## SECTION 2

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# Guidelines and recommendations for antiretroviral (ARV) drugs, antiretroviral treatment (ART) and Prophylaxis

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#### **KEY MESSAGES**

- The crucial importance of sufficient duration of prenatal ART and maternal adherence in reducing the risk of vertical transmission cannot be over-emphasised.
- The very low risk of HIV transmission through breastfeeding with appropriate interventions needs to be weighed against the risk of illness and death due to interventions employed to reduce/eliminate postnatal transmission of HIV e.g. replacement feeding with formula, especially in resource-limited settings.
- In resource-rich settings, the extremely low risk of postpartum transmission with exclusive breastfeeding when mothers living with HIV with an undetectable viral load are adherent to their ARV regimens permits support for exclusive breastfeeding.
- Universal ART is an important element of the prevention of vertical HIV transmission(PMTCT), but in order to achieve elimination of new infection among children, these programmes must incorporate a spectrum of activities, such as (WHO, 2016b):
  - HIV prevention for HIV-negative women.
  - access to family planning to prevent unintended pregnancy.
  - widespread testing of pregnant women early in antenatal care.
  - support to women living with HIV to remain adherent to ART and to be retained in care throughout pregnancy and breastfeeding, for life.

# 2.1 GUIDELINES ON ANTIRETROVIRAL (ARV) DRUGS AND ANTIRETROVIRAL TREATMENT (ART)

The first clinical trial of ARVs to reduce vertical HIV-transmission was conducted in 1994 (CDC, 1994; Connor et al., 1994). Treatment with the drug AZT reduced HIV transmission from mothers living with HIV to their infants during pregnancy and birth by two-thirds. Following this research, between 1994 and 1999 the number of babies born with HIV in developed countries dropped by 78% (Mofenson, 2004). Subsequent protocols using AZT that

could be implemented in breastfeeding populations in resource-limited settings were also found to reduce postnatal transmission by half (Wiktor et al., 1999; Lallemant et al., 2000; Mofenson, 2010a).

A less expensive regimen such as single-dose nevirapine (sdNVP) administered to the mother in labour and to the infant within 72 hours of birth also reduced postnatal transmission by 50%, even when breastfeeding continued (Guay et al., 1999). This regimen has been the mainstay of ARV prophylaxis in most countries. The addition of sdNVP to antenatal short-course AZT resulted in significantly reduced breastmilk viral loads at 2 weeks postpartum suggesting a reduced risk of MTCT during the early postpartum period. However, it seems that the receipt of sdNVP in labour may defer rather than blunt the postpartum viral load rebound seen in breastmilk after the discontinuation of ZDV (Rossenkhan et al., 2009).

The 2009 research had shown that antiretroviral (ARV) drugs given to mother living with HIV and her HIV-exposed baby can substantially reduce HIV transmission through breastfeeding without causing life-threatening adverse effects that replacement feeding by mothers living with HIV resulted in decreased HIV-free survival rates.

These transformational findings resulted in the release of new recommendations over the next few years outlining interventions to improve the health of women living with HIV and give HIV-exposed infants the greatest chance of HIV-free survival:

The following recommendations were made in 2010:

- Various options on the use of antiretroviral drugs (ARVs) for treating pregnant women and/or providing prophylaxis to prevent HIV infection in the infants (WHO, 2010a).
- Revised Guidelines for the prevention of vertical transmission of HIV (PMTCT) recommended two treatment/prevention antiretroviral options (WHO et al., 2010):
  - In Option A, zidovudine (ZDV) is provided to HIVinfected pregnant women during the antepartum period followed by nevirapine (NVP) prophylaxis for their infants during breastfeeding period.
  - In Option B, maternal triple ARV prophylaxis is initiated during pregnancy and continued throughout breastfeeding.
  - The decision about which antiretroviral option is suitable was determined by the mother's CD4 count:

- Prophylaxis (option A) for a CD4 cell count of above 350 cells/ mm³,
   results of maternal mortality according to ART in the DREAM programme in Malawi and
- Therapy (ART, option B) for a CD4 cell count of less than 350 cells/mm<sup>3</sup>.

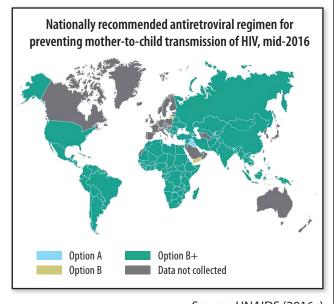
#### In 2012:

- WHO issued a programmatic update (WHO, 2012c) which:
  - further updated and simplified guidance on ARVs to merge treatment and prophylaxis options for mothers living with HIV and their infants.
  - proposed a third option: Option B+ → maternal triple ARV drugs are continued throughout life regardless of CD4 count.

In 2013 the following were recommended:

- consolidated guidelines on the use of ARVs for treating and preventing HIV infection (WHO, 2013a).
  - WHO finalised a comprehensive revision of all ARV guidelines, including guidance on ARVs for pregnant women, anticipated since 2012.
- the guidelines on use of antiretroviral drugs for treating and preventing HIV infection (IATT et al., 2013b) were published, recommending either:
  - ARV drugs for women living with HIV during pregnancy and breastfeeding (2010 guidelines Option B), or
  - Lifelong ART for all pregnant and breastfeeding mothers living with HIV (2010 guidelines Option B+).
- This effectively phased out Option A. See Figure 1 for nationally recommended ARV regimens in 2016.

FIGURE 1: Nationally recommended antiretroviral regimen in 2016



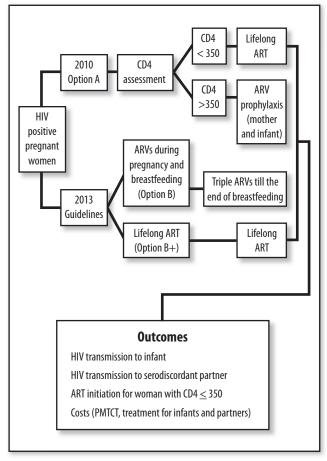
Source: UNAIDS (2016c)

- results of maternal mortality according to ART in the DREAM programme in Malawi and Mozambique were released. ART had been promoted for all 10,150 pregnancies amongst HIV+ mothers in the programme since 2002. Mortality was 8% vs 2% for patients with shorter vs longer antenatal HAART. They therefore recommended that PMTCT programmes should provide universal HAART to all HIV+ pregnant women (Liotta et al., 2013).
- A systematic review was conducted in 2013 to support the recommendation to optimise early initiation, adherence and retention of women on HIV care (WHO, 2016b). Providers showed satisfaction as a result of integrated services e.g. increased efficiency, decreased waiting time, improved relationship among health care providers and women. This resulted in less stigmatisation and higher ART adherence and retention, which can contribute to zero vertical transmission through breastfeeding.

#### In 2014 there was:

• further consolidated guidance with emphasis on a public health approach (WHO, 2014a).

FIGURE 2: The 2014 algorithm, treatment options to prevent HIV vertical transmission



Source: Ishikawa et al. (2014)

In 2016 the following were published:

- Guideline Updates on HIV and Infant Feeding, specifically focussing on duration of breastfeeding and support from health services (WHO & UNICEF, 2016).
- Consolidated Guidelines (second edition) on HIV prevention, diagnosis, treatment and care for key populations (WHO, 2016b).
- Consolidated Guidelines (second edition) on The Use of Antiretroviral Drugs for Treating and Preventing HIV Infection, which includes recommendations for a Public Health Approach 2016 (WHO, 2016c).

### Recommendations for adopting ARV regimen

#### **General recommendations**

Recent developments suggest that substantial clinical and programmatic advantages can be derived from adopting a single, universal ARV regimen both to treat pregnant women living with HIV and to prevent prenatal, intra-partum and postpartum transmission of HIV.

- New evidence has emerged to support ARV treatment as HIV prevention, i.e. provision of ART individuals living with HIV with higher CD4 cell counts, who are not eligible for treatment, significantly reduces sexual transmission to a serodiscordant (uninfected) partner (Cohen et al., 2011; WHO, 2012c). This evidence has led to new WHO recommendations on couples counselling and treatment for serodiscordant couples regardless of CD4 count (WHO, 2012a).
- Earlier provision of ARVs to pregnant women living with HIV can benefit both the health of the mother and reduce HIV transmission to her child during pregnancy.
- ARVs should be provided to the baby for the first 6
  weeks of life to reduce the risk of HIV transmission
  being passed to the baby during labour and birth
  (WHO, 2016c).
- There is enough evidence for WHO to recommend ARVs to either the mother living with HIV or the HIVexposed baby while breastfeeding.
- HIV-free survival is optimised when mothers living with HIV receive lifelong ARV therapy to reduce transmission through breastfeeding.
- ART should be initiated for all pregnant and breastfeeding women living with HIV regardless of WHO clinical stage and at any CD4 cell count and continued lifelong (WHO, 2016c; WHO & UNICEF, 2016).
- Duration of breastfeeding should not be restricted in settings where health services provide and support lifelong ART, including adherence counselling and

promotion and support of breastfeeding among women living with HIV (WHO, 2016c).

#### **Recommendation where ARVs are available**

In low-income settings where ARVs are available, mothers living with HIV are recommended to breastfeed exclusively for the first 6 months of life should continue for up to 24 months or more with appropriate complementary foods (WHO & UNICEF, 2016).

#### Recommendation where ARVs are not available

When ARVs are not (immediately) available, breastfeeding still provides a greater chance of survival for HIV-exposed infants. Pending universal access to ARV interventions, national authorities should not be deterred from recommending that mothers living with HIV should breastfeed, when this is the most appropriate infant feeding practice in their setting. All efforts should be made for access to lifelong ART (Kuhn & Aldrovandi, 2012; Chikhungu et al., 2016).

# Recommendation to optimise early initiation, adherence and retention of pregnant and breastfeeding women to ART

Differential care model on ART regimen should be used for pregnant women, breastfeeding women, infants and children (WHO, 2016b). Pregnant and breastfeeding women on ART, infants and children require close, near and continued follow up with psychological support, counselling with assistance by a multidisciplinary skilled and trained team, considering the integration and linking to other key health programmes and services relevant to women, maternal and child health.

Integrating and linking services increases efficiency which is likely to reduce missed opportunities for initiating ART, enhance adherence support and optimise retention in care (WHO, 2016b).

### **Immediate ART on diagnosis of HIV**

There is recent recognition that universal treatment for all HIV-infected individuals, regardless of CD4 count, achieves better health outcomes than delaying treatment until an individual's immune system has become depleted by the virus. Effective ART started earlier not only treats HIV to allow a normal lifespan, but also reduces the likelihood that the virus will be passed on to an uninfected sexual partner. WHO currently recommends early initiation of ART at any CD4 cell count and continuing on lifelong ART treatment (WHO, 2016c).

#### **Recommendations on ART**

### Recommendations on testing and ART initiation for HIV-exposed infants and women living with HIV

- Nucleic Acid Testing (NAT) is recommended at infants' birth.
- The Rapid Diagnostic Test (RDT) can be used only in infants less than 4 months of age, at 9 months in asymptomatic HIV-exposed infants and older than 18 months following the national testing strategy.
- In the HIV context, children with unknown status for HIV, when admitted at health service, attending malnutrition clinic or immunisation clinic must be tested for HIV.
- Pregnant and breastfeeding women living with HIV must initiate ART regardless of WHO clinical stage and any CD4 cell count. The ART should continue lifelong.
- ART should be initiated in all children living with HIV regardless of WHO clinical stage (WHO, 2016c).

### WHO 2016 recommendations related to laboratory monitoring before and after initiating ART

- For all adults living with HIV, routine viral load monitoring should be carried out at 6 months, 12 months and then every 12 months (WHO, 2016c).
- In settings where routine viral load monitoring is available, CD4 count monitoring should also be carried out in case of pregnancy.
- For mothers living with HIV, the time of viral load monitoring at health clinics should be linked to support optimal breastfeeding practice as part of package on infant feeding community-based intervention.

### **ART updated guidance**

The 2016 consolidated guidelines recommendation (WHO, 2016c):

### In high HIV prevalence settings (settings with greater than 5% HIV prevalence in population tested)

- Provider-initiated testing and counselling (PITC) for women should be considered a routine component of the package of care in all antenatal, childbirth, postpartum and paediatric care settings. In highprevalence settings where breastfeeding is the norm, lactating women should be periodically retested for HIV.
- ALL HIV-negative pregnant women should be retested in the third trimester, postpartum and/or during labour, because of the high risk of acquiring HIV during pregnancy.

# In low HIV prevalence settings (settings with less than 5% HIV prevalence in the population tested)

PITC can be considered for pregnant women in antenatal care as a key component of the effort:

- To eliminate vertical HIV transmission.
- To integrate HIV testing with other key testing for diseases relevant to the setting, such as viral hepatitis and syphilis.
- To retest HIV-negative pregnant women who are in serodiscordant couple relationships, from a key population group or have known ongoing HIV risk.
- Efforts should be made to reduce the time between HIV diagnosis and ART initiation.

ART should be initiated in ALL pregnant and breastfeeding women living with HIV regardless of WHO clinical stage and at any CD4 cell count and continued lifelong. Monitoring using viral load would be especially valuable for pregnant and breastfeeding women who may have tested late in pregnancy – for instance, a maternal viral load above 1000 copies/mL during the last few weeks before delivery is a reliable determinant for increased risk of HIV transmission in utero. Viral load testing during pregnancy would be a useful tool for clinical decision-making. As viral load testing is introduced on a national-scale, pregnant and breastfeeding women should be prioritised for access. Fixed-dose combinations and once-daily regimens are preferred for ART for ALL adults, including pregnant and breastfeeding women.

Key information on the provision of ART, irrespective of CD4 count, includes (WHO, 2016c):

- ALL children with HIV under 5 years of age;
- ALL pregnant and breastfeeding mothers with HIV;
- ALL HIV-positive partners where one partner in the relationship is uninfected;
- Viral load testing as the preferred approach of monitoring ART success and diagnosing treatment failure rather than the use of CD4 count to complement clinical and immunological monitoring of people receiving ART;
- Offering all adults and older children at initiation of ART the same daily single fixed-dose combination pill as a single pill, given once daily, which is easier to take and safer than alternative combinations previously recommended; and
- It appears that the regime above offers significant benefits for both maternal health and transmission prevention to uninfected partners and to babies. Despite being more costly in the short-term, over time it is likely to be cost effective (Ahmed et al., 2013).

### HIV treatment cascade according to WHO guidance 2016

These revisions streamline (WHO & UNICEF, 2016) strategies that can be employed along the cascade of HIV-care related services, including:

- Testing.
- Antiretroviral (ARV) drugs for HIV prevention.
- Linkage and enrolment into care.
- Retention and adherence in care and treatment.
- Management of HIV or AIDS-related infections.
- When to start ART and preferred ART regimens. See Table 1 for more details.

The 2016 second edition Update on ART (WHO, 2016c) includes guidance on universal lifelong ART and the

recommendation of the Nucleic Acid Testing (NAT) at birth. Infants at high risk to acquiring HIV should receive dual prophylaxis with twice daily AZT and once daily NVP or NVP alone for the first 6 weeks of life with additional 6 weeks (total of 12 weeks of infant prophylaxis).

The above developments provide the rationale for promotion of sequential steps to treat and reduce the spread of HIV, as follows:

- HIV testing and Counselling.
- Diagnosis.
- Enrolment into care.
- Timely initiation of ART.
- Viral suppression.
- Adherence to treatment.
- Lifelong ART treatment.

TABLE 1: Summary of HIV Treatment Cascade for Women Before, During and After Pregnancy (WHO, 2016b; WHO, 2016a)

HIV treatment cascade	Before pregnancy	During pregnancy	After pregnancy	Important notes (WHO, 2016c)
1. HIV Testing and Counselling (HTC)				<ul> <li>HTC is the essential first step for a woman to know her HIV status before pregnancy, integrating access to family planning to prevent unintended pregnancy, STDs screening and mental health programmes.</li> <li>HTC is an opportunity to put women from key populations at risk for HIV infection into prevention programmes and encourage later HIV retesting when a test result is HIV negative.</li> <li>Retesting women already on ART is not recommended, as there is potential risk of incorrect diagnosis.</li> <li>In case of inconclusive HIV status, with HIV testing not confirmed, women should be encouraged to return in 14 days for additional testing.</li> <li>HTC must promote women's confidentiality, avoiding practices that can reveal their HIV status in the community, e.g. conversations at waiting rooms, family planning groups, antenatal care groups or mother's support groups.</li> <li>As part of HTC when the test result is HIV positive during pregnancy, to encourage women to deliver at a health facility, discuss the importance of partner testing, access of sexual partner to point-of-care HIV counseling and testing, clarify the importance of lifelong ART, screening for TB and testing for other infections such as syphilis and hepatitis B counseling on women's nutrition, including iron and folic acid supplementation during pregnancy.</li> <li>As a means of being more convenient to people coming to health facilities and at the same time including women in other programmes relevant to women, e.g. maternal and child health, WHO recommends the integration of HTC with several other clinical services programmes.</li> <li>Women who are HIV negative before and during pregnancy, during the period of breastfeeding.</li> </ul>

2. HIV Diagnostics  3. Initiation		<ul> <li>Identifying HIV before pregnancy brings enormous benefits for women to understand their HIV status and enroll in HIV treatment earlier.</li> <li>Prompt and accurate diagnostics before pregnancy or earlier during pregnancy and enrolling in HIV treatment has benefits for the woman, the infant and the woman's sexual partner.</li> <li>In high HIV prevalence settings, a diagnosis of infection with HIV should be provided with two sequential reactive tests. For instance, when assay result 1 is reactive but assay 2 is non-reactive and assay 3 is reactive, such results should be considered inconclusive and the woman should be asked to return for retesting in 14 days.</li> <li>In low prevalence settings, a diagnosis of HIV-positive should be provided with three sequential reactive tests. For instance, inconclusive results are considered when assay 1 result is reactive assay 2 result is non-reactive, or assay result 1 and 2 results are reactive but assay result 3 is non-reactive. In both cases the woman should be retested in 14 days.</li> <li>All efforts should be made to reduce the time between HIV diagnosis and ART initiation.</li> <li>ART should be initiated in all pregnant and breastfeeding women</li> </ul>
of ART		ART should be initiated in all pregnant and breastfeeding women living with HIV, regardless of WHO clinical stage and at any CD4 cell count and continued lifelong.
4. Viral Suppression		<ul> <li>Viral suppression is an indicator of treatment success and reduced potential transmission, including HIV vertical transmission.</li> <li>Adherence to ARV can reduce the amount of HIV in the blood to levels that are undetectable by standard laboratory tests (Forum for Collaborative HIV Research, 2011).</li> </ul>
5. Adherence to Lifelong ART		<ul> <li>Lifelong ART has individual health benefits for all living with HIV the recommendation applies to both breastfeeding and non-breastfeeding women.</li> <li>The transition from antenatal care and maternal, newborn and child health services to ART is critical to avoiding loss follow up of women and infants. Programmes should provide close community support with follow up to maintain drug adherence for women living with HIV.</li> <li>Adherence can improve with peer counselors, mobile text messages, reminder devices, cognitive-behavioral therapy, behavioral skills training, medication adherence training, fixed-dosed combination and once-daily regimens.</li> </ul>
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### 2.2 RECOMMENDATIONS ON PROPHYLAXIS

### WHO 2016 recommendations on HIVexposed infants' prophylaxis

Breastfed or infants receiving infant formula who are at high-risk of acquiring HIV should receive dual

- prophylaxis with twice daily doses of AZT and once daily dose of NVP for the first 6 weeks of life (WHO, 2016c).
- Breastfed infants who are at high-risk of acquiring HIV, as well the ones exposed to HIV during the postpartum period should extend the period of prophylaxis with additional 6 weeks (total of 12 weeks of infant prophylaxis) with AZT twice daily and NVP once daily or NVP alone.

Prompt and effective HIV therapy has public health benefits. Evidence in support of a population-based impact of treatment on the prevention of HIV transmission continues to emerge in diverse global settings. Such effects have been described in Taiwan more recently in Vancouver, Baltimore, San Francisco, China and KwaZulu-Natal (Montaner et al., 2014; WHO, 2014a).

### **HIV Pre-Exposure Prophylaxis (PrEP)**

Oral PrEP is the use of ARV drugs before HIV exposure by people who are not infected with HIV in order to block the acquisition of HIV (WHO, 2016c).

The following are recommendations on oral PrEP, 2016:

- Oral pre-exposure prophylaxis (PrEP) containing TDF should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches (WHO, 2016c).
- Promising results in providing ART to HIV-exposed but uninfected individuals in sero-discordant relationships (known as Pre-Exposure Prophylaxis) have been achieved in several preliminary studies. With an estimated 39.5 million people living with HIV worldwide and 4.3 million new infections per year, there is hope for pre-emptive measures to prevent further dissemination amongst vulnerable groups of HIV-exposed people. Of interest, it has actually been the success of PMTCT initiatives, using ARV prophylaxis to prevent transmission from mother to infant which has spurred research in this area (Mofenson, 2010b).
- Initial results of a large-scale trial reported at the Forum for Collaborative HIV Research (2011) in Washington found that PrEP provided at least 44% protection to men and transgender women who have sex with men and that greater adherence showed greater efficacy, e.g. 90% adherence resulted in a 73% reduced risk.
- Pending further research, the US CDC made several recommendations regarding the use of PrEP (CDC, 2011a; Marinda et al., 2017) including:
  - it should be used only for HIV-negative individuals.
  - regular testing should be employed.
  - daily dosing is critical.

### **HIV Post-exposure Prophylaxis (PEP)**

- Exposures that may warrant HIV PEP includes exposure to body fluids such as, blood, blood-stained saliva, breastmilk, genital secretions, cerebrospinal, amniotic, peritoneal, synovial, pericardial or pleural fluid (WHO, 2016c);
- HIV PEP should be offered and initiated as early as possible in all individuals with an exposure that has the potential for HIV transmission, preferably within 72 hours;
- Eligibility assessment should be based on the HIV status of the source whenever possible may include consideration of background prevalence and local epidemiological patterns;
- A 28-days prescription of antiretroviral drugs should be provided for HIV PEP following initial risk assessment; and
- A regimen for HIV PEP with two ARV drugs is effective, but three drugs are preferred.

### 2.3 RECOMMENDATIONS FOR POLICY AND PROGRAMMES

### Leadership and investment for best practices

WHO confirms that the consolidated guidelines on antiretroviral therapy will be reviewed comprehensively every two years to incorporate the key clinical, operational and programmatic implications of new science and emerging best practices across populations, age groups and settings. To ensure a timely dissemination of technical, policy and programmatic information, WHO will issue supplements to the consolidated guidelines. The supplements, intended for clinical and technical leaders as well as for programme managers, will provide new recommendations, describe best practices and provide important updates to the most recent consolidated guidelines.

Effecting the changes set out in current WHO guidelines will require acknowledgement that good healthcare requires investment that resources need to be committed by governments and other relevant agencies to protect, promote and support breastfeeding (Vitiello & Willard, 2010; National Breastfeeding Consultative Meeting, 2011; WHO et al., 2012).

# Good practice recommendations for national and sub-national public health policy on HIV and infant feeding

National policy should be based on international recommendations and consideration of the socio-economic and cultural contexts of the populations served by maternal, newborn and child health services. Policy should:

- consider the availability and quality of health services.
- local epidemiology including HIV prevalence among pregnant women.
- address the main causes of maternal and infant and child under nutrition and mortality.
- clearly address which infant feeding alternative will be recommended and supported as a national recommendation disseminate the policy that both government-employed and NGO counsellors will follow in a coordinated manner.
- create and define revised counselling algorithms to eliminate counselling on individual choice.
- provide concrete planning steps for introduction and implementation of these policies and guidelines, e.g.
   The roll-out of ARVs.
- be well-coordinated to avoid confusion, mixed messaging and ensure coverage at scale.
- inform the population at large and pregnant women, health workers and HIV and nutrition counsellors about the content of the policy.
- adequately and harmoniously address issues of infant feeding in the context of HIV in both PMTCT programmes and general IYCF programmes.
- train and re-train health workers and counsellors according to updated evidence presented in the WHO HIV and infant feeding guidelines, 2010 (WHO et al., 2010) the WHO consolidated guidance on the use of antiretroviral drugs for treating and preventing infection, 2013 (WHO, 2013a) and the WHO-UNICEF Guideline: Updates on HIV and Infant Feeding, 2016 (WHO & UNICEF, 2016).
- Support supervision of health workers throughout the processes of change.

### Current ART regimen and interlinked programmes 2017

#### **Universal ART**

The majority of countries are moving to adopt universal ART for all pregnant women and breastfeeding women living with HIV. The benefits of lifelong ART, Option B+,

for pregnant and breastfeeding women include (WHO, 2016c):

- improved maternal and infant health outcomes.
- lower rates of vertical HIV transmission.
- the potential for reduction of horizontal transmission.

#### **Recommendations for caesarean section**

Although elective caesarean section has been shown to protect against HIV acquisition, especially in the absence of ARV drugs or in the case of high viral load, WHO does not recommend caesarean section in resource limiting settings specifically for HIV infection, rather it is recommended for obstetric and other medical indications (WHO, 2016c).

HIV-infected women living in industrialised countries, where caesarean section was routinely recommended to prevent vertical transmission are now able to choose vaginal delivery if they have a viral load of <50 copies/mm³ (Wax, 2006; De Ruiter et al., 2008; Havens et al., 2009). This has come about due to the lack of clear evidence of benefit of caesarean section in industrialised countries and observations of transmission rates in developing countries where caesarean delivery was often not available and yet the risk of HIV transmission has steadily declined with more efficient antiretroviral therapy.

### **Recommendations for vaginal delivery**

Vaginal delivery is recommended if an HIV-infected woman has viral load of < 50 copies / mm³ (Wax, 2006; De Ruiter et al., 2008; Havens et al., 2009).

Continuous therapy (e.g. meticulous adherence) to ART is necessary to maintain low or undetectable viral levels.

Concerns have been expressed that postnatal transmission can take place in spite of maternal treatment with HAART (American Academy of Pediatrics, 2012) citing 0.2% treatment failure in the landmark Botswana study conducted by Shapiro et al. (2010). However, closer examination of the history of transmitting mothers shows that either there were adherence issues, or the mother had not received her medication for long enough before delivery of the baby to achieve an undetectable viral load (Greiner & Morrison, 2013).

### Importance of adherence to ART

Confirmatory results from a more recent pilot programme involving 194 Zambian HIV-positive mothers and their infants reported in 2011 ((Ngoma et al., 2011)) showed that the only postnatal transmissions during not only 6 months exclusive breastfeeding but also 6 months of continued breastfeeding occurred in women who

were non-adherent to their medications. Publication of these results now show that there is a low risk of HIV-transmission during 24 months of breastfeeding so long as HIV-positive women are adherent to their medication (Liotta et al., 2013; Ngoma et al., 2015).

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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).