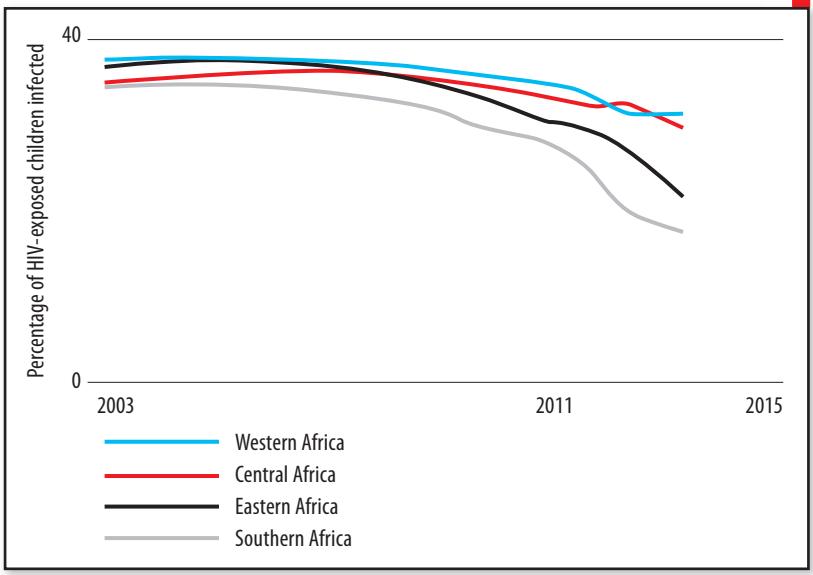
- HIV infection of children at healthcare facilities has been reported through reuse of injection equipment, and dental and medical procedures including blood transfusions that fail to observe adequate infection control practices. This also has implications for vertical transmission to previously uninfected mothers (Dunn et al., 1992). Paediatric infection can also be caused by body cutting or sexual abuse (WHO, 2010d; Chinkonde et al., 2012);
- Without treatment, 30% of HIV-infected children die in the first year of life, 50% before the age of 2 (Drake et al., 2014);
- In countries such as South Africa that have achieved 90% ARV coverage, the vertical transmission of HIV has been reduced drastically (UNAIDS, 2010c);
- Providing pregnant women with ART has averted >900 000 new HIV infections amongst children since 2009 (UNAIDS, 2014);
- Although new HIV infections among children (aged 0 to 14 years old) dropped significantly from 290 000 in 2010 to 150 000 in 2015, in the same period Nigeria, India, Kenya, Mozambique and Tanzania had the greatest number of new infections among children worldwide (UNAIDS, 2016c; Roser, 2017). See Figures 5 and 6 for details.

FIGURE 5: Distribution of new HIV infections among children (aged 0-14 years), by country in 2015



Source: UNAIDS (2016c)

FIGURE 6: Trends in postnatal HIV transmission rates by sub region in Sub-Saharan Africa, 2000-2011



Source: Roser (2017)

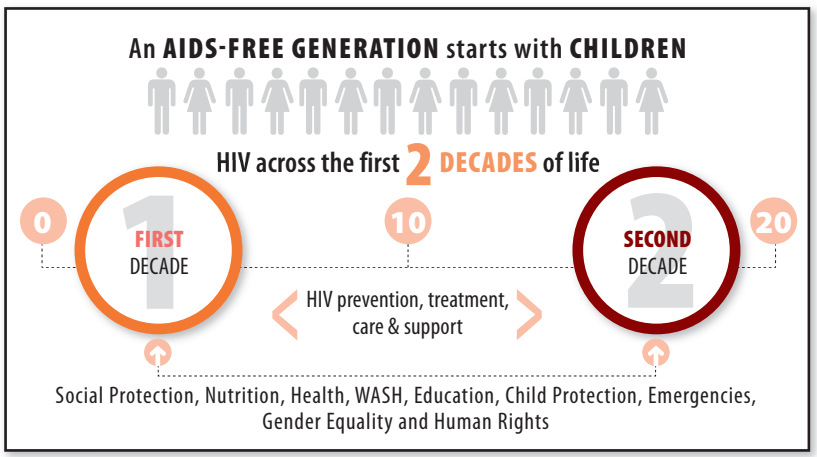
- In 2015, 300 000 women were not under ARV thus increasing the potential risk of vertical HIV transmission (UNAIDS, 2016c);
- When pregnant and lactating women abandon ARV treatment the threat of an increase in the risk of vertical HIV transmission remains high (UNAIDS, 2016c). In addition, there are indications of a close link between poor adherence of maternal ARV to a lack of newborn and infant HIV testing and HIV therapy;
- Although there are reports of women dropping out of maternal ARV adherence, as a result of expansion of ARV provision for women living with HIV over the past five years, there has been a substantial decline in new child infections and child mortality relating to AIDS (UNAIDS, 2016c);
- In 2015, South Africa and Kenya had the highest rates of HIV treatment in Africa. However, countries such as Botswana, Eritrea, Kenya, Malawi, Mozambique, Rwanda, South Africa, Swaziland, Uganda, Tanzania, Zambia and Zimbabwe also increased treatment coverage by more than 25% between 2010 and 2015 (UNAIDS, 2016b);
- In 2015, WHO recommended OPTION B+, the lifelong ARV therapy, going beyond pregnancy, childbirth and breastfeeding, would make future pregnancies safer. Thus, 91% of 1.1 million women received lifelong ARV to prevent vertical HIV transmission (UNAIDS, 2016c);

- Preventing new HIV infections among women of childbearing age not only promotes their good health but also is an important step in eliminating mother-to-child transmission (UNAIDS et al., 2016).
- Considerable gains were achieved in preventing unintended pregnancies in countries with high HIV prevalence. Ethiopia, Kenya, Lesotho, Malawi and Rwanda achieved a reduction of 10% in needs for family planning among married women (UNAIDS, 2016c). UNICEF and UNAIDS provide frameworks for how HIV can be prevented, treated and supported. See Figure 7 for more details;
- The 'Start Free, Stay Free, AIDS Free' Super-Fast-Track framework and action plan aims to galvanise global momentum around a shared and ambitious agenda to build on the progress achieved under the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive (UNAIDS, 2017e). See Figures 8 for more details;
- HIV services should be integrated within a package of core interventions for maternal, newborn and child health that include: high quality antenatal, perinatal and postnatal services; prevention, screening and care for malaria and tuberculosis; syphilis screening and care; skilled birth attendance backed by emergency obstetric care; and newborn and child care, infant feeding support, immunisation and family-centered nutritional care and support (Drake et al., 2014).

"Children should be the first to benefit from our successes in defeating HIV, and the last to suffer from our failures."

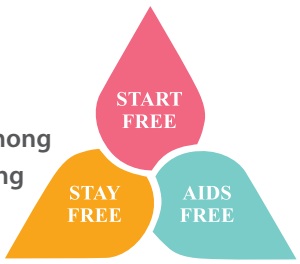
Anthony Lake, Executive Director, UNICEF

FIGURE 7: UNICEF future work plan for HIV across the First 2 decades of life, 2014



Source: UNICEF (2014b)

Figure 8: A super-fast-track framework for ending AIDS among children, adolescents and young women by 2020 – Start Free, Stay Free, AIDS Free



START FREE

- ✓ Eliminate new HIV infections among children (aged 0-14) by reducing the number of children newly infected annually to less than 40 000 by 2018 and 20 000 by 2020.
- ✓ Reach and sustain 95% of pregnant women living with HIV with lifelong HIV treatment by 2018.

STAY FREE

- ✓ Reduce the number of new HIV infections among adolescents and young women (aged 10-24) to less than 100 000 by 2020.
- ✓ Provide voluntary medical circumcision for HIV prevention to 25 million additional men by 2020, with a focus on young men (aged 10-29).

AIDS FREE

- ✓ Provide 1.6 million children (aged 0-14) and 1.2 million adolescents (aged 15-19) living with HIV and antiretroviral therapy by 2018.
- ✓ Provide 1.4 million children (aged 0-14) and 1 million adolescents (aged 15-19) with HIV treatment by 2020.

Source: UNAIDS (2017e)

1.4 TYPES OF TESTS

Provider initiated testing and counselling

Over the years, policy and practice on HIV testing and counselling has evolved from a cautious approach that emphasised confidentiality to greater acceptance of the routine offer of HIV testing. This has resulted in greater uptake of testing and access to treatment.

By 2005-6, 43% of African countries had adopted a policy of recommending provider-initiated HIV testing and counselling for PMTCT (known as PITC).

In 2007, WHO and UNAIDS issued new guidelines (WHO & UNAIDS, 2007) advocating PITC for:

- all patients who present with signs or symptoms of underlying HIV disease.

- all patients attending healthcare facilities in countries where HIV-prevalence exceeds 1%.

Subsequently it was suggested that PITC should:

- require informed consent.
- provide sufficient information for clients to make an informed decision.
- enable clients to decline testing.
- be done in private.
- tailor post-test counselling to the test result, guarantee confidentiality.

Between 2009 and 2010 HIV testing and counselling of pregnant women in low and middle-income countries increased from 26% to 35%. In sub-Saharan Africa, the region with the highest number of pregnant women living with HIV, coverage increased from 35% to 42%, with increases from 52% to 61% in Eastern and Southern Africa, increasing to 79% by 2012. Although women in antenatal clinics were not always aware that they had the right to decline an HIV test, most countries considered PITC to be their standard of care (Baggaley et al., 2012).

Western Blot Testing, which detects the HIV antibody, was used in the past to confirm results from an ELISA or Rapid test/RDT. However nowadays Western Blot Testing is no longer considered reliable and not widely used any more (Fletcher, 2017).

In the past, offering testing alone before antiretroviral treatment (ART) was available, did not achieve high coverage due to:

- lack of access to testing services.
- fear that the test will be positive.
- fear of stigma and discrimination, and/or gender inequality.
- lack of access to treatment.

Different types of HIV Testing

HIV infection and accompanying immune-suppression are detectable by various tests. Key information for HIV tests and CD4 counts/monitoring are:

- ELISA testing–detects antibodies to HIV.
- Rapid Test/RDT–detect HIV antibodies in the absence of laboratory.
- Nucleic Acid Testing/NAT–early infant diagnosis.
- Serial/Parallel Rapid Testing Algorithm–detection of antibodies to HIV.
- Self-testing–a process whereby a person who wants to know his or her HIV status utilises a commercial test product which provides results without requiring processing in a laboratory.
- CD4 counts–to monitor immune function.
- PCR or RNA Test or Viral Load Test–multiplies viral copies, making them easier to measure.
- Testing for Acute HIV Infection During Pregnancy–test for women with symptoms suggestive of acute HIV.

ELISA testing

The Enzyme Linked Immunosorbent Assay (ELISA) is relatively inexpensive and tests for antibodies to HIV. Antibodies are produced by an individual's immune system to fight off foreign pathogens. There is a 'window period' of 3 to 12 weeks, between infection and the appearance of antibodies when HIV can be passed to another person more easily. During this period, an individual may test negative, but may have high levels of HIV in their blood, semen, vaginal fluids and breastmilk.

RAPID test/RDT

These are recommended for settings where laboratory services are weak or absent. They allow a quick turnaround, do not require specialised equipment, usually have internal controls, and can be operated by trained non-laboratory personnel, including lay service providers. Most HIV rapid diagnostic tests provide results in less than 30 minutes. They have a 6- to 12-week window period, the time between suspected HIV infection and the point when the assay can detect HIV antibodies.

Nucleic Acid Testing/NAT

NAT at birth can be added to existing early infant diagnosis (EID) testing approaches to assist in identifying HIV infection in HIV-exposed infants. Infants testing positive on NAT testing are likely to have been infected in utero. Infants infected at or around childbirth will not be detected by NAT for several days or weeks. Furthermore, the ARV taken by the mother or infants as the postnatal HIV prophylaxis can affect the NAT, giving false-negative results. Overall, there is insufficient empirical evidence to recommend universal inclusion of NAT at or around childbirth (0-2 days) (WHO, 2016c). See Table 1 for details.

TABLE 1: Recommendation of RDT and NAT according to the child's age group, HIV exposure and breastfeeding status

Use of RDT for HIV serology based on age, exposure status and breastfeeding practice (WHO, 2016c)			
Age group	**Known HIV exposed**	**Unknown HIV exposure status and breastfeeding**	**Unknown HIV exposure status and not breastfeeding[a]**
0-4 months	Not useful, as exposure is known and RDT cannot determine infection status.	Test mother If the mother is not available, RDT in the child can reliably assess exposure.	Test mother If the mother is not available, RDT in the child reliably determines exposure.
5-8 months	Not useful, as exposure is known and RDT cannot determine infection status at this age.	Test mother If the mother is not available, a positive RDT establishes exposure, but a negative RDT does not fully rule it out. Infants with positive RDT will still need NAT to confirm infection. Infants with negative RDT who are still breastfeeding will need NAT at the end of breastfeeding. If sick and the mother is not available, perform NAT directly to assess HIV infection status.	Test mother If the mother is not available, RDT for the child does not fully rule out exposure. If sick and the mother is not available, perform NAT directly to assess HIV infection status.
9-18 months	RDT useful to rule out established HIV infection. Infants with *positive* RDT will still need NAT to confirm infection. Infants with *negative* RDT who are still breastfeeding will need NAT at the end of breastfeeding.	Test mother If the mother is not available, a positive RDT establishes exposure, but a negative RDT does not fully rule it out. Infants with positive RDT will still need NAT to confirm infection. RDT useful to rule out established HIV infection. Infants with positive RDT will still need NAT to confirm infection. Infants with negative RDT who are still breastfeeding will need NAT at the end of breastfeeding. If sick and mother is not available, perform NAT directly to assess HIV infection status[b].	Test mother If the mother is not available, RDT in the child does not fully rule out exposure. RDT is useful to rule out established HIV infection. • Infants with positive RDT will still need NAT to confirm infection. • Infants with negative RDT who are not breastfeeding can be considered uninfected. If sick and mother is not available, perform NAT directly to assess HIV infection status.
>18 months	Serological testing (including RDT) is still recommended to assess HIV infection status unless still breastfed. If still breastfed, serological testing (including RDT) should be provided 3 months after cessation of breastfeeding.		

[a] *Not breastfed for at least 12 weeks before testing.*

[b] *Consider initiating ART for presumed HIV infection if there is high degree of suspicion while waiting for NAT results, especially if RDT positive.*

Rapid Testing Algorithm

HIV Rapid tests for detection of antibodies to HIV have improved the speed of HIV diagnosis, with more efficiency for provision of results that do not require conventional laboratory facilities like conventional ELISA testing. In tackling vertical HIV transmission, it is important to link rapid testing to other services in scaling up reduction of HIV and AIDS infection. Nevertheless, algorithm testing was introduced to improve accuracy and efficiency of rapid tests. (Mbachu et al., 2015; Ssebaggala et al., 2017). There are two types of rapid testing algorithms: serial and parallel.

- **Serial Rapid Testing Algorithm**
  Serial Testing Algorithm approach is more often recommended for public health settings with sensitivity close to 100%, which consists of two different rapid tests with different blood samples, applied one after another in the case of a positive result. For instance, a second test (a confirmatory test) is used when the initial test is positive. WHO recommends sensitivity of rapid tests of 99%. According to a study from Nigeria, a rapid HIV kit is used for screening and confirmation of HIV diagnosis. However, in settings where false results with rapid tests are more often observed, it is a sign that local HIV testing strategies might have to be reviewed.

- **Parallel Rapid Testing Algorithm**
  Parallel testing is more expensive and most often used in settings of lower HIV incidence and prevalence, and in research settings. Parallel screening consists of the use of two tests simultaneously with the same blood sample, when each test checks on the other:
  - in the case of both tests showing HIV-positive the result is reported as HIV-positive.
  - when both tests show HIV-negative the result is reported as HIV-negative.
  - when one test shows positive and the other shows negative, a third test is conducted as a 'tie breaker test'.

Self-testing

HIV self-testing is a process whereby a person who wants to know his or her HIV status. The person collects a specimen, performs a test and interprets the test result in private using a commercial test.

HIV self-testing also:

- Enables discretion, convenience and privacy
- May increase testing among people not currently reached by existing testing and counselling services
- Is a screening test for the presence of HIV antibodies or HIV-1 p24 antigen
- Does not provide a definitive diagnosis
- Always requires further testing according to relevant national testing algorithms

CD4 counts

CD4 or T-cell number measures the strength of the immune system. In the past, when ART was not available, CD4 cell counts were used to monitor the progress of HIV. A healthy individual has a CD4 cell count of around 700 to 1000 cells per cubic millimetre (mm^3) of blood. Within weeks of an initial HIV infection, the CD4 count falls sharply, followed by a small recovery and increase, then a second slower decline over time. With a high CD4 cell count of >500 mm^3 the risk of postnatal transmission is relatively low. Nevertheless, updated programmatic guidance recommends triple ARVs for all pregnant women as soon as diagnosed, and continuing for life (WHO, 2012c). Good health and nutrition as well as ARVs can help to keep the CD4 cell count high.

Polymerase Chain Reaction (PCR) testing

Polymerase Chain Reaction (PCR) multiplies viral RNA to enable its measurement in blood. PCR tests are usually more expensive and technically difficult, though specimens can be collected on filter papers which are easily transported to a central laboratory, even in tropical conditions. A PCR will give an earlier diagnosis of HIV-infection because the window period is shorter. Early versions of the PCR did not always test for all HIV sub-types, and not all PCR tests have the same sensitivity. The choice of assay should be dictated by the prevailing HIV sub-types in the country (Creek et al., 2007).

Before 18 months a PCR test is required to make a definitive diagnosis of HIV infection in children. WHO recommends PCR testing of HIV-exposed infants by 4-6 weeks of age (WHO et al., 2010) when it is possible to detect low levels of circulating virus in the infant's blood. Early testing is important so that infected infants, regardless of clinical or immune status, can immediately start ART to improve the chances of survival. A second confirmatory HIV test should be done, but this should not delay starting ART (WHO & UNAIDS, 2007).

Testing for acute HIV infection during pregnancy

Acute HIV infection dramatically increases the risk of HIV vertical transmission. Women with symptoms suggestive of acute HIV, even with previous HIV testing with negative result, might be tested with HIV RNA testing in conjunction with HIV serologic testing, when such testing is available–preferably with a fourth generation HIV antigen/antibody combination test (Perinatal Transmission Prevention Guideline Committee, 2017).

How the risk of vertical transmission of HIV is determined

The first step in treating individuals living with HIV lies in testing to see who needs treatment. "Point-of-care testing" is conducted at or near the place where women and infants receive care. The test results should return rapidly for a clinical decision to be made in time, to be cost effective and without any harm to the health of women and children (WHO, 2016c).

It is strongly recommended that test results from virological testing in infants be returned to the clinic and child/mother/caregiver as soon as possible, at the very latest within 4 weeks of the specimen collection. Positive test results should be fast-tracked to the mother and the baby as soon as possible to enable prompt initiation of ART (WHO, 2016c).

Infants with HIV detected by NAT at birth suggest HIV infection acquired in uterus. The disease will progress rapidly in the absence of treatment, thus increasing the chance of death in the first months of life (WHO, 2016c).

HIV testing for couples

Counselling and testing of a couple together in the home is often more helpful than providing services for one partner alone at a clinic.

HIV testing for women

Early treatment enables pregnant women to receive prompt antiretroviral treatment (ART) for themselves and early antiretroviral (ARV) prophylaxis to reduce the risk of transmission of HIV to their babies during pregnancy, birth and breastfeeding. See Table 2 for details.

- Repeat testing during late pregnancy has recently been recommended for mothers who have tested negative in early pregnancy (Gutierrez et al., 2012).
- All pregnant women not living with HIV should be retested in the third trimester, during labour and/or during the postpartum period, because of the high risk of acquiring HIV during pregnancy (WHO, 2016c).
- Current availability of ART and changed policies enable women who test HIV-positive to receive life-long ART for their own health.
- However, without access to HIV testing and counselling followed by prompt linkage to treatment and prevention services, people living with HIV risk ill health, death and the transmission of HIV to others.

HIV testing for untreated HIV-infected infants

Because mortality in the first year of life is very high among untreated HIV-infected infants, early HIV testing, prompt return of results and rapid initiation of treatment are ESSENTIAL (WHO, 2016c).

- Infant mortality in the first year is very high in untreated HIV-infected infants. In order to improve survival, HIV-exposed infants should receive continuation of breastfeeding and early HIV testing with prompt return of results and rapid initiation of treatment;
- As a result of poor coverage of interventions, in settings where HIV transmission is high (>5% at 6 weeks) the proportion of children infected in utero is lower, but the proportion of overall HIV infection will be substantially higher;
- HIV infection can be definitively confirmed only with virological testing using NAT technologies.

HIV testing for HIV-exposed infants

It is strongly recommended that ALL HIV-exposed infants have virological testing at 4-6 weeks or at the earliest opportunity thereafter (WHO, 2016c). Early infant diagnosis (EID) of HIV infection is critical to ensure optimal treatment outcomes for children. EID is the testing of infants to determine HIV status, following possible exposure to HIV during pregnancy, delivery and postpartum through breastfeeding (WHO, 2016c).

- Testing at 4-6 weeks is also recommended so that babies who are infected during late pregnancy or during birth can receive early ART (WHO, 2010b);
- Infant testing at 6 weeks postpartum also enables prompt treatment of mothers who became newly infected during late pregnancy, or may have self-reported HIV-negative status for fear of stigma;
- Testing soon after birth ensures that mothers of infected infants can be advised on how to adopt

TABLE 2: Summary of HIV testing for women and couples

HIV testing	HIV test for couples	HIV test during pregnancy	HIV test during labour	HIV test during postpartum	HIV test for lactating women	Important notes
1. ELISA Testing (Feucht et al., 2012; Gutierrez et al., 2012; WHO, 2016c)	✓	✓		✓	✓	• Women should be tested earlier or at the first visit at antenatal care, and it is strongly recommended retested in the third trimester of pregnancy (between 34 and 36 weeks) especially in areas of high incidence and prevalence of HIV, among women of key population or women with STDs; • If ELISA is negative, re-testing needs to be repeated after 3 (three) months.
2. Rapid Test/ RDT (Pebody, 2012; WHO, 2014a)			✓		✓	• Considering the 'window period', RDT Testing may not identify new HIV infection (WHO, 2014a) • RDT Test may perform poorly with HIV subtype clade CHIV-1, more common in countries with highest HIV prevalence (Pebody, 2012)
3. Serial Rapid Test Algorithm (Mbachu et al., 2015; Ssebaggala et al., 2017)		✓	✓	✓	✓	• If applicable, two tests are applied with different blood samples; • If the test result shows negative, it is reported as negative. But, if the test result shows positive, another test with another blood sample is done, as the second rapid test (confirmatory test). If the second rapid test is positive, the final test result is positive.
4. Self Testing (Pai et al., 2013)	✓					• Self Testing does not provide a definitive test result, but requires further repeat testing; • Self Testing can result in a false negative test result especially in the case of oral-fluid-based rapid diagnostic testing.

an optimal infant feeding regime (early initiation, exclusive and sustained breastfeeding for up to 2 years and beyond);

- Testing within a short time after breastfeeding is ended enables identification and treatment for babies who may have been infected through breastfeeding (WHO et al., 2011).

Recommended practices to improve HIV Testing Services (HTS)

- Integration of HTS with other health services, e.g. integration of HIV services, including HTS with other relevant clinical services, such as TB, maternal and child health, sexual reproductive health, and other programmes more relevant to each context;

- Decentralisation of HTS within primary healthcare facilities and beyond e.g. collaboration between community programmes and health facilities;
- Task sharing of HTS responsibility to increase the role of trained lay providers, e.g. training and supervising lay providers to provide HIV testing in health facilities and communities (WHO, 2016c).

1.5 IMPORTANCE OF TREATMENT AND PREVENTION

The antiretroviral therapy and prevention of vertical transmission of HIV to infants have the potential to reduce postnatal transmission of HIV to extremely low rates and achieve the highest rates of HIV-free survival. Furthermore, ART has the potential to:

TABLE 3: Summary of HIV testing for newborn, infant and children

HIV testing	HIV-exposed newborn at birth	HIV-exposed infant age 4-6 weeks	HIV-exposed infant age 5-8 months	HIV-exposed infant/ children age 9-18 months	HIV-exposed children age >18 months	Important notes
1. Nucleic Acid Testing/ NAT (WHO, 2016c)	✓	✓		✓		• Testing at birth through NAT test identifies infants who may have been infected during pregnancy; • Testing at 4-6 weeks is also recommended so that babies who are infected during late pregnancy or during birth can receive early ART; • NAT Test can be a confirmatory test for RDT Test, for infants at age 9-18 months.
2. Polymerase Chain Reaction/ PCR (Morrison, 1999a; WHO, 2007a; WHO, 2010d)		✓	✓			• HIV infection in utero can be detected within 48 hours of delivery using PCR or viral culture (Morrison, 1999a) • PCR Testing on infants from 4 weeks to 9 months.
3. Rapid Test/ RDT (Pebody, 2012; WHO, 2014a)				✓	✓	• Infants with *positive* RDT would need NAT or PCR to confirm infection; • Infants with *negative* RDT who are still breastfeeding will need NAT at the end of breastfeeding (three months after cessation of breastfeeding).
4. ELISA (Feucht et al., 2012; Gutierrez et al., 2012; WHO, 2016c)					✓	• An infant under 12 months will test positive on ELISA due to circulating maternal antibodies. ELISA testing of children is more accurate after 18 to 24 months (Feucht et al., 2012) to detect an HIV-infected child's own antibodies.

- Protect the health of mothers living with HIV and prolong their lives.
- Facilitate consistent breastfeeding messages and support for all mothers for at least the first 12 and up to 24 months of an infant's life or beyond.
- Provide additional ARV interventions for mothers living with HIV, as well as for their infants.
- Allow promotion of infant feeding practices that are closer to customary breastfeeding patterns for all mothers, whether living with HIV or not. In turn this would:
  - protect mothers living with HIV from the stigma attached to formula feeding (Doherty et al., 2006)
  - resolve previous difficulties and confusion experienced by health workers about feeding choice
  - reverse spill over of replacement feeding to uninfected mothers (Coutsoudis et al., 2002; Moland et al., 2010)
- Avert at least an additional 3 million deaths and prevent close to an additional 3.5 million new infections between 2012 and 2025 in low- and middle-income countries, compared to previous treatment guidelines (Vitiello & Willard, 2010).
- Contribute significantly towards achieving SDGs by reducing infant morbidity, mortality, malnutrition and illness, thus benefiting the entire population.

Antiretroviral therapy (ART) and reduction in risk of transmission

Early antiretroviral interventions

Drugs developed to disrupt the action of HIV are known as ARVs. Various ARVs to treat HIV and prevent vertical transmission have been employed in the last 25 years and effective ARV regimens have transformed HIV from an acutely lethal to a chronic disease. The aim is to reduce the amount of virus in the patient's body – their viral load – ideally to an undetectable level. The single most important indicator that HIV treatment and public health programmes should be concerned about today is viral load, which is key to both transmission and disease progression. The mechanism by which ART reduces HIV transmission from one individual to another (either a partner or a child) is by lowering the infected individual's viral load to undetectable. Appropriate ARV regimens reduce both horizontal and vertical transmission (Cohen et al., 2011; Rodger et al., 2014).

Guidance on antiretroviral treatment (ART) is constantly being updated as new research results are released. Improving women's health so that they can continue to be vital and productive members of society, as well as care for their children adequately, is of crucial importance.

- Antiretroviral regimens have been classified into therapeutic and preventive regimens
  - treatment: Previously, mothers usually received ART for their own health if their CD4 cell count fell below a certain number of viral copies per cubic millimetre of blood (usually <200 mm^3 in the earliest guidelines, more recently <350mm^3, and very recently <500mm^3). Current recommendations are that women who test HIV-positive should receive immediate ART, which should be continued for life (WHO, 2014a; WHO, 2016c)
  - prophylaxis: pregnant or breastfeeding mothers may have received ARV prophylaxis to prevent vertical transmission to their babies which was withdrawn after delivery of the baby, or when breastfeeding ended
- A combination of three or more drugs that attack the virus in several ways at the same time is called highly active antiretroviral therapy, or HAART. WHO treatment guidelines recommend 3-drug ART for all people infected with HIV. While ART taken during pregnancy may increase risk of preterm birth, stillbirth, and small size for gestational age (Zash et al., 2017), the overall health benefits for mother and baby are considered to offset the risk.
- Neither ART nor HAART are cures. If treatment is discontinued, the virus becomes active again, so a person who has started on ART needs to take it for life.

Preparing people living with HIV for ART

Before starting ART, the health care provider should provide full information related to the ARV drug regimen, dosage, schedule, benefits, adverse effects, and the importance of treatment follow-up and monitoring visits. It is important to add psychosocial support to optimise ART adherence especially in cases of pregnant women as it is highly recommended in initiatives to accelerate initiation of ART (WHO, 2016c).

Expectations during the first months of ART (WHO, 2016c):

- even with a lifelong ART regimen, the first month of ART is highly important–possibly requiring closer monitoring and follow up.
- opportunistic infections and/or immune reconstitution inflammatory syndrome (IRIS) can develop during the first three months of ART.
- although ART decreases mortality, death rates are highest in the first three months of treatment.
- side effects of ART (WHO, 2016c) are closely linked to:
  - advanced HIV disease with severe immunodeficiency
  - existing co infections and/or co morbidities
  - severely low haemoglobin
  - low body mass index
  - very low CD4 cell counts
  - severe malnutrition
  - drug hypersensitivity

Principles for ART guidance (WHO, 2016c):

- ART should be started based on a person's informed decision.
- interventions should be implemented to remove barriers to ART initiation once an individual is diagnosed HIV positive.
- HIV programmes should promote treatment literacy among all people living with HIV, including information on the benefits of early treatment, the lifelong commitment required, the risk of delaying treatment, and available adherence and retention support.
- care providers should be trained to support shared decision-making.
- ART initiation is urgent in case of serious ill health and for pregnant women in labour whose HIV test result is positive.

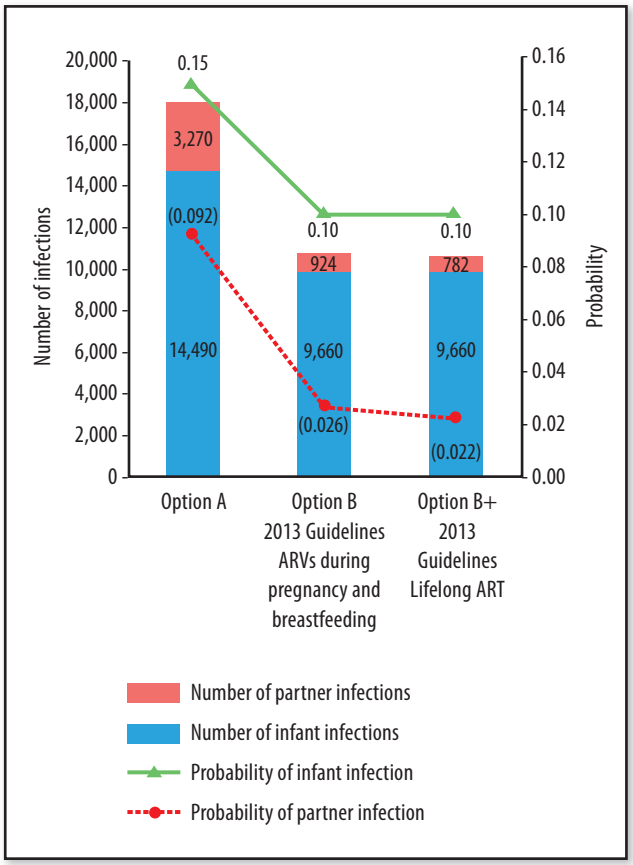
Barriers to ART acceptance

Treatment initiation is sometimes undermined by negative perceptions of treatment delivery and desire for normalcy. Fear of physical body changes and perceptions of feeling healthy are also factors to consider. The social and economic costs and future unavailability of treatment, as well as social relationships are further barriers to ART acceptance. As alternatives to ART, some HIV positive individuals may opt for herbal remedies and faith healing (Musheke et al., 2013)

Provision of triple ARV drugs to HIV-infected pregnant women is important:

- to prevent HIV transmission to their infants.
- to extend prevention benefits to HIV negative partners.
- to improve own health. The maternal survival benefits from Option B+ may ultimately have more health impact on children than the prevention of infant HIV in isolation (Roxby et al., 2014). See Figure 9 for details.

FIGURE 9: Health outcomes–HIV infections among exposed infants and serodiscordant partners, 2014



Source: Ishikawa et al. (2014)

1.6 TOOLKITS AND RECOMMENDATIONS

Toolkit for prevention and treatment of HIV infection in pregnant women, mothers and children

In 2013, the Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children (IATT) together with WHO and

UNICEF, working with CDC in the USA, published Toolkit on Expanding and Simplifying Treatment for Pregnant Women Living with HIV: Managing the Transition to Option B/B+ (IATT et al., 2013b).

The toolkit draws on lessons learned from the experience of Malawi as the first country to implement Option B/B+. It provides broad guidelines, summarises the main questions to address when implementing Option B/B+ and includes checklists and guidance related to key components of the health system, which can be viewed together or separately, based on the interests or needs of the user. It is designed for:

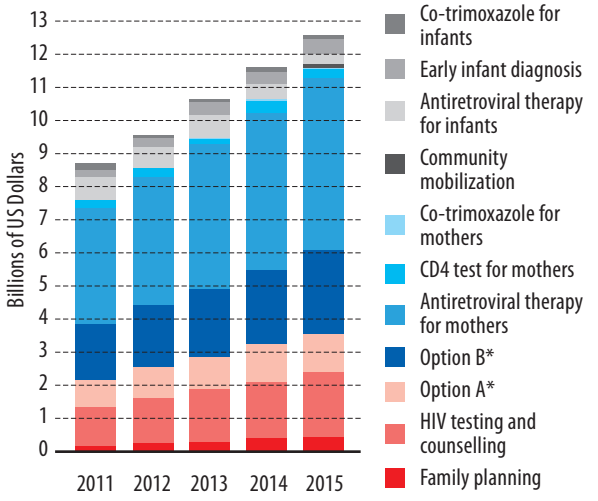
- policymakers, the Ministry of Health staff and national health programme managers.
- implementing partners, non-governmental organisations and multilateral organisations working towards EMTCT.
- networks of people living with HIV, civil society organisations (CSOs) and faith-based organisations (FBOs).
- donors.
- private sector health providers.
- public interested in better understanding challenges a country may be facing.

Cost estimates of interventions to prevent HIV and treat women and children living with HIV

WHO has undertaken to work with countries to rapidly implement the updated ART, PMTCT and Infant feeding recommendations and in particular to secure access to ARVs for all mothers living with HIV (WHO et al., 2010). Other agencies and foundations have pledged financial support (UNAIDS, 2011b). Overall, the cost of interventions to eliminate new HIV infections among children and keep their mothers alive in the 22 countries of highest HIV-prevalence where 90% of pregnant women living with HIV who need services live, was estimated to be approximately US$ 1 billion per year between 2011 and 2015 (UNAIDS, 2011a). Significant reductions in the price of first-line antiretroviral medicines (ART) means that low-income countries can provide a year of ART at a median cost of US$137 per person (WHO, 2011). US$500m is already invested annually for PMTCT, so that the shortfall is <US$300m, or US$2.5billion for the period 2011-2015 (UNAIDS, 2011a) (See Figure 10 for more details). This includes costs for:

- HIV testing and counselling.
- CD4 counts for pregnant women testing HIV-positive.
- antiretroviral prophylaxis.
- antiretroviral treatment and cotrimoxazole for eligible women and children.
- family planning for women living with HIV.
- community mobilisation.
- capacity building.

FIGURE 10: Investment to eliminate new HIV infections among children and keep their mothers alive in 22 priority countries, 2011- 2015



**Option A: Twice daily AZT for the mother and infant prophylaxis with either AZT or nevirapine for six weeks after birth if the infant is not breastfeeding. If the infant is breastfeeding, daily nevirapine infant prophylaxis should be continued for one week after the end of the breastfeeding period.*

**Option B: A three-drug prophylactic regimen for the mother taken during pregnancy and throughout the breastfeeding period, as well as infant prophylaxis for six weeks after birth, whether or not the infant is breastfeeding.*

Source: UNAIDS (2011a)

Key recommendation on cost effective prophylaxis to reduce postnatal transmission

Modelling indicates that any feeding strategy that includes provision of free infant formula to mothers living with HIV in a low-income setting, even for a limited period of six months, is 2-6 times more costly than a strategy that provides ARVs as lifelong treatment to eligible mothers and as prophylaxis to reduce postnatal transmission (WHO & UNICEF, 2016).

When the Malawi Ministry of Health began implementing the simplified Option B+ approach referred to above

it was hypothesised (Fasawe et al., 2013) that it would materially facilitate:

- Achievement of the Global Plan target of elimination of new paediatric HIV infections by 2015.
- Universal access to HIV treatment for mothers in a setting where it is difficult to effectively distinguish between:
  - those mothers eligible for treatment and
  - those needing prophylaxis.

Good practice recommendation for ART

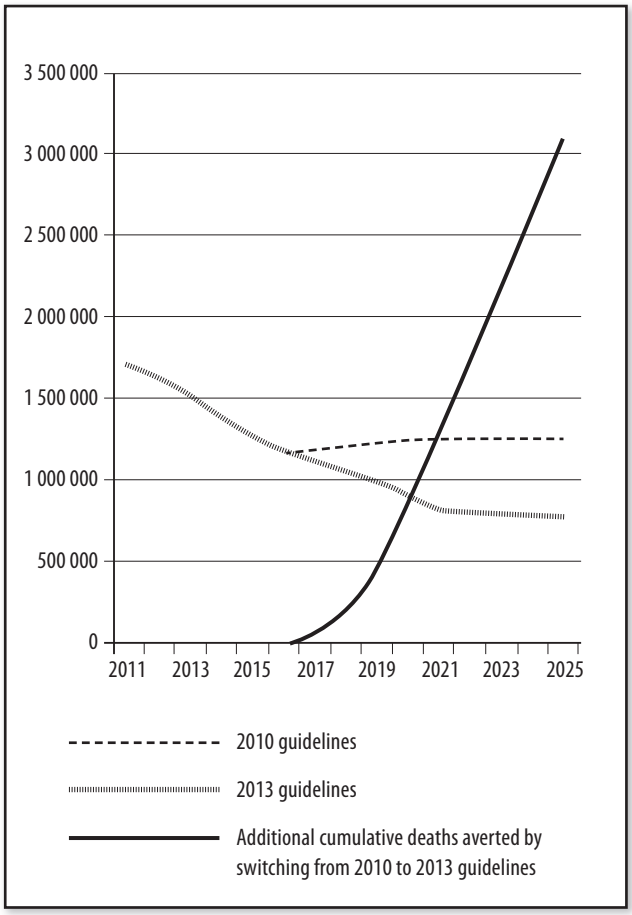
It was found that Option B+ or lifelong ART represents a favourable policy option. It is cost-effective, prevents future infant infections, saves mothers' lives and reduces orphanhood.

Although Option B+ would require more financial resources initially, it would save societal resources in the long-term and represents a strategic option to simplify and integrate HIV services into maternal, newborn and child health programmes.

In 2013, WHO personnel estimated that progressively scaling up ART would require increased funding, but the anticipated reductions in mortality and infection would also generate greater returns (Doherty et al., 2013). See Figure 11 for details.

Assuming that ART coverage increases gradually to about 80% of the total number of people eligible for treatment, total annual investment in the entire global HIV response in 2025 would need to increase by just 10%, from US$ 22 to 24 billion. This cost need is projected to level off over time before declining after 2025, a trend that reflects the accumulated prevention benefits of expanding ART provision.

FIGURE 11: Number of projected annual deaths averted comparing WHO 2010 and 2013 guideline recommendations for ART initiation, 2013



Source: Doherty et al. (2013)

The World Alliance for Breastfeeding Action (WABA) is a global network of individuals and organisations concerned with the protection, promotion and support of breastfeeding worldwide. WABA action is based on the Innocenti Declaration, the Ten Links for Nurturing the Future and the Global Strategy for Infant & Young Child Feeding. WABA is in consultative status with UNICEF and an NGO in Special Consultative Status with the Economic and Social Council of the United Nations (ECOSOC).