

**GUIDELINES FOR
PREVENTION OF MOTHER TO CHILD
TRANSMISSION (PMTCT) OF HIV/AIDS IN KENYA
4TH EDITION, 2012**



Republic of Kenya



Ministry of Health

GUIDELINES FOR PREVENTION OF MOTHER TO CHILD TRANSMISSION (PMTCT) OF HIV/AIDS IN KENYA

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Fourth Edition, 2012

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Fourth Edition

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Ministry of Health

Foreword

The Ministries of Health (MoH) are committed to development of effective PMTCT programmes. Guidelines are an important part of the Government strategy to reduce MTCT and is in line with the National Health Sector Strategic Plan II (NHSSPII) and Kenya National AIDS Strategic Plan (KNASP III) 2009-2013 which focuses on priority areas of prevention of new infections, improving quality of life of those infected and affected, and mitigation of social and economic impact of the infection. MTCT is the predominant mode of transmission of HIV in infants and young children. This transmission occurs during pregnancy, labour and delivery and, among breastfed babies, in the post-partum period. Members of the Technical Working Group (TWG) on PMTCT reviewed the modules of the third edition, revised and in some cases re-wrote the modules based on up to date knowledge and in line with current scientific evidence and experience. The TWG consists of a group of professionals drawn from various disciplines that are implementing and/or managing PMTCT. The group adopted and adapted the latest recommendations of the WHO on PMTCT as well as various national guidelines on HIV prevention, treatment and care. A four-pronged approach through the various reproductive life cycles as proposed by the Inter-Agency Task Team (IATT) on children and HIV and AIDS was adopted in these guidelines with emphasis being place on all the four prongs. For any of the PMTCT interventions to be successfully implemented counseling and testing (CT) must first be done. Routine HIV testing with opt-out option is recommended. This is followed by appropriate medical, surgical interventions including antiretroviral prophylaxis, safer obstetric practices as well as infant feeding counseling and provision of appropriate infant feeding. HIV-positive women are assessed clinically using WHO staging and where feasible immunological assessment using CD4 cell count. HIV exposed infants are tested through early infant diagnosis (EID).

In these guidelines more efficacious regimens including the use of option B plus, are introduced for the first time while information and counseling on infant feeding follows the AFASS (Available, feasible, acceptable, safe and sustainable) criteria. The module on monitoring and evaluation addresses issues of data collection, collation and reporting as well as use of data for decision-making at the facility-level.

We hope that appropriate implementation instruments will be used to operationalize these guidelines.



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Abbreviations and Acronyms

3TC	Lamivudine
Ab	Anti-body
AFASS	Acceptable, Feasible, Affordable, Sustainable and Safe
AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Transferase
ANC	Antenatal Care
AOP	Annual Operations Plan
ARM	Artificial Rupture of Membranes
ART	Antiretroviral Therapy
ARV	Antiretroviral
AZT	Azidothymidine (Zidovudine or ZDV)
AZT/3TC	Combivir
BCC	Behaviour Change Communication
BCG	Bacille Calmette Guérin vaccine
BFHI	Baby Friendly Hospital Initiative
BID/BD	"Twice a day"
CDC (K)	Centres for Disease Control and Prevention, Kenya
CNS	Central Nervous System
CS	Caesarean Section
CT	Counselling and Testing
CTX/CTZ	Cotrimoxazole
d4T	Stavudine
DASCO	District AIDS/STI Coordinator
DBS	Dried Blood Spot specimen
DHIS	District Health Information System
DHRIO	District Health Records Officer
DNA	Deoxyribonucleic Acid
DRH	Division of Reproductive Health
ECV	External Cephalic Version
EFV	Efavirenz
EID	Early Infant Diagnosis
ELISA	Enzyme Linked Immunosorbent Assay
EMTCT	Elimination of Mother to Child Transmission of HIV/AIDS
FBC	Full Blood Count
HAART	Highly Active Antiretroviral Therapy
Hb	Haemoglobin
HEI	HIV Exposed Infant
HIV	Human Immunodeficiency Virus
IATT	Inter-Agency Task Team
IMCI	Integrated Management of Childhood Illness
IPPT	Intermittent Presumptive Treatment for Malaria
ITNs	Insecticides Treated Nets
IUCD	Intra Uterine Contraceptive Device
KAIS	Kenya AIDS Indicator Survey

KDHS	Kenya Demographic and Health Survey
KEPI	Kenya Expanded Programme on Immunization
KNASCP	Kenya National Aids Strategic Plan
KNH	Kenyatta National Hospital
KOGS	Kenya Obstetrical and Gynaecological Society
LAM	Lactational Amenorrhoea Method
M&E	Monitoring and Evaluation
MCH	Maternal and Child Health
MoH	Ministry of Health
MTCT	Mother-To-Child Transmission
NASCP	National AIDS and STD Control Programme
NHSSP	National Health Sector Strategic Plan
NVP	Nevirapine
OD	"Once a Day"
OI	Opportunistic Infection
OPV	Oral Polio Vaccine
PASCO	District AIDS/STI Coordinator
PASCO	Provincial AIDS/STI Coordinator
PCP (PJP)	Pneumocystis Carinii (Jerovecii) Pneumonia
PCR	Polymerase Chain Reaction
PI	Protease Inhibitor
PLWHIV	Persons/People Living With HIV/AIDS
PMTCT	Prevention of Mother To Child Transmission
PWP	Prevention with Positives
RDA	Recommended Daily Allowance
RH	Reproductive Health
RNA	Ribonucleic Acid
RTI	Reproductive Tract Infection
SdNVP	Single dose Nevirapine
SRH	Sexual and Reproductive Health
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
TB	Tuberculosis
TBAs	Traditional Birth Attendants
TLC	Total Lymphocyte Count
TT	Tetanus Toxoid vaccine
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
UNICEF	United Nations Children's Fund
UoN	University of Nairobi
VCT	Voluntary Counselling and Testing
VDRL	Venereal Disease Research Laboratory (test for syphilis)
VIA	Visual Inspection using Acetic acid
WHO	World Health Organisation

Executive Summary

The Revised Guidelines (4th edition) for Prevention of Mother to Child Transmission (PMTCT) of HIV and AIDS addresses the risks of mother-to-child transmission (MTCT) of HIV and AIDS using more efficacious interventions in more detail than in the previous editions. In these revised guidelines, there is more emphasis on early initiation of ARV prophylaxis starting at 14 weeks hence the importance of early ANC attendance for all women. The Guidelines are in line with Kenya's National Health Sector Strategic Plan II (NHSSP II) and are anchored on the Kenya National AIDS Strategic Plan (KNASP III) 2009-2013 which focuses on the priority areas of prevention of new infections, improving the quality of life of people infected and affected by HIV and AIDS, and mitigation of the social and economic impact of the infection. One of the priority areas of NHSSP II is adherence to set clinical and public health standards. The Guidelines were developed through a participatory and consultative process that drew participants from public health institutions, NGOs, FBOs, academic and research institutions and development partners. The process was co-ordinated by NASCOP with technical and financial support from CDC (K).

HIV infection has reversed gains realised in child health and survival in the last decade in Kenya. The infection has also contributed significantly to the common complications of pregnancy in many countries. Globally, more than 370,000 children were newly infected with HIV, mostly through MTCT in 2009 with 260,000 deaths among children in the same year. In 2009, Kenya had a population estimated at 38.6 million, the number of births per annum was 1.55 million, the HIV prevalence among pregnant mothers was 6.3 per cent and the total number of births to HIV-infected mothers exposed to MTCT was 97,272. Assuming a transmission rate of 40 per cent, and in the absence of any intervention, the number of HIV positive infants per annum would be 38,900. Kenya AIDS Indicator survey (KAIS) 2007 HIV seroprevalence among adults aged 15-49 years is 7.8% and dropping to 6.3% in 2009 (KDHS 2008/9).

Various interventions have been put in place to respond to the emerging challenges and constraints to MTCT across the country. Analysis of effectiveness of the various approaches needed to manage risks of MTCT provides valuable insights that necessitate the adoption of more efficacious care and treatment regimens. In addition, in 2009 WHO provided updated guidance on PMTCT based on global evidence on the benefits of starting ARVs earlier in pregnancy as well as on the effectiveness of postnatal ARVs to mother or baby on reducing MTCT.

These insights have informed the development of new Guidelines. The Guidelines incorporate these changes and are recommended for use by health professionals and health institutions at all levels of care. The Guidelines will enhance the capacity of health care providers to give more efficient and effective services to HIV positive expectant mothers and newborns.

The Guidelines have ten chapters and cover the following: justifying the need for specific management of HIV positive women; care before, during and after pregnancy; use of antiretroviral therapy in pregnancy; postnatal care; family planning; early infant diagnosis; feeding, care and follow-up of HIV-infected infants; and monitoring and evaluation. Additional information on WHO staging, contraceptive options for PLHIVs and a summary of ARV use in PMTCT is given in the appendices.

The Guidelines have also incorporated basic information that program managers need in order to make their institutions PMTCT-friendly. This information is found in the boxes and appendices. Summaries of the information contained in the text are found in the tables.


The Guidelines provide a background to the PMTCT problem in the world, in Africa and in Kenya. They also give details on HIV in pregnancy, the transmission patterns of MTCT and describe the benefits of preventing mother-to-child transmission (PMTCT). They also provide information on interventions necessary to reduce MTCT that include counselling and testing, WHO staging, laboratory investigations, obstetric interventions, early infant diagnosis (EID) and ARV prophylaxis or treatment (ART) for the HIV infected woman and her family.

The antenatal management for HIV positive women, including policy guide, job aids with summarised essential package of integrated antenatal care services are detailed in Chapter 2.

Chapter 3 provides information on intrapartum care. This is the management of women from the onset of labour to delivery. At this stage, it is important to establish the HIV status of women prior to delivery or during labour. Guidelines should be followed for all women admitted to labour and delivery. To conduct vaginal deliveries for HIV positive women, modified routine care is given. The guidelines provide a reminder on the activities essential to carry out for safe vaginal delivery for all women, not just for those infected with HIV. It is recommended that there should be no discrimination or isolation of HIV positive women during labour and delivery. Delivery through elective caesarean section where appropriate and feasible reduces the risk of HIV MTCT as compared to vaginal delivery among HIV positive women with high viral load. Where C/S is performed as an emergency or electively, antibiotics should be given.

Antiretroviral therapy (ART) is discussed in detail in Chapter 4. This includes ARV therapy for the eligible mother before labour, during labour and after delivery, and for the infant after delivery. Short course efficacious ARV drug regimens are recommended for those not eligible for ART. Where feasible and monitoring is assured, HAART can be used for PMTCT among HIV positive women who are not eligible for ART.

Guidelines for the postpartum care of the mother and care for HIV exposed infants are detailed in Chapter 5. In Chapter 6, the Guide provides detailed information on late postnatal care and family planning. HIV positive women can use all types of family planning based on standard eligibility criteria as explicitly outlined in the text.



Guidelines for infant diagnosis, care and treatment are discussed in Chapter 7. Currently there is no test to differentiate between antibodies from the mother and those produced by the baby. To identify HIV infected infants less than 18 months, DNA or RNA – PCR test is currently recommended at 6 weeks or first contact thereafter. All sick infants should have access to DBS for DNA PCR as well. HIV exposed infants should be started on cotrimoxazole as from 6 weeks. All HIV exposed infants (irrespective of breast feeding) should have an Ab screening test at 9 months followed by confirmatory DNA PCR if Ab test is positive.

Guidelines for feeding infants and young children born to HIV infected mothers are discussed in Chapter 8. The Ministry of Health recommends exclusive breast feeding with ARVs for the first 6 months of life and followed by introduction of complementary feeding thereafter. Complete cessation of breastfeeding is recommended at 12 months a time at which Infant ARV prophylaxis should be stopped (Stop ARVs for infant at one week after complete cessation of breastfeeding). Where replacement feeding is acceptable, feasible, affordable, sustainable and safe (AFASS), avoidance of breastfeeding by HIV-infected women is recommended (WHO 2006/9). Discussion on different types of feeding alternatives to breastfeeding is captured in the text. These options exist for the mother to choose with the aid of counselling. Ideally, couple decision-making is encouraged for the HIV positive mother. For the HIV negative mother, exclusive breastfeeding is recommended for 6 months or less followed by introduction of complementary feeding thereafter.

Care and follow-up of children of HIV-infected mothers is discussed in detail in Chapter 9. All children born to HIV infected mothers should be followed up closely from birth through 18 months-2 years then linked to chronic care. Table 9.3 provides the WHO recommended follow up details. Similarly, the mothers should be supported to provide optimal infant feeding and to avoid mixed feeding within the first 6 months.

In Chapter 10, the Guidelines explain the benefits of monitoring and evaluation of PMTCT programs. M&E provides an opportunity to measure and appraise performance within defined time frame to ensure accomplishment of set goals and objectives. PMTCT services must be guided by timely and accurate data reported from the health facilities, through the district and provincial levels, to the national level at NASCOP.

CHAPTER 1

Background

1.1 The Global Pandemic

Over 33 million people are living with HIV/AIDS worldwide, and about two-thirds or 22.5 million of PLHIV live in sub-Saharan Africa. HIV/AIDS mainly affects people of reproductive age and increasingly affects women, who now account for 69% of new infections in sub-Saharan Africa, where women are 30% more likely to be living with HIV/AIDS than men, and young women aged 15-24 are nearly four times more likely to be infected than their male counterparts. Young, married women, who are often monogamous, have become one of the groups most vulnerable to HIV in the region. This requires new and rapid responses that broaden the focus beyond traditional “high risk” groups like commercial sex workers, truck drivers, and drug users.

To reach young married women, who may not be aware of their vulnerability, HIV/AIDS prevention, care and support activities must be integrated into already established health services that are used by the general population. An estimated 370 000 world-wide became infected with HIV in 2009, down from a high of 630,000 children in 2003 — most through MTCT. The risk of an HIV-infected mother passing the virus to her infant during pregnancy, labour and delivery or in the postnatal period is 1 in 3 if nothing is done to reduce this risk. In other words, out of 100 infants born to women with HIV/AIDS and without intervention, 60-75 of them will not be infected. Of the one-third who become infected, about 5-10 babies will be infected during pregnancy, 15 will be infected during labour and delivery while 5-15 will be infected during breastfeeding, largely being dependent on breastfeeding practices and on the duration of breastfeeding. In 2009, nearly 260,000 children died of AIDS-related causes. Most children born with HIV die before they reach their fifth birthday, with 50% not surviving beyond two years¹.

The high rates of MTCT in developing countries, compared to much lower rates in richer countries, illustrate growing inequalities in global health. In the wealthy countries, the rate of MTCT is less than 2% because of widespread access to anti-retroviral therapy (ART), planned caesarean sections (CS) where applicable, the means to safely formula feed, and access to quality medical services. In countries like Kenya, there is a 30-40% chance that an HIV-positive breastfeeding mother will pass HIV to her child in the absence of these services. ARV prophylaxis pregnancy, labour and delivery and during breastfeeding period can substantially reduce MTCT. In resource poor settings, it is critical that prevention procedures be integrated into existing sexual and reproductive health (SRH) and maternal and child health (MCH) services, reaching as many women as possible and lowering transmission rates. Concerted efforts between governments, pharmaceutical companies, donor and implementing partners have helped expand access to HIV testing for pregnant women and use of antiretroviral drugs. For instance, in 2003 only 10% of pregnant women globally had access to ARVs compared to 54% in 2009.

HIV/AIDS transmission from mother to child in Kenya is one of the biggest health and development challenges in Kenya. According to the 2008/9 Demographic and Health Survey, 6.3% or over 1.4 million Kenyan adults were living with HIV/AIDS in 2010. There has been stabilization of HIV seroprevalence in Kenya. In 2005, the prevalence rate was estimated at 5.9% and as per the 2006 statistics the prevalence rate among adults had dropped to 5.1%. According to 2007 Kenya AIDS Indicator Survey (KAIS) the HIV seroprevalence in Kenya is 7.8% among adults aged 15-49 years, being higher in women (8.7%) than in men (5.6%). Young women are more vulnerable in Kenya than men, as evidenced by a nearly 9% prevalence rate among women and under 5% among men.

There are wide variations between urban and rural areas, between regions, between adults and young people and between men and women. There has been a notable variation in the number of new infections, with an estimated 60,000 new infections in 2005, dropping to 55,000 in 2006 and rising to an estimated 105,000 in 2010. Infants and young children under 15 years account for 16% of all new HIV infections mainly as a result of MTCT. Most of the new infections occur among young people, in whom the main mode of transmission is through sexual intercourse.

Table 1.1: Adult HIV-Prevalence Estimate by Province in 2009 (KDHS 2008/9)

Province	Number of HIV +	Prevalence (%)	Distribution by sex		
		Total	Male	Female	Male/Female Ratio
Nairobi	219,685	7.0	3.4	10.8	0.3
Central	201,652	4.6	2.6	6.2	0.4
Coast	139,662	4.2	2.3	5.8	0.4
Eastern	198,384	3.5	3.0	3.8	0.8
N. Eastern	20,796	0.9	0.9	0.9	1.0
Nyanza	756,536	13.9	11.4	16.0	0.7
Rift Valley	470,319	4.7	2.8	6.3	0.4
Western	286,062	6.6	3.4	9.2	0.4
Total	-	6.3	4.3	8.8	0.5

1.2 Magnitude of HIV in Pregnancy in Kenya

Kenya National AIDS/STI Control Programme (NASCOP) estimates that there were 1.55 million babies born in 2011 in Kenya and that as many as 6.3% of pregnant women in Kenya were living with HIV/AIDS.

With an estimated population of 38.6 million in the year 2010, the number of HIV - exposed babies is estimated to be 97,272, and at least 38,900 HIV-positive babies are born, assuming a 40 % transmission without any interventions (Table 1.2).

Table 1.2: Estimated magnitude of MTCT in Kenya, 2010

Population	Estimate	Source
Population (Estimates 2010)	38.6 million	KNBS, census 2009
Births per annum	1.54 million	KDHS 2008/9
HIV prevalence in mothers	6.3%	Sentinel surveillance 2010
Total number of births to HIV-infected mothers exposed to MTCT assuming no multiple pregnancy	97,272	Estimate
Number of HIV positive infants per annum in Kenya assuming 40% transmission with no interventions	38,900	Estimate

1.3 Risks of Transmission of MTCT at different time Periods

In Kenya, an estimated 37,000 to 42,000 infants are infected with HIV annually due to mother-to-child transmission. This can occur in utero, during labour and delivery and through breastfeeding. During pregnancy, about 5 to 8 percent of HIV-exposed babies become infected through transmission across the placenta. Labour and delivery poses the greatest risk for transmission with 10 to 20 percent of exposed infants becoming infected at this time.

Breastfeeding also exposes infants to HIV. When mothers breastfeed for 18 to 24 months another 10 to 15 percent of infants become infected. Thus, in non-breastfeeding populations, without antiretroviral treatment, approximately 15 to 30 percent infants will become infected; with prolonged breastfeeding, 25 to 45 percent infants will become infected. Table 1.3: Transmission patterns in breastfeeding and non breastfeeding populations.

Table 1.3 Transmission Patterns in breastfeeding and non breastfeeding populations assuming no PMTCT interventions

Transmission rate in %

Timing	No Breastfeeding	Breastfeeding through 6 months	Breastfeeding through 18 to 24 months
During pregnancy	05 to 10	05 to 10	05 to 10
During labour	10 to 20	10 to 20	10 to 20
Through breastfeeding	0	05 to 10	05 to 10
Early (first 2 months)	0	05 to 10	05 to 10
Late (after 2 months)	0	01 to 05	05 to 10
Overall	15 to 30	25 to 35	30 to 45

Source: De Cock K.M (2002)

1.4 Risk Factors for MTCT of HIV

Many factors are known or suspected to increase the risk of an HIV infected mother transmitting the virus to her infant. These factors include the HIV viral load in the mother, as well as other maternal, obstetrical, viral and infant factors (Table 1.4).

The most significant risk factor appears to be the HIV viral load in the mother, though the other factors may also contribute to increasing an infant's exposure or susceptibility to acquiring HIV. Some factors may cause a breakdown in the protection offered to the foetus by the placenta, which in normal circumstances would not allow HIV to cross the placenta from mother to foetus. Transmission during labour and delivery occurs when the infant sucks, imbibes or aspirates maternal blood or cervical secretions that contain HIV, or when it has other mucous membrane exposure.

Table 1.4: Risk factors for MTCT

	Strong evidence	Limited evidence
VIRAL	High viral load	Viral resistance (theoretical possibility) Viral genotype and phenotype
MATERNAL	Immune deficiency (low CD4 count), HIV infection acquired during pregnancy or breastfeeding period	Vitamin A deficiency, anaemia, sexually transmitted diseases, chorioamnionitis, frequent unprotected sexual intercourse, multiple sexual partners, smoking, injecting drug abuse
OBSTETRICAL	Vaginal delivery (compared to elective caesarean section), rupture of the membranes for more than 4 hours	Invasive or traumatic procedures: instrumental deliveries, amniocentesis, episiotomy, external cephalic version (ECV), etc., intrapartum haemorrhage
FETAL/INFANT	Prematurity	Lesions of skin and/or mucous membranes
BREAST-FEEDING	Duration of breastfeeding, mixed feeding, breast disease (mastitis/cracked nipples)	Oral thrush (baby)

1.5 Benefits of Preventing Mother-to-Child Transmission of HIV

AIDS related deaths are reversing gains made in child health and survival in Kenya. Caring for HIV-infected children has major economic and social impacts on families and health systems. Thus at the national level, preventing MTCT has the potential to increase the understanding and acceptance of the HIV/AIDS epidemic and those living with HIV/AIDS. Counseling, testing and community sensitization can contribute to reducing stigma.

Reduction of MTCT of HIV:

- Decreases numbers of HIV infected children
- Increases child health and survival
- Decreases the load on the health system
- Gives an opportunity to improve and expand health services as well as to strengthen the existing health infrastructure

1.6 Benefits of HIV Counselling and Testing (CT)

- (a) It promotes behaviour change by:
 - Reducing high risk behaviour for HIV
 - Identifying HIV discordant couples
 - Increasing the use of dual methods of family planning and STI prevention
 - Improving antenatal care
 - Guiding infant feeding
- (b) It enables preventive therapy for:
 - Malaria
 - Opportunistic infections (e.g. *Pneumocystis jirovecii* pneumonia and TB)
- (c) It promotes access to early medical care:
 - Obstetrical care
 - TB therapy
 - Malaria treatment
 - STI treatment
 - ARV therapy for mother and family
- (d) It helps to plan for the future
 - Infant feeding support systems
 - Family planning
 - Personal and financial decisions
- (e) It enables preventive therapy of malaria and other opportunistic infections such as PCP
- (f) It gives time to plan for the future e.g. infant feeding support systems

1.7 The Four-Pronged Approach to PMTCT

The Inter Agency Task Team (IATT) on Prevention of HIV Transmission in pregnant women, mothers and their children has proposed a four-pronged comprehensive approach for the prevention of HIV transmission that targets non-pregnant and pregnant women, mothers and their children.

The four prongs are:

1. Primary prevention of HIV infection in women
2. Prevention of unintended pregnancy among HIV-infected women
3. Interventions to reduce transmission from HIV-infected pregnant and lactating women to their children
4. Care and support of women, children and families infected and affected by HIV and AIDS (The PMTCT-plus)

Overall, the coverage of PMTCT programmes and the uptake of services provided through these programmes including HIV testing and counselling and ARV prophylaxis are still very low. In 2009, only 54% of pregnant women worldwide who tested HIV-positive received ARV drugs for PMTCT1. In Kenya, according to the 2007 Kenya AIDS Indicator Survey (KAIS) , there has been a small increase

in HIV testing among women and men compared to the 2003 KDHS KAIS shows that though a vast majority (83%) of HIV-infected women and men in Kenya do not know their HIV status, there has been a clear and dramatic increase in coverage of HIV-testing among ANC clinic attendees. PMTCT services are therefore important entry points for HIV prevention and treatment. Overall ARV coverage for HIV infected people who need treatment in Kenya is only 35%

- 92% of Kenyan women who delivered in the last 4 years attend ANC (KDHS 2008/9)
- 81% of those attending ANC tested for HIV in 2010 and 78% received ARVs for PMTCT

1.8: Towards virtual elimination of MTCT (eMTCT)

For the first time, elimination of MTCT (eMTCT) (MTCT rate of <5% among breast feeding populations or 90% reduction in mother to child HIV transmission rates by 2015) is now considered a realistic public health goal and an important contributor to achieving MDGs by 2015. The eMTCT goal has been achieved in many developed countries and is within reach in some African countries including Kenya. In 2009, UNAIDS called for the virtual elimination of mother-to-child transmission of HIV by 2015. In the 10 most severely affected countries, this is a realistic aim and can be achieved with significantly increased action to implement proven strategies to eliminate HIV transmission to young people. Kenya is one of the 22 high HIV burden countries in the world.

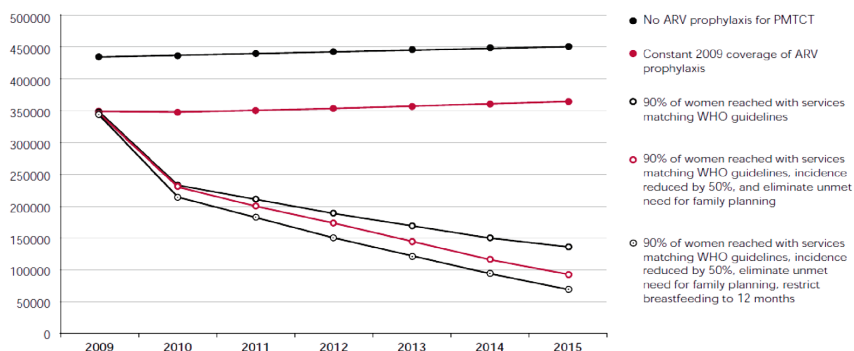
The PMTCT program has embarked on a plan (initiative) to eliminate MTCT. This eMTCT plan is anchored on the Kenya National HIV/AIDS Strategic Plan (KNASP III) which focuses on prevention of new infections and PMTCT is one of the key strategies for achieving this goal. This plan also focuses attention on the reduction of HIV-related illnesses and deaths, and mitigation of the effects of the epidemic on households and communities through key strategic directions namely extraordinary leadership and commitment, Health systems strengthening including capacity building for improved access to PMTCT services and RH/HIV integration. Other components include: community systems strengthening, sustainable financing and regular countdown to track progress.

There are indications that MTCT transmission rates as determined by DNA PCR results of children between 6 weeks and 1 year of age have been declining. From a high of 27% five years ago MTCT rates currently are reported to range from 10-15% as per the EID programme implementation data. Concern still remains about the risk of MTCT during breastfeeding period. Elimination will mean that MTCT transmission at 18-24 month of below 5%.

To achieve this goal, the UN recommends a comprehensive four pronged approach where elimination targets for each prong have been established. These include: Prong 1: A 50% reduction of HIV incidence among women, Prong 2: Reduction of unmet need of family planning to zero among all women, Prong 3: -reaching over 90% of HIV positive women with More efficacious ARVs to reduce vertical transmission rate to <5% and Prong 4: -90% reduction of HIV related maternal deaths up to 12 months post-partum and 90% reduction in HIV attributable deaths among infants and children <5 years.

The virtual elimination of mother-to-child transmission of HIV is indeed possible if comprehensive interventions are made available to eligible women. Below is a model of scenarios if countries were to do business as usual or moved to meet the targets set above for eMTCT.

Figure 1.1: Estimated New HIV infections among children 0-14: Different scenarios for 25 countries



Source: Mahy M, Stover J, Kiragu K, et al. What will it take to achieve virtual elimination of mother-to-child transmission of HIV? An assessment of current progress and future needs. Sex Trans Infect (Suppl) 2010.

1.9 Overview of the New PMTCT Guidelines

Kenya's Ministry of Health (MOH), through NASCOP, has taken several actions to expand and strengthen PMTCT interventions in the country. In 2000, a National Technical Working Group (TWG) on PMTCT was formed. The TWG, co-chaired by NASCOP and the Division of Reproductive Health, coordinates implementation and provides technical support to the National PMTCT Program. The national PMTCT program was officially launched in 2002. The TWG serves as a forum to update stakeholders and discuss challenges and upcoming activities and is also responsible for updating national guidelines for PMTCT.

Currently more than 80% of all pregnant women in Kenya receive PMTCT services in over 5000 PMCT sites. These guidelines are based on a public health approach to care, taking into consideration issues of feasibility and acceptability, in addition to efficacy and cost-benefit in different settings. The guidelines are expected to improve the uptake, quality and effectiveness of PMTCT services in the country.

1.10 Objectives and Organisation of the Guidelines

The specific objectives of the new PMTCT guidelines are to:

- Outline the policy issues in providing PMTCT services
- Recommend operational guidelines to be followed by health care providers of PMTCT services
- Enable providers of PMTCT to select and prescribe ARVs for prophylaxis against MTCT and for treatment (ART) of pregnant women, infants and young children
- Standardise the care and counselling given by PMTCT service providers regarding risk of MTCT and on PMTCT
- Improve PMTCT services using easy-to-use job aids and a standardised M&E system.

The PMTCT guidelines are part of the implementation instruments towards universal access to PMTCT services, and a response to the call to action towards HIV-free and AIDS-free generation. Together with two other guidelines (ARV Therapy in Adults and Adolescents and ARV Therapy in Infants and Young Children), they form a trilogy aimed at contextualising and mainstreaming the WHO trilogy of guidelines on HIV/AIDS prevention and treatment.

The context, resources and demands of PMTCT programmes differ greatly across countries and even across programmes within the same country. Considering this variability, these guidelines include the current consensus on best practices as well as alternatives which might be more appropriate in particular settings. Experts agree that the “state of the art” in PMTCT is changing rapidly and that recommendations will certainly alter with advances in medical science and as more programme experience is documented and disseminated. The areas of ARV prophylaxis and infant feeding are particularly subject to rapid change.

Over the years, WHO has been issuing proposed revisions to its recommendations on the use of antiretroviral drugs for PMTCT. The recommendations are the product of experts who convene to discuss important new information concerning more efficacious regimens and ARV resistance especially to Nevirapine. Based on the new WHO guidelines, Kenya’s TWG has developed simple, practical and evidence-based recommendations on PMTCT that would work in a variety of resource-limited environments and clinical situations that confront healthcare workers, not only in Kenya but also in other developing countries.

1.11 Using the Guidelines

These guidelines are intended primarily for use by PMTCT providers. These include nurses, midwives, clinical officers, doctors, counsellors, nutritionists, lab technicians and other healthcare professionals. They will also be useful as a reference for programme managers at facility, district, provincial and national levels throughout the health sector. The guidelines are divided into ten chapters as outlined in Table 1.5 below.

For each of these chapters (except chapter one on background), the guidelines give an introduction followed by policy statements, then operational guidelines of what providers should do to reduce mother-to-child transmission of HIV and/or to improve their performance and the effectiveness of their services.

Table 1.5: The Four-Pronged approach applied to the PMTCT guidelines

Chapter	Prong 1 Primary prevention of HIV infection in women	Prong 2 Prevention of unintended pregnancy among HIV infected women	Prong 3 Interventions to reduce transmission from HIV infected pregnant and lactating women to their children	Prong 4 Care and support of women, children and families infected and affected by HIV/AIDS
Chapter 1: Background				
Chapter 2: Antenatal Care and Prevention of MTCT of HIV	√	√	√	
Chapter 3: Intrapartum Care	√		√	√
Chapter 4: Use of Antiretroviral Drugs in Pregnancy for Treatment and Prevention of Mother to Child Transmission of HIV Infection.			√	√
Chapter 5: Immediate Postnatal and Neonatal Care	√	√	√	√
Chapter 6: Late Postnatal care and family planning	√	√	√	√
Chapter 7: HIV diagnosis in Children				√
Chapter 8: Feeding infants and young children born to HIV infected mothers			√	√
Chapter 9: Care and Follow-up of children of HIV infected mothers				√
Chapter 10 Monitoring and Evaluation of PMTCT services	√	√		√

CHAPTER 2

Antenatal Care and Prevention of MTCT of HIV

2.1 Introduction

HIV infection has emerged in Kenya as the most important health risk factor for mothers and their children and has a great impact on the long term outcome of pregnancy and child survival.

All pregnant women should be encouraged to learn their HIV infection status, as well as that of their sexual partners. Only by knowing one's HIV status can the health workers make appropriate health care management recommendations and the couple make appropriate decisions about maintaining their health and that of their unborn baby. Pre-conception care is encouraged where an opportunity arises and a birth plan is discussed with the pregnant woman.

In most cases, the pregnant woman will not have HIV infection. Pregnancy offers an opportune time to discuss prevention of HIV infection as many women come into contact with health services for the first (and in some cases the only) time during pregnancy. In Kenya, 44% of married/cohabiting HIV positive persons have an HIV negative spouse (KAIS 2007). Therefore, knowing the HIV infection status of one's partner is critical. Additionally, this forms an important entry point for establishing prevention with positive (PWP) programs among couples as well as providing access to HIV prevention, care and treatment services for the whole family.

PMTCT provides an opportunity for preventing new paediatric HIV infections as well as identifying HIV-infected family members. New infections and high viral loads during pregnancy pose the greatest risk of MTCT to the unborn baby, thus primary prevention, ARV prophylaxis as well as treatment at this time is critical. Given that 25 percent of women in Kenya have an unwanted pregnancy and 60% unmet need for family planning among HIV positive women; strengthening the link to FP services and condom access for dual protection offers a chance to further prevent MTCT.

2.2 Operational Guidelines

Antenatal care and prevention of MTCT during this period can be summarised using an essential package of integrated antenatal care services as shown in Table 2.1. This outlines the package of care to be provided to every woman attending ANC services. HIV testing and counselling in pregnancy should be guided by the following;

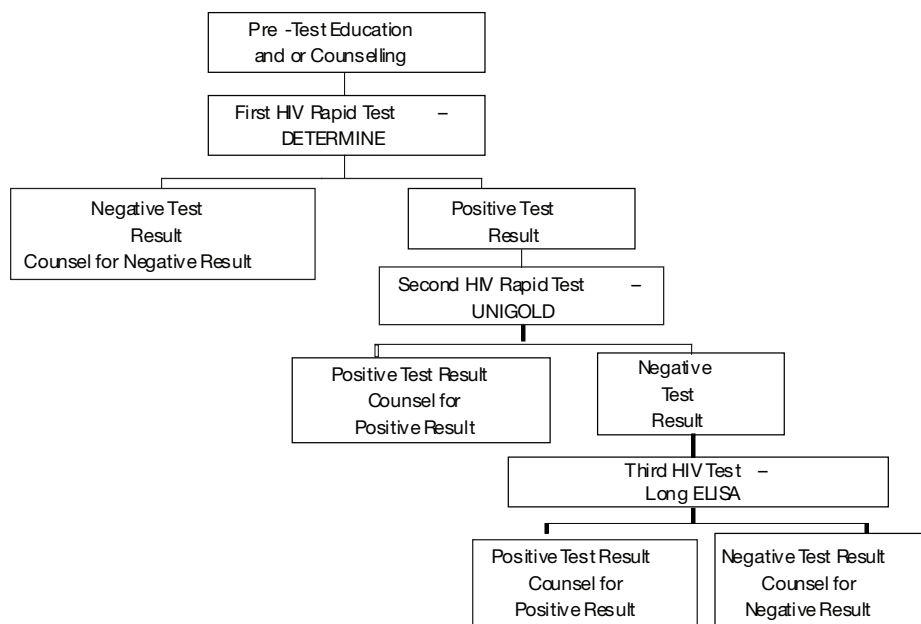
- All pregnant women of unknown HIV status should be offered opt-out testing at the first ANC visit.
- Repeat HIV testing (After 3 months) in the third trimester should be offered to all women whose first antenatal test was performed before 28 weeks gestation.
- Women who decline HIV testing at the first antenatal visit should have follow up counseling at subsequent visits, and offered HIV testing.
- Women presenting in labor without documented HIV testing should have opt-out testing done urgently.
- All facilities providing antenatal and maternity care must have capability for providing HIV testing at all hours of operation.
- Postnatal HIV counseling and testing should be offered to all women with unknown HIV status

Table 2.1 Essential Package of Integrated Antenatal Care Services

Group education: Include information on four ANC visits, breastfeeding, maternal and infant nutrition, personal hygiene, birth preparedness, danger signs, prevention of complications, skilled birth attendance, family planning, immunization schedule, post-natal care and HIV and AIDS management.
Client history: Obtain routine data including medical, obstetric, and psychosocial history. Determine drug history, known allergies, and use of alternative medicines such as herbal products.
Physical examination: Include vital signs, inspection, auscultation and palpation, breast examination
Abdominal and genital examination: Include inspection, palpation, foetal auscultation, speculum and bimanual examinations, where indicated, STI screening, cervical cancer screening(VIA)
ANC Profile: Routine tests for syphilis, Hb, blood group and Rhesus factor, urinalysis and provide rapid HIV testing to the pregnant woman and her partner if accompanying her. If indicated check sputum for AAFB and CD4 count.
Counselling on birth preparedness: Support the pregnant woman and her partner to develop an individual birth plan that includes place of delivery with skilled birth attendance, emergency transport, birth companionship and readiness for infant care.
Counselling on pregnancy danger signs: Provide women with information and instructions on seeking early care for pregnancy complications such as bleeding, fever, severe headache, swollen feet, fits or convulsions.
Counselling on infant feeding: All women require infant-feeding counselling and support. Exclusive breastfeeding for six months should be promoted as the norm for all women regardless of HIV status. Women infected with HIV need to be guided in the selection of safer infant-feeding options (refer to WHO guidelines and MOH circular on infant and young child feeding).
Nutritional assessment, counselling and education: Include iron, multivitamin and folate supplementation, monitor for anaemia, adequate caloric and nutrient intake, and recommend realistic diet adjustments based on local resources and needs of HIV+ pregnant women (at least 10% more of the RDA).
Counselling on HIV and AIDS: Provide women with information and instructions on seeking health care for symptoms of HIV disease progression, such as frequent and recurrent illnesses, chronic persistent diarrhoea, candidiasis, fever, wasting or signs of any opportunistic infection. Link women to HIV/AIDS treatment and other support programmes where available.

Counselling the HIV negative woman and her partner: Provide information on repeat testing, risk reduction and partner testing.
RTI screening: All women with high risk sexual history or presenting with signs of RTI such as abnormal genital discharge, genital ulcers and pelvic inflammatory disease should be screened and managed according to Kenya protocols.
Tuberculosis (TB): All women presenting for ANC services with a cough of more than 2 weeks' duration should be screened for TB regardless of HIV status. Follow Kenya protocols for screening, prophylaxis and treatment.
Tetanus toxoid immunisations: Administer according to current KEPI TT Immunization Schedule.
Deworming: All pregnant women should receive anti-helminthes after first trimester as per the guidelines on maternal nutrition.
Antimalarials, ITNs: All pregnant women in malaria endemic areas should sleep under an LLITN and receive SP intermittent presumptive treatment according to the National Malaria guidelines
ARV and Opportunistic Infections prophylaxis (during pregnancy): Provide ARV, CTX, and other prophylactic medications according to the Kenya ART protocol on OI prophylaxis and use of ARVs in pregnancy.
ARV treatment during pregnancy: Provide HAART within the MCH setting according to the Kenya protocol on use of ARVs. Establish clear referral networks with senior clinicians.
Prevention with Positives: Encourage positive living, disclosure, correct and consistent condom use, and provide psychosocial support to the affected families. For the HIV-infected and affected families, establish and/or strengthen linkages to care, treatment and support services including post-partum follow up.
Effective contraception plan: Counsel about other family planning methods emphasising on partner involvement and dual protection methods to avoid unwanted pregnancy, new infection, re-infection and further transmission.

Figure 2.1 A rapid HIV testing algorithm for serial testing is illustrated below.



CHAPTER 3

Intrapartum Care

3.1 Introduction

Intrapartum care is the management of women from the onset of labour to delivery. This period poses the greatest risk for transmission of HIV from the mother to the child (MTCT) with 10 to 20 percent of exposed infants becoming infected at this time in the absence of any intervention. In the context of HIV/AIDS, it is, therefore, important to establish the HIV status of women prior to, or during labour and delivery and provide interventions aimed at reducing the risk of transmission. With appropriate interventions, the risk of MTCT can be reduced significantly.

3.2 Operational Guidelines

a) Optimal Intrapartum Care

The following guidelines should be followed for all women admitted to labour and delivery units

- Minimise vaginal examinations.
- Use aseptic techniques in conducting delivery.
- Avoid routine artificial rupture of membranes (ARM).
- Avoid prolonged labour by use of a partograph.
- Avoid unnecessary trauma during delivery.
- Minimise the risk of postpartum haemorrhage.
- Use safe blood transfusion practices.

b) Specific Management of HIV Positive Pregnant Women

Prophylactic Antiretroviral therapies⁴

The ARV prophylactic regimen depends on whether the mother had ARVs during pregnancy or not. Thus, the health care worker should establish the regimen used during the ANC, whether the woman had taken ARVs at the onset of labour and determine the appropriate intra-partum ARV care as per the algorithms on as summarised below.

i) No ARVs taken in pregnancy

Mother in early labour (up to 1 hour before delivery)

Mother:

Intrapartum period; Give mother SdNVP 200mg at onset of labour+ AZT 600mg OR AZT 300mg BD + 3TC 150mg BD in labour and delivery

Postpartum: Give mother AZT 300mg and 3TC 150mg BD for 7days.

Assess for ART eligibility and initiate HAART as indicated

Infant:

Breastfeeding infant

Daily NVP from birth until one week after all exposure to breast milk has ended

(See table 4.6)

Non-breastfeeding infant
NVP for 6 weeks

ii) **Mother received AZT 300mg BD in Pregnancy**

Mother: Intrapartum and post-partum period regimen are same as above

Infant

Breastfeeding infant

Daily NVP from birth until one week after all exposure to breast milk has ended

Non-breastfeeding infant
NVP for 6 weeks

iii) **Mother received HAART in Pregnancy**

Regardless of duration received HAART (Applies to both women taking ART and Option B plus)

Continue the HAART regimen through labour and delivery and post partum period

Give infant Nevirapine syrup as above

Link the mother baby pair to chronic HIV care in the post partum period

C) Mode of delivery

Elective caesarean section (CS) reduces the risk of HIV MTCT as compared to vaginal delivery if the viral load is >1000 copies per ml, but may not be available in many settings. Where CS is performed (elective or emergency) in HIV positive women, prophylactic antibiotics should be administered. If the CS is performed after prolonged labour or rupture of membranes, full courses of antibiotics should be prescribed.

Indications for elective CS

Although elective CS will not be available in most health facilities for PMTCT, there may be some cases that merit consideration for CS. These include pregnancies where labour is expected to be prolonged or where other obstetric complications may be associated with increased risk of transmission (e.g. abruptio placentae, placenta praevia, pre-term rupture of membranes, previous CS, and breech presentation).

placentae, placenta praevia, pre-term rupture of membranes, previous CS, and breech presentation).

Support during labour

Emotional support during labour is important for all women, more so for a HIV positive woman who is concerned about her condition and risk of HIV transmission to her child. Whenever possible, during labour, ward staff must be sensitive to the fears and concerns of the HIV positive mother about her infection, and issues of disclosure to her partner.



Induction of labour

Induction of labour may be associated with increased risk of HIV MTCT. Careful assessment of the need for and desirability of induction rather than CS is necessary. When induction of labour is chosen, membranes should be left intact for as long as possible. Remember: Syntocinon should not be used with intact membranes.

Management of labour and delivery

Labour and delivery management should follow optimal obstetric management guidelines. (Refer to Optimal Intrapartum care above and National Guidelines for Quality Obstetrics and IMPAC Care Manual).

Delivery and role of the Community

A large proportion (60%) of women in Kenya delivers outside the health systems with assistance from family members, neighbours and TBAs. Great effort should be made to reverse this trend by implementing the community Health strategy, to achieve 80% skilled birth attendance/hospital delivery. Efforts to link households with community health workers who are also linked to the health facility should be supported.

CHAPTER 4

Use of Antiretroviral Drugs in Pregnancy for HIV Treatment and Prevention of Mother-to-Child Transmission of HIV Infection

4.1 Introduction

Without any intervention, up to 40 percent of HIV positive women will transmit the infection to their children during pregnancy, labour and breastfeeding. With a combination of antiretrovirals for the mother and baby, Kenyan infants of HIV-infected mothers may be protected from infection during pregnancy and delivery and during the prolonged period of breastfeeding that promotes infant survival and is the accepted culture in Kenya. Achieving this goal requires a program of adherence support that begins with the diagnosis of HIV and pregnancy and continues through the period of breastfeeding.

The PMTCT prophylaxis ARV drug regimens can reduce the risk of MTCT to 2-4 percent and can be implemented in resource-limited settings on a population-based public health scale. ARVs are used both for the treatment of HIV disease and for PMTCT in HIV-infected pregnant women and their neonates. Antiretroviral treatment (ART) for women, who qualify for it, prolongs and improves the quality of their lives. The survival of the child is closely interlinked with the health and survival of the mother. Women eligible for ART should be started on treatment as soon as possible. Pregnancy is not a reason to delay ART. Women who are already on ART before becoming pregnant should continue with their treatment. In certain situations, modifications may be needed to make treatment safer for the mother and the unborn baby.

The benefits of using ARVs to treat HIV-infected pregnant women and for PMTCT outweigh the risks. However, when ART or other short course ARV regimens are used, baseline evaluation and monitoring is encouraged to ensure the safety of the mothers and their newborns. Linkages of HIV-infected pregnant women and their children to other care and support programs at health facility and community level should be ensured.

4.2 Operational Guidelines

- All HIV-infected pregnant women should be counselled on comprehensive HIV care including use of ARVs for their own health and for PMTCT.
- All HIV-infected pregnant women should have their HIV disease staged using:
 - o WHO clinical staging (see Appendix 2) and
 - o Immunological staging (CD4 count)The women should also be screened and treated for opportunistic infections (OIs) including Tuberculosis (TB).
- All HIV-infected pregnant women should have baseline laboratory and other necessary diagnostic evaluations. These should include:
 - o Routine antenatal care laboratory investigations that are normally done for all pregnant women (haemoglobin (Hb), rhesus blood group and ABO typing, VDRL, urine analysis and screening for STI).
 - o ALT and creatinine levels for women eligible for HAART.

- OI prophylaxis & micronutrient supplementation:
 - o Multivitamins
 - o Co-trimoxazole (CTX) one double strength or two single strength tablets once daily for all PLHIV.

NB: Sulphur-based intermittent presumptive malaria treatment (IPPT) should NOT be given to women who are on CTX prophylaxis.

ARV use:

ARVs are used for treating HIV-infected eligible women and/or for prevention of mother-to-child transmission. (See appendix IIIA and III B)

- o **ARVs for Treatment (ART) & for PMTCT:** HIV-infected pregnant women **eligible for ART** should initiate ART as soon as possible (after adherence counselling) as shown in Table 4.1. HIV-infected pregnant women already on ART before becoming pregnant should continue ART. Regimen substitution may be necessary in some cases. Evaluation for treatment response/failure should be done as soon as feasible (Refer to ART guidelines)
- o **ARVs for prophylaxis (PMTCT):** Mothers who are not eligible for ART (women needing **ARV prophylaxis**) should be started on ARV prophylaxis. They should be initiated on AZT (300 mg BD) from 14 weeks of pregnancy or as soon as possible thereafter. At the onset of labour, give AZT 600 mg PLUS 3TC 300 mg PLUS NVP 200 mg at once followed by AZT (300 mg BD) and 3TC (150 mg BD) should be for seven days post-delivery. Single dose NVP given at the beginning of labour has the ability to rapidly decrease intracellular and extracellular HIV viral levels and to act synergistically with AZT and 3TC. However, to reduce the risk of development of NVP resistance following sd-NVP, a 7-day post partum regimen of AZT and 3TC is given to the mother after delivery. This is called **OPTION A** of ARV prophylaxis.
- o However, in settings with the capacity to initiate and monitor triple therapy on HIV infected pregnant women, triple ARV prophylaxis can be used. This is called **OPTION B**. When continued for life without interruption, it's called **OPTION B PLUS**. Due to the risk of NVP-associated hepatic toxicity in women with a CD4 count >250 cells/mm, it may be necessary to use LPV/r-based triple therapy. Emerging evidence has shown increased morbidity and mortality in patients who interrupt ART hence women who are initiated on triple ARV prophylaxis for PMTCT should continue with lifelong therapy irrespective of CD4 count or WHO clinical stage or breastfeeding status.

Table 4.1: Criteria for initiating ARV treatment (ART) in pregnant women based on clinical stage and availability of CD4 Count

WHO Clinical Stage	CD4 testing not available	CD4 testing available
1	Do not Treat	ART if CD4 \leq 350 cells /mm ³
2	Do not Treat	ART if CD4 \leq 350 cells /mm ³
3	Treat	ART irrespective of CD4 count. (Consider CD4 values for better management)
4		ART irrespective of CD4 cell count

Source: WHO Anti retroviral drugs for treating pregnant women and preventing HIV infections

Table 4.2: Recommended first-line ART regimen for treating pregnant women and prophylactic regimen for infants

First line ART regimen for women

Nevirapine exposure within 12 months	Preferred	AZT + 3TC+ LPV/r
	Alternative	TDF + 3TC + LPV/r
Nevirapine exposure >12 months ago OR No Nevirapine exposure	Preferred	AZT + 3TC + NVP/EFV*
	Alternative	TDF + 3TC + NVP/EFV*

*EFV should not be used in first 8 weeks (1st trimester) of pregnancy and should be changed to NVP if in 1st trimester of pregnant.

2 NRTIs (AZT and 3TC) acting as a “treatment backbone”, with addition of an NNRTI (NVP) remains the preferred first-line ARV therapy in resource-poor settings

Protease inhibitors based regimens are preferable when CD4 count is higher than 250

**EFV may be used instead of NVP after first trimester

Table 4.3 Management of HIV and ARV options in Women with Anaemia

Haemoglobin g/dL	Grade	Remarks
8 - 10	Mild	Look for treatable causes and manage, Give haematinics irrespective of gestation
6 - 8	Moderate	AZT contraindicated. Initiate ART irrespective of CD4 with TDF in place of AZT i.e. (TDF+3TC+NVP/EFV). Transfuse if >36 weeks gestation and if <36 weeks gestation give haematinics
6	Severe	AZT contraindicated. Initiate ART irrespective of CD4 with TDF in place of AZT i.e. (TDF+3TC+NVP/EFV). Transfuse irrespective of gestation

Notes: Important considerations that modify choice of ARVs during pregnancy include CD4 count, maternal anaemia and stage of pregnancy

Table 4.4: Scenarios for ARV prophylaxis to prevent mother to child transmission of HIV infection

Mother's presentation (Scenario 1)	Is the Mother on ART?	Antenatal and Intra-partum Interventions – Mother	ARV Intervention – Infant	Follow up after delivery
Asymptomatic (stage I or II) or/ and CD4>350 cells/mm ³ ; presents before onset of labour	No	<ul style="list-style-type: none"> - Start CTX, micronutrient and multivitamin supplementation, - standard ANC package <p>ARV Prophylaxis: Option A</p> <ul style="list-style-type: none"> - start on AZT 300mg BD from 14 weeks or at first contact thereafter and - In labour and delivery give AZT 600mg PLUS single dose NVP 200mg and 3TC 300 mg all at once 	<p>If breastfeeding</p> <ul style="list-style-type: none"> - Daily NVP (from birth until one wk after all exposure to breast milk has ended) <p>If not breastfeeding</p> <ul style="list-style-type: none"> - Daily NVP* for 6 weeks 	<ul style="list-style-type: none"> - Mother to continue both AZT 300mg BD and 3TC 150 mg BD for one week. Provide the mother with comprehensive HIV care as per national guidelines - Subsequent follow-up of infant care for HIV Exposed Infant
		<p>Option B Plus (Triple ARV prophylaxis for life):</p> <p>Preferred TDF+3TC+EFV (single OD pill started at 14 weeks)</p> <p>Alternative</p> <ul style="list-style-type: none"> - AZT+3TC+EFV /r - AZT/TDF + 3TC + LPV 	Daily Nevirapine for 6 weeks irrespective of breastfeeding practices.	<ul style="list-style-type: none"> - Provide the mother with comprehensive HIV care as per national guidelines - Subsequent follow-up of infant care for HIV Exposed Infant <p>Pregnant women starting triple ARV prophylaxis should not stop</p>

OPTION B Plus: Alternative Maternal triple ARV prophylaxis to prevent MTCT

In line with the national PMTCT goal to achieve virtual elimination of MTCT of HIV by 2015, facilities with ability to initiate and monitor patients on HAART will be encouraged to initiate triple ARVs (HAART) for life (uninterrupted) on all HIV positive pregnant mothers regardless of their WHO clinical stage or CD4 count in order to attain maximal viral load suppression. However, WHO staging and CD4 testing is recommended at baseline to monitor progress. Infants born to mothers on HAART would be put on daily NVP for 6 weeks regardless of feeding option. These mothers should be enrolled for chronic care and monitored accordingly.

The provision of maternal triple ARV prophylaxis during pregnancy in women who are not eligible for ART results very low in utero and peripartum transmission rates. A high value is also placed on the simplicity of the intervention as it contains only one maternal and one infant regimen and may be available as a once daily fixed dose combination.

The recommended maternal triple ARV regimens for option B plus include TDF+3TC+EFV, AZT+3TC+EFV, AZT+3TC+LPV/r, AZT+3TC+ABC. Nevirapine based regimens are not recommended because of the risk of hepatotoxicity for women with high CD4 counts (>250 cells/mm).

Why option B plus and not Option B

- Emerging evidence show that Non ART eligible women started of Triple ART followed by interruption leads to deterioration with morbidity and mortality*
- Other evidence suggests that most women Not eligible for ART during pregnancy will become eligible anyway within a period of 2 years.

*(N Engl J Med. 2006;355:2283–2296. 30). (SMART study. J Infect Dis. 2008;197:1133–1144)

Benefits of option B plus:

1. For regimen simplicity. No Staging or CD4 testing. (Although CD4 counts or viral load assays are still desirable for determining baseline immunological status and monitoring)
2. Extended protection from mother-to-child transmission in future pregnancies from conception
3. A strong and continuing prevention benefit against sexual transmission in serodiscordant couples and partners likely benefit to the woman's health of earlier treatment and avoiding the risks of stopping and starting triple ARVs, especially in settings with high fertility.

Table 4.5: Antiretroviral Prophylaxis for
Prevention of Mother to Child Transmission of HIV Infection in Labour

Mother's presentation (Scenario)	Is the Mother on ART?	Intra-partum Interventions – Mother	ARV Intervention – Infant	Follow up after delivery
Scenario 2 Mother presents in labour)	No	Single dose NVP 200mg plus AZT 600mg and 3TC 300 mg all at once.	If breastfeeding - Daily NVP (from birth until one wk after all exposure to breast milk has ended) If not breastfeeding - Daily NVP for 6 weeks	- Mother to continue both AZT 300mg BD and 3TC 150 mg BD for seven days. - Enrol mother into Comprehensive Care. - Subsequent follow-up of infant care as per HIV exposed infant
Scenario 3			Infant intervention	
Mother on HAART			NVP for 6 weeks	
Mother not on HAART and Baby breastfeeding			NVP till 1 week after cessation of breastfeeding	
Baby not breastfeeding			NVP for 6 weeks	
Note:If mother starts HAART during postpartum period, give infant NVP until 6 month OR 1 week after cessation of breastfeeding.				

Table 4.6 Infant Nevirapine Prophylaxis for HIV Exposed Infants

Age	Nevirapine Dose
0 – 6 weeks	Birth weight < 2500 g – 10 mg (1 ml) once daily Birth weight > 2500 g – 15 mg (1.5 ml) once daily
6 weeks – 14 weeks	20 mg (2 ml) once daily
14 weeks to 6 months	25 mg (2.5 ml) once daily
6 months – 9 months	30 mg (3 ml) once daily
9 months – 12 months	40 mg (4 ml) once daily
> 12 months	50 mg (5 ml) once daily

NOTE:

- AZT 15mg/kg twice a daily is an alternative for infants on TB treatment or NVP toxicity
- 3TC is an alternative for infants with severe NVP toxicity (grade 3 or 4)/or if baby is on TB treatment with rifampicin containing regimen

Table 4.7 Infant Lamivudine prophylaxis for infants who cannot take NVP

Age	Dosage
0-4weeks	2mg/kg twice daily
>4 weeks	4mg/kg twice daily

Table 4.8 Infant AZT prophylaxis dosage for HIV exposed infants

Birth weight	Dosage
<2500g	10mg/kg twice a day
>2500g	15mg/kg twice a day

NOTES:

As early as 14 weeks, the HIV positive pregnant woman should be put on AZT and counselled on adherence. They should be encouraged to come for a minimum of four ANC visits and deliver in the health facility. The woman takes AZT 300mg bd from first contact, 600mg AZT and sdNVP 200mg at onset of labour, and AZT 300mg/3TC 150mg BD for 7 days after delivery. At first contact, HIV infected pregnant women after 38 weeks should be given sdNVP tablets to take home with them. They should be instructed to take the tablets at the onset of labour, if labour occurs outside health facility settings. They should also be given NVP syrup for their babies to be administered from birth.

When single dose NVP (sdNVP) is used in PMTCT, some women and children may develop resistance to NVP that may limit future use of Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) to treat them. If an HIV positive mother has previous exposure to sd NVP, she should not be put on a NNRTI based regimen until 12 months have elapsed...If single dose NVP is used, AZT /3TC should be given for 7 days to cover the NVP tail in the mother. The baby is then continued on NVP until one week after cessation of breastfeeding.

HIV-infected pregnant women starting zidovudine (AZT) containing regimens should have haemoglobin (Hb) levels above 8 gm/dl. The Hb level should be checked every three months and clinical assessment at every visit. Clinical judgement can be used to estimate Hb levels and initiate ARV prophylaxis if laboratory tests are unavailable, but effort must be made to obtain HB for purposes of monitoring every 3 months.

Some women with a CD4 count greater than 250 cells / μ l on Nevirapine (NVP)-based ART may develop NVP hypersensitive reactions that can be life threatening. In these guidelines it is recommended that for pregnant women with CD4 more than 250, NVP-based regimen may still be used but with close monitoring. Otherwise the recommended regimen to use with CD4 count above 250 is a PI-based HAART regimen.

Efavirenz (EFV) is teratogenic if used in the first 8 weeks. If the patient is on EFV before becoming pregnant, it should be substituted with NVP in the 1st 8 weeks (1st trimester)

In case of severe hyperemesis gravidarum, ART may need to be briefly interrupted.

CHAPTER 5

Immediate Postnatal and Neonatal Care

5.1 Introduction

Immediate postnatal and neonatal care refers to the package of services provided to the mother and infant before they leave the health facility (up to 48 hours) after delivery. The period provides an opportunity to educate all mothers on optimal postnatal care including HIV, to provide HIV counselling and testing if it was not done previously, and to reinforce the education provided during the antenatal period. Both HIV infected and HIV uninfected mothers should receive this education and counselling before discharge.

5.2 Operational Guidelines

The following guidelines should be followed for all women and infants in the immediate post partum period:

a) Optimal postpartum care

- Support infant feeding options. For all HIV negative women, women of unknown HIV status and HIV positive mothers opting for exclusive breastfeeding, initiate breastfeeding within half hour of birth and follow other guidelines as per Baby Friendly Hospital Initiative (BFHI).
- Package of services provided to mothers and neonates within first 48 hours after delivery
- Services targeting HIV infected and HIV uninfected mothers would include:
- Health education on maternal nutrition; Advice on danger signs (mother and newborn), emergency preparedness and follow up; care of the newborn Following the standard guidelines on the care of a newborn (Kenya New born care Manual)
- Identification of complications in mother and newborn - manage and/or refer appropriately
- Routine postpartum care: blood pressure measurement; breast examination; examination of the uterus, the perineum and lochia. Ensure regular passage of urine and proper hygiene to prevent infection; checking for signs of anaemia, fever and tachycardia and Vitamin A supplementation
- Establish the HIV status of all postnatal mothers including those who delivered outside the health institution setting; Provide HIV testing and counselling for mothers with unknown HIV status and all those who tested negative and did not get re-tested in the antenatal period; Encourage HIV results disclosure and partner testing.
- All babies should receive their routine immunization (OPV and BCG) in their first hours of life.

b) Specific postpartum care for HIV positive women

- Support exclusive breastfeeding (with cover of ARVs) until six months unless the mother has been counseled on replacement feeding and meets the AFASS criteria.
- Initiate/continue Cotrimoxazole for all HIV positive women
- For the newly diagnosed, perform WHO Staging, CD4 Count and treat/refer for ART appropriately.
- For mothers on ART/HAART; continue with treatment (for detail; see chapter 4)

c) Specific care for HIV exposed infants

- Initiate Nevirapine syrup prophylaxis, for detail see chapter 4
- Refer to chapter 8 for infant feeding options

CHAPTER 6

Late Postnatal Care and Family Planning

6.1 Introduction

Late postnatal care is provided to the mother and the child 48 hours to 6 weeks after delivery. During this period, the health of the mother and child is assessed and closely monitored.

The risk of MTCT during the postpartum period can be reduced by providing HIV counselling and testing, ARV prophylaxis to the mother or exposed babies, counselling on appropriate infant feeding options and breast care. Postpartum care for HIV positive women should include clinical staging, CD4 count and ART for those who qualify.

Family planning services are among the core interventions of PMTCT provided to help women determine future childbearing patterns including the prevention of HIV-infected births. Reproductive health counselling can help a woman practise safer sex and determine her future childbearing patterns on a more responsible and informed basis¹.

6.2 Operational Guidelines

Optimal postpartum care for all women

This entails routine postpartum care including;

- Breast examination, examination of the uterus, examination of the perineum and lochia, passage of urine regularly, proper hygiene to prevent infection, checking for signs of anemia, fever and tachycardia and advice on doing perineal exercises.
 - Counselling and testing for mothers of unknown HIV status and for those who tested negative during early antenatal period.
 - Counselling on maternal nutrition; infant feeding options, risk reduction; hygiene, breast care and dual protection
 - Provision of condoms and initiation of viable method of contraception;
 - Screening for STI s and Cancer of the Cervix at 4-6 weeks
 - Counselling on post-partum danger signs in the mother and appropriate action
 - Counselling on avoidance of penetrative sex until there is no lochia.
 - Counselling on Malaria prevention
 - Care and support for the mother – partner support and linkage to psychosocial support groups
- Initiation of care and treatments as per national ART guidelines.

Optimal postpartum care for HIV positive women

Breast care in breastfeeding mothers

- Encourage daily cleaning of the breasts and avoiding the application of lotions.
- Treat maternal vaginal candidiasis and infant oral candidiasis.
- Educate mother on optimal breast feeding technique including latching on technique, exclusive breastfeeding and removing baby from breast.
- Educate the mother on breast care to prevent complications (cracking and engorgement).
- Express and heat treat the milk if breast has mastitis or abscess.

Breast care in non breastfeeding mothers

- Should wear a good supporting brassiere day and night.
- Whenever breasts are engorged, ask the mother to express to comfortable level (not emptying breast).
- Give analgesics for pain.
- Initiate contraception within 4 weeks of delivery (see section on contraception).

Lochia:

- Put emphasis on good perineal hygiene and proper handling of body fluids.
- Avoid contaminating the baby with body fluids or with bedding soiled with lochia.
- Sharing of beds by mothers in the hospital should be discouraged.

Caesarean Section

- Broad spectrum antibiotics should be used routinely after CS.

Essential maternal education and follow-up

- Monitor for breast and pelvic infection at all post natal clinic visits.
- Educate on prompt health seeking behaviour.
- Health education on hygiene, lochia and breast care.
- Avoid sexual intercourse for at least 2 weeks after birth or until there is no longer any lochia rubra or serosa.
- Do pap smear or VIA at 4-6 weeks.
- For every sexual activity, the couple should use condoms.

Contraception

Persons living with HIV and AIDS have been shown to have a higher (over 50%, KAIS 2007) unmet FP need as the non-infected (26%, KDHS 2008/9) persons. FP service providers must ensure that safe and effective contraception is accessible to women who are HIV positive in order to help them not only plan their future child bearing patterns but also to prevent the births of HIV positive children.

All mothers, regardless of their HIV status, have a right to receive adequate information on available methods of family planning and to make an informed choice on what is best for them. With very few exceptions, all methods of contraception can be used by HIV positive women based on standard medical eligibility criteria including taking care of drug interactions as outlined below. (See details in appendix IV and V)

In addition, all FP clients regardless of their status, should receive counseling about dual protection including Dual method use with emphasis on the importance of correct and consistent use of condoms

- **Lactational Amenorrhoea Method (LAM):** Suitable for exclusively breastfeeding HIV infected women who have not resumed menses. However, for HIV positive women, dual method contraception is advised.
- **Hormonal contraception:** All hormonal contraceptives can be used in HIV positive women including those on HAART. Combined oral contraceptives may be contraindicated for use with drugs that induce hepatic micro-enzyme that may reduce the effectiveness of hormonal contraceptives: Included in this group, are some anti-TBs, some antiretrovirals, antifungals and anti-epileptics, and in conditions that cause malabsorption.

- **Intra-uterine contraceptive devices (IUCDs):** IUCDs are not contraindicated in HIV positive women. In severely immunosuppressed women, IUCD use should not be discontinued but new insertion is discouraged as it may be associated with increased risk of infection during the insertion process. However, the IUCD may be inserted once the client is put on ARVs and is doing well on them
- **Surgical methods:** Surgical contraception should be offered to HIV positive women and their partners.
- **Barrier methods:** Female and male condoms provide protection against STIs and reduce the risk of HIV transmission and should be encouraged alone or preferably used together with other more effective contraceptive methods to what is referred as Dual method use
- **Emergency contraception:** Emergency contraception (EC) is a safe and effective way to prevent pregnancy after unprotected intercourse. It can be started up to five days (120 hours) after unprotected intercourse. Emergency Contraceptive Pills should not be used as a regular contraceptive method. ECPs can be used by HIV positive women. HIV positive women should be informed about emergency contraception, where it is available, how to access and use it.
- **Fertility Awareness Based method:** Women who are HIV-positive who may or may not have AIDS and those on ARV therapy can use FAB methods without restrictions, although women who want to use the Standard Days Method or Calendar method should have regular menstrual cycles. Women and couples relying on FAB methods should be counseled that they are not protected from STI and HIV transmission and should be encouraged to use condoms even on days when risk of pregnancy is low.

Care, support and treatment for HIV positive mother and child

HIV-positive mothers require care and support which includes:

- Counselling.
- OI prophylaxis and treatment.
- Link to support groups and assessment of the need for ART.
- Early infant diagnosis (EID) should be provided at six weeks and thereafter using EID algorithm (see Chapter 7)

Chapter 7

HIV Diagnosis in Children

7.1 Introduction

In general, a child may be tested under a number of circumstances. These include: shortly after birth for early diagnosis of HIV acquired prenatally; for the purposes of individual diagnosis in a child who is ill (e.g. those presenting with an HIV related illness); in cases where a child has either been exposed or is potentially exposed to HIV e.g. through mother-to-child transmission, sexual abuse, sexual activity, within a healthcare setting (e.g. through contaminated needles or receipt of potentially infectious blood), through other means, and in orphans.

Early infant diagnosis (EID) refers to the making of HIV diagnosis in infants and young children before 18 months of age. EID gives an opportunity for early identification of HIV exposed and infected infants (due to sub-optimal PMTCT service or lack of it) and early linkage to prevention for the exposed and care and treatment for the infected disease progression in HIV infected infants is fast, with a high mortality rate (> 50%) by 2 years of age. The median age of death in the first two years is 6 months.

HIV antibody testing among children aged 18 months or more is able to determine whether a child is infected or not. During pregnancy, there is transplacental transfer of HIV antibodies to the unborn baby from the mother, these antibodies disappear with time from the infant's blood. Antibody testing in children aged less than 18 months identifies children who have been exposed to their mothers' HIV infection or who may be truly infected and are making HIV antibodies. Currently, there is no test to differentiate the mother's antibodies from those produced by the baby. In order to identify the HIV-infected child aged less than 18 months, a second test is required for all babies testing positive on antibody testing or known to be HIV-exposed (mother is HIV-positive). Infant DNA (or RNA) PCR testing is the current recommended method for EID.

Since most babies lose maternal antibodies (Ab) by 9 months, a negative antibody test will identify uninfected babies as long as they are not breastfeeding. A positive antibody test at >9 months, although highly likely to be diagnostic, may still be due to passively carried maternal antibodies. A confirmatory PCR test should be done for all positive antibody tests before 18 months of age. An antibody test at /after 18 months of age is confirmatory of HIV infection in HIV exposed infants.

7.2 Operational Guidelines

7.2.0 Guidelines for HIV diagnosis in children

- Perform routine rapid HIV antibody tests for all mothers or infants presenting with unknown HIV status to establish expose status of the infants.
- Perform routine dry blood spots (DBS) for DNA PCR for all infants known to be HIV-exposed at 6 weeks or at first contact thereafter
- Perform routine antibody testing for all sick infants in outpatient and paediatric wards to establish HIV exposure/infection status.
- Perform a confirmatory DNA, PCR test for all HIV-exposed sick infants with a positive antibody test before 18 months of age.
- All HIV-exposed infants should be started on co-trimoxazole from 6 weeks of age or on first contact thereafter.
- Refer to chapter on care and follow up of the HIV-exposed/infected infant.

7.2.1 HIV negative infant at age 6 weeks or first contact

- Perform antibody testing at 9 months and 18 months of age.
- If HIV negative at 9 months and still breastfeeding, continue cotrimoxazole and repeat Ab test at 2 months after cessation of breastfeeding or at 18 months whichever comes first.
- If HIV antibody test is positive before 18 months perform a confirmatory DNA PCR test.
- If NOT breastfeeding for at least 2 months and HIV test is negative, stop co-trimoxazole.
- Perform confirmatory antibody testing at 18 months.

7.2.2 HIV positive infant by DNA PCR

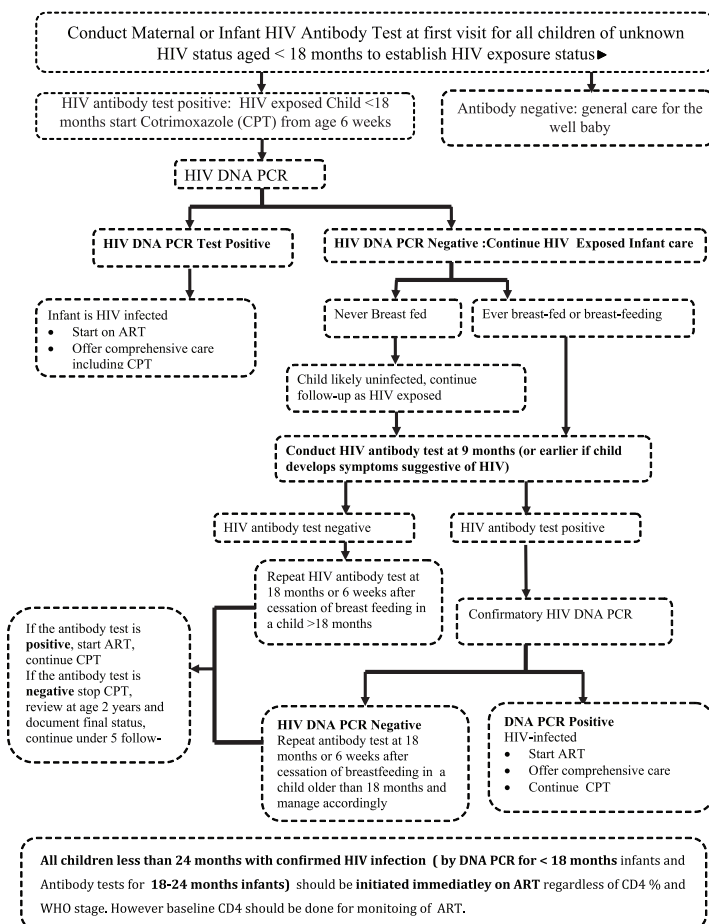
- All HIV-positive infants should be started on HAART , regardless of their WHO stage , CD4 count or CD4%.
- However, WHO clinical staging and CD4 count/percentage should be done for all HIV positive infants as a baseline.
- All HIV-positive infants should have a visible guardian or care-taker before they can be started on ART to assure adherence.
- All HIV positive infants should be started on Cotrimoxazole from 6 weeks or on first contact thereafter.
- Breastfeeding should be encouraged for all infants who test HIV-positive for a minimum of one year.

All HIV positive infants should be started on HAART regardless of WHO stage or CD4 count or %.

7.2.3 Comprehensive care for HIV-exposed children

Both HIV-infected and uninfected children require comprehensive care (Refer to Chapter 8 and 9).

Figure 7.1: Algorithm for Early Diagnosis of HIV Infection in children



CHAPTER 8

Feeding Infants and Young Children Born to HIV Infected Mothers



8.1 Introduction:

Transmission of HIV through Breastfeeding

In Africa, 3 to 4 out of every 10 infants born to HIV infected women acquire HIV infection. Use of ARVS either for the mother or the infant significantly reduces the risk of HIV transmission from the mother to the child. Exclusive replacement feeding if done appropriately reduces the risk of HIV transmission but hygiene should be observed to avoid the morbidity and mortality associated with it.

Feeding options for a HIV exposed infant;

1. Exclusive breastfeeding with ARVS
2. Exclusive Replacement feeding

8.2 Operational Guidelines on Infant feeding (0-6 months)

The following should guide infant feeding for the first 6 months

1. All mothers who are HIV negative or are of unknown HIV status should be encouraged and supported to exclusively breastfeed for the first 6 months and continue breastfeeding with appropriate complementary feeding introduced thereafter.



2. All HIV positive mothers should be given information on available infant feeding options and counseled using recent scientific information on benefits and challenges for each option in order to help them make an informed choice.
3. All HIV positive mothers who choose to breastfeed should be encouraged and supported to exclusively breastfeed for the first 6 months and continue breastfeeding up to 1 year with appropriate complementary feeds. Infants of these mothers should be provided with nevirapine prophylaxis for up to 1 week after complete cessation of breastfeeding.
4. HIV positive mothers who choose not to breastfeed and meet AFASS criteria and should be encouraged and supported to do exclusive replacement feeding for the first six months and appropriate complementary feeding introduced thereafter. Infants of these mothers should be provided with nevirapine prophylaxis for 6 weeks.
5. In special circumstances determined by clinicians involving infants who cannot breastfeed e.g. orphans or abandoned babies or where the mother has condition like mastitis preventing breastfeeding the infant should be provided with exclusive replacement feeding with appropriate complementary feeds introduced thereafter.

8.3 Operational Guidelines on Feeding Children 6 months and older

The following should guide feeding for children 6 months and older
From 6 months, milk alone is not adequate to meet the baby's nutritional requirements.
Therefore;



Start complementary feeding at 6 months

- Complementary foods should be introduced with continued breastfeeding or with replacement feeding until a nutritionally adequate diet can be sustained without milk.
- For HIV exposed infants, continued ARVs for the infants should be provided up to complete cessation of breastfeeding.
- Abrupt cessation of breastfeeding is NO longer recommended as this causes psychological trauma for both the mother and the baby.
- From 6 months animal milk can be introduced and should continue as an important component of the child's diet.
- Complementary foods should be prepared from locally available family foods.

8.4 Nutritional Care and Support of HIV infected children

- Energy needs for asymptomatic HIV infected children increase by 10 percent to maintain growth as compared to the non-infected children while for symptomatic HIV infected child this increases by 50-100% (See HIV and Nutrition guidelines)
- There is no evidence of increased protein requirements. The requirements should be based on individual symptoms and needs.
- Micronutrient requirements do not change. WHO recommends not more than one RDA. (For further details, refer to Kenyan Guidelines on nutrition and HIV/AIDS).

8.5 Extracts from Research on Infant Feeding and HIV/AIDS

Evidence available from current research data shows that:

- Increased risk of mortality with replacement feeding is significant.
- HIV free survival rate at 18 months of age does not significantly vary between an exclusively breastfed and exclusively replacement fed child.
- Modified animal's milk is no longer recommended for children less than 6 months of age.
- Abrupt cessation of breastfeeding is no longer recommended.
- Therefore, exclusive breastfeeding (With ARVs) up to 6 months is recommended unless a mother chooses replacement feeding and can meet AFASS criteria.
- If breastfed infant is given solid foods (Mixed fed) before 6 months, the risk of HIV infection is eleven times as high as the exclusively breastfed infant.

8.6 Maternal nutrition in the context of HIV



Nutritional requirements of pregnant and lactating mothers

- A pregnant and nursing mother needs to consume 200 and 500 extra calories per day respectively
- Total calorie consumption in lactating mothers increases to about 2500 calories per day
- Eat more of protein rich foods.
- Eat frequent meals and snacks in between.
- Take plenty of fluids preferably hot drinks.
- Avoid tobacco, alcohol and other substances of abuse
- It is recommended to consult the doctor before taking any kind of medication.

Factors affecting maternal nutrition

- Cultural beliefs
- Quantity and quality of the food she eats every day
- Her daily workload
- HIV-related symptoms that can affect appetite or eating e.g. painful swallowing from candidiasis

Common breast feeding conditions

- Flat and inverted nipples
- Engorgement
- Blocked duct and mastitis
- Sore nipples and nipple fissuring

CHAPTER 9

Care and Follow-up of Children of HIV-infected Mothers

9.1 Introduction

Comprehensive PMTCT interventions reduce the risk of HIV transmission from mothers to their infants and young children. Moreover, elimination of MTCT by 2015 is now considered feasible. Both HIV-infected and exposed children have increased risks of infection and death from common childhood infections. The survival of HIV-exposed children, whether or not they are infected, is closely linked to the health and survival of their mothers. Therefore, long-term benefits of PMTCT programs will only be sustained if there is ongoing comprehensive care for the children and their mothers and/or care givers. This is in line with the UN action plan of virtual elimination of MTCT and keeping mothers alive.

Regular follow up care is critical for an infant born to a mother with HIV/AIDS. The comprehensive care of HIV exposed children including nutrition, immunisation, monitoring of growth and development, prevention and treatment of opportunistic infections and early infant diagnosis of HIV is feasible in resource-constrained settings and significantly improves the survival of these children.

HIV exposed children are vulnerable to the common illnesses affecting other children. These infections include neonatal infections, malaria, pneumonia, diarrhoea, measles and other vaccine preventable diseases. HIV infected children are likely to suffer more severely and have a higher likelihood of dying from common childhood illnesses than non-infected children. Whereas malnutrition causes 53% of all childhood deaths, HIV infected children are more vulnerable to it than non-infected children. This is because HIV infected children have higher caloric requirements as a result of their HIV infection, the presence of opportunistic infections and other complications related to AIDS.

Regular follow up care is critical for an infant born to a mother with HIV/AIDS. The comprehensive care of HIV exposed children including nutrition, immunisation, monitoring of growth and development, prevention and treatment of opportunistic infections and early infant diagnosis of HIV is feasible in resource-constrained settings and significantly improves the survival of these children.

9.2 Operational Guidelines

The following guidelines should be followed in the care and follow-up of children of HIV-infected mothers:

- All HIV exposed infants should be seen in the health care facility within two weeks of delivery.
- For all HIV exposed infants, monthly follow up visits are recommended beginning at six weeks through 2 years.
- Where possible, visits should be linked to the immunisation and growth monitoring visits.
- All HIV exposed infants should be started on co-trimoxazole prophylaxis from 6 weeks of age.

For infants who test HIV positive by DNA PCR before 18 months or by antibody test after 18 months of age, co-trimoxazole should be given daily for life.

For infants who test HIV negative,

- If they have stopped breastfeeding for 2 months or more, stop co-trimoxazole
- If still breastfeeding, confirm status after stopping breastfeeding. Co-trimoxazole should be continued until two months after complete cessation of breastfeeding.

Comprehensive care for the HIV exposed or infected infants should be provided in the broader context of other child health care strategies (MCH integration model).

Health workers should provide the following package of care as a minimum to these children:

1. Confirm HIV status as early as possible. (Refer to Chapter 7)
2. Mothers should be supported to provide optimal infant feeding and particularly exclusive breastfeeding and to avoid mixed feeding in the first 6 months of life.
3. Monitor the child's growth and development as a means of identifying the child who is failing to thrive and also as a tool for monitoring the effect of interventions.
4. Ensure that immunisations are started and completed according to the recommendations of the national immunisation schedule.

Additional considerations are as follows:

- When considering BCG vaccination at a later age (re-vaccination for no scar or missed earlier vaccination), exclude symptomatic HIV infection first.
- Do not give yellow fever vaccine to symptomatic HIV-infected children. However, asymptomatic children in endemic areas should receive the yellow fever vaccine at 9 months of age.
- Measles vaccine should be given to HIV exposed and infected children at 6 and 9 months of age.

(1) Provide prophylaxis for opportunistic infections:

A) Prophylaxis against *Pneumocystis jirovecii* Pneumonia

Pneumocystis jirovecii (formerly *Pneumocystis carinii*) pneumonia (PCP), is a significant cause of morbidity and mortality among young infants in Africa. Co-trimoxazole (CTX) prophylaxis significantly reduces the incidence and severity of PCP. Additional benefits of co-trimoxazole include protection against common bacterial infections, toxoplasmosis, and malaria.

Who Needs PCP Prophylaxis?

- All HIV exposed infants, until the infant is no longer breastfeeding and is confirmed HIV negative. .
- All infants/children confirmed to be HIV infected by PCR or antibody test. .
- Any child with a history of PCP should continue with secondary prophylaxis (daily CTZ) for life.

Clinicians should clearly inform HIV infected mothers at delivery that their children need prophylaxis against PCP starting at 6 weeks of age until it is established that the child is not HIV infected. A practical way to ensure that mothers and other health workers are informed is to make a note on the child's immunization card at birth stating "Please give co-trimoxazole (5 mg/kg/day orally daily) from 6 weeks of age."

Table 9.1: Dose of Co-trimoxazole for PCP Prophylaxis

Trimethoprim /Sulphamethoxazole (TPM/SMZ) Cotrimoxazole		
Age	Suspension (40mg TPM/200mg SMZ) per 5ml	
<6months	2.5ml daily	¼* single strength tab daily
6months-5years	5ml daily	½ single strength tab daily
6years-14years	10ml daily	1 single strength tab daily
>14years	20mls daily**	2 single strength tabs daily Or 1 double strength tab daily

*It should only be used where suspension is not available

**If tabs are not available

NB: In rare cases, as in children with G6PD deficiency, CTX may be contraindicated.

Prophylaxis against *Pneumocystis jirovecii* Pneumonia (PCP)
in children where Cotrimoxazole is contraindicated

A second choice would be either dapsone or atovaquone

Dapsone

Dose: Children > 1 month: 2 mg/kg/24 hours orally once daily.

If both CTX and Dapsone are contraindicated (e.g., in children with G6PD deficiency who get haemolysis with CTX and Dapsone), then use either:

Atovaquone : 30mg/kg/day for age 1-3 months. Higher dose 45mg/kg/day for age 4-24 months

OR

Pentamidine (Aerosolized): 300 mg in 6 ml water via inhalation nebulizer once monthly for Children > 5 years

(B) Preventing TB

HIV-infected children with no evidence of active tuberculosis should be offered isoniazid preventive therapy (IPT). The indications for IPT in such children are as follows;

Children with history of contact with a Pulmonary TB case,

- ALL should be evaluated for active TB disease (See Appendix VII).
- If they do not have active TB, they should ALL receive 6 months of IPT (including TB exposed newborns of mothers with untreated PTB)
- If they have active TB, they should receive full anti-TB treatment as per national TB guidelines.
- Isoniazid Prophylactic Therapy (IPT) in Children
- Isoniazid preventive therapy (IPT) for young children with infection who have not yet developed disease will greatly reduce the likelihood of developing TB during childhood

Which child should receive IPT?

- All children below 5 years who have had recent (past 12 months) exposure to an adult or adolescent with PTB or suspected PTB, provided they have no evidence of active TB disease.
- All HIV infected children above one year of age provided they have no evidence of active TB disease.
- All HIV infected children below one year – give IPT only to those with recent (past 12 months) contact with a TB case, provided they have no evidence of active TB disease.

These children should receive six months of IPT (10 mg/kg/ day) as part of a comprehensive package of HIV prevention and care services.

- Children living with HIV who are more than 12 months of age and who are unlikely to have active TB on symptom-based screening, and have no contact with a TB case should receive six months of IPT (10 mg/kg/ day) as part of a comprehensive package of HIV prevention and care services.
- In HIV positive infants (<12 months of age), only those who have contact with a TB case and who are evaluated for TB (using investigations) should receive six months of IPT if the evaluation shows no TB disease
- Dose and duration of INH for IPT in children: IPT should be given at a dose of 10mg/kg for duration of 6 months.

Table 9.2: IPT dosing in Children

Weight	Dose in mg/day	Number of 100mg, INH tablets	Number of 300mg (Adult) tablets
<5	50	½	-
5.1 – 9.9	100	1	-
10 - 13.9	150	1½	½
14 - 19.9	200	2	-
20 - 24.9	250	2½	-
>25 and adults	300	3	1

IPT Follow-up:

- Review monthly and continuously reinforce message of adherence
- Screen for TB disease i.e. persistent cough, fever, fatigue, poor weight gain
- Monitor INH adverse effects.
- Maintain a contact register

Isoniazid (INH) for preventive therapy is given at a dose of 10 mg/kg (maximum dose 300 mg) once daily for six months. IPT is protective for a period of 2 years.

(2) Treatment of acute infections and other HIV-related conditions:

HIV-exposed children are susceptible to common infections while HIV infected children are susceptible to OIs. HIV may alter the incidence, presentation and response to conventional therapy. In some cases, more aggressive and longer treatment courses may be necessary, as treatment failures are more frequent.

(3) Regular follow-up care & referrals:

Regular follow-up is the backbone to caring for the HIV exposed children and ensures optimal healthcare and psychosocial support to the family.

Table 9.3: Recommendations for Follow-up of an HIV-Exposed Child

Follow up of a HIV exposed/ infected child should be as for any other child under 5 years of age. Interventions are as shown in the table below.

Age	Interventions
At birth	Immunization (OPVo, BCG), infant feeding counseling(IFC), ARVs prophylaxis, counsel on return visits including CTX initiation and PCR at 6 weeks
At age 1 to 2 weeks	Adverse drug reactions and adherence to ARVS, Immunization for missed (OPVo, BCG), IFC
At age 6weeks	Immunizations, DBS collection, start CTX, IFC, Growth and development monitoring. Mother- FP, ART, CxCa screening
At age 10, and 14 weeks	Immunization, Growth and development monitoring and IFC
At age 6 months	Measles vaccine, Vit A, complementary feeding counseling, Growth and development monitoring
At age 9 months	HIV Antibody test with confirmatory PCR if Ab test is positive, Measles vaccine , IFC ,Growth and development monitoring
At age 12 months	AB test if not done at 9 months, Vit A, Deworming, adherence counseling , Growth and development monitoring, Counsel on stoppage of breastfeeding
At 18 months	Confirmatory HIV antibody test, Growth and development monitoring, Young child feeding counseling, Vit A and deworming.
After 2 year	Growth and development monitoring and Young child feeding counseling, Vit A and deworming.

(4) HIV disease staging in HIV-infected children:

Disease staging, with or without laboratory support, follows HIV diagnosis. Staging HIV disease provides a guide to the prognosis and interventions needed at the different stages. (Refer to ART guidelines)

(5) ARV therapy:

HIV infected children should be started on HAART irrespective of WHO stage and CD4 count/percent as soon as an HIV diagnosis is made according to National Guidelines (See guidelines for ART in Kenya, 4th edition, 2011 chapters 11-14. Early treatment significantly reduces mortality in HIV infected children.

(6) Communication:

Communicating and providing psychosocial support for the child, mother/caregiver and family are a crucial component of care. Also see chapter 18 of 4th edition of ART guidelines, 2011.

Parents/caregivers and/or the child need to participate in making decisions and planning appropriate care for the child, including decisions about therapy and where the child should receive care. In this respect, health workers must ensure that the family considers the social needs of HIV infected and affected children.

Health care workers should ensure that they provide adequate time for caregivers to ask questions so that they can fully understand the implications of HIV and HIV testing, for themselves and for their children. Health care workers should counsel caregivers on disclosure, including disclosure to the child.

(7) Referrals:

Referrals are an important part of managing an HIV exposed or infected child. These include referrals to:

- Higher levels of specialised care for further investigations and treatment.
- Social support programmes.
- Community-based care programmes.
- PITC sites for parents and siblings.

CHAPTER 10

Monitoring and Evaluation of PMTCT Services

10.1 Introduction

PMTCT program monitoring and evaluation activities provide the opportunity to measure and appraise performance within defined parameters that ensure accomplishment of goals and objectives. Kenya is committed to the “Three-in-ones” principles which are:

- One agreed AIDS Action Framework that provides the basis for coordinating the work plan of all partners
- One National AIDS Coordinating Authority with a broad-based multi-sectoral mandate.
- One agreed country-level Monitoring and Evaluation (M&E) system.

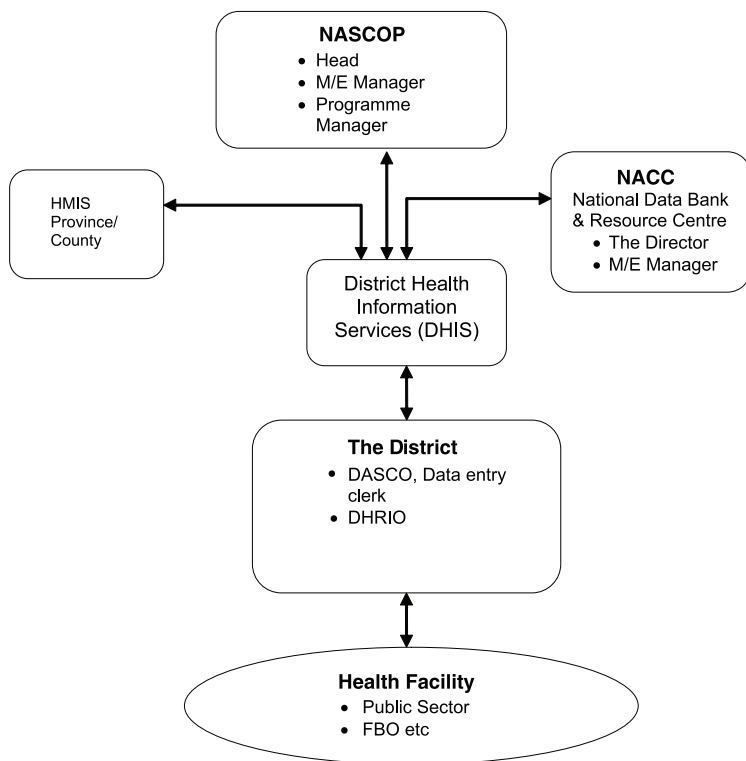
In line with this, the country has developed the National HIV/AIDS Monitoring and Evaluation Framework that provides stakeholders with a tool for well coordinated, interlinked and functional HIV/AIDS M&E system that allows for efficient monitoring of interventions in achieving the national programmatic goals using defined targets. This provides the framework for M&E activities within PMTCT programs.

National PMTCT data is reported using MoH Integrated Monitoring and Evaluation Report Forms, Form 731 (Appendix VIII) and 711. Individual PMTCT data is collected at the health facilities offering PMTCT services using standard MoH registers (ANC, Maternity, Postnatal Registers and HEI Registers).

On monthly basis, the health facilities will aggregate the data from the registers on to Form 731 and MOH 711 which are then forwarded upwards to the District office (DHRIO or DASCO) for onward transmission to the national office via DHIS. Facilities with direct internet access can upload their report directly into DHIS. A copy is left at the health facility for their own data use. At the district data is entered into DHIS by facility then automatically aggregated at constituency, district, county, province and National level.

HIV M&E data flow pipeline from the individual health facilities, to the district and the central or national levels is summarised in Fig. 10.1.

Figure 10.1: HIV Monitoring and Evaluation data flow pipeline in Kenya



10.2 Operational Guidelines

The following guidelines should be followed in the monitoring and evaluation of PMTCT services:

1. Within PMTCT programs, data is collected and reported at the following levels: Individual, facility, district/county, provincial and national.
2. Individual level: The combined mother-baby health booklet provides detailed information on the woman and child including the HIV status, other HIV care services, drugs, delivery information, and immunisation, growth monitoring and other parameters.
3. Facility level data capture tools: The MoH has standardised registers for recording data at facilities. These include the Revised ANC Register, Revised Maternity Register and Post Natal Register and HIV Exposed infant (HEI) register. Other registers include Child Health (MCH) and Nutrition Information System and In-patient Morbidity and Mortality, Commodity registers etc. Form 711, 731 and the Reproductive Health Services monthly reports are used for making facility level summaries on PMTCT reproductive health services.
4. Sub National Level: Using the web based system (DHIS), the data is automatically aggregated to produce required district, constituency, county and province level reports
5. Provincial level and National level: The provincial and National level now serve as crucial levels for improving data quality, this is achieved by reviewing the submitted reports for timeliness, completeness and accuracy followed by provision of immediate feedback.
6. Data dissemination: This is carried out at all levels starting from facility to national level. It is the responsibility of HIS, NACC and NASCOP to coordinate the dissemination and use of all HIV/AIDS data and information for national response. JAPR, a joint programme of all stakeholders in HIV/AIDS receives and uses the data to discuss the challenges, achievements and lessons learnt from HIV/AIDS and gives feedback for national response.
7. PMTCT indicators and their sources: Health care facilities collect the following data as a minimum to be used in the monitoring of PMTCT programs.

Summary of data collection and reporting tools for PMTCT

PMTCT is monitored using a set of standard tools categorised as individual or facility for both commodity and service delivery

Individual:

These include

- Mother Baby booklet
- HIV Exposed infant cards

Facility recording tools:

These include;

1. Service delivery
 - ANC Register (MOH 405)
 - Maternity Register (MOH 333)
 - Post Natal Register (MOH 406)
 - HIV Exposed Infant Register (MOH 408)
2. Commodity tools
 - Daily activity registers for ARVs and OIs (MOH 367A)
 - Daily activity register for OIs (MOH 367B)
 - Daily activity Register for Lab activities (MOH 642)

Facility reporting tools

Service delivery:

- MOH 731 for integrated HIV program reporting
- MOH 711/726 for integrated health sector reporting Commodity tools:
- Facility Monthly ART patient summary (F-MAPS)
- District Monthly ART Patient summary (D-MAPS)
- Facility Consumption Data Reports and Requests (FCDRR) for ARVs -
- Lab Facility Consumption Data Reports and Requests (FCDRR) – MOH 643
- District stores/ central sites Data Report and Requests (DCDRR)

Summary of PMTCT Data elements:

- i. **New clients/first antenatal clinic visits:** Number of pregnant women attending their first antenatal visit for the current pregnancy at the health facility. This is obtained from the antenatal register. This data element can be used to determine the average length of PMTCT prophylaxis and hence the effectiveness of the same. Mothers coming quite late for the first antenatal visit will not receive the optimal dose and duration of ARV prophylaxis.
- ii. **No of women attending four antenatal visits:** These are the number of women who have made four visits as per the Focused antenatal care (FANC) schedule. This can be used to measure retention of clients in antenatal care hence assess the provision of the minimum package of ANC care as provided for in the FANC approach. This is obtained from the antenatal register.
- iii. **Counselling and testing for HIV in antenatal clinic:** Total number of pregnant women with unknown status counselled and tested for HIV at the antenatal clinic, although the practise is to do this at the first visit, this should be recorded at the visit at which this is done, and this can be on the first antenatal visit or a later visit. This is obtained from the antenatal register.
- iv. **HIV counselling and testing at first antenatal clinic visit:** Number of pregnant women attending their first antenatal clinic visit for current pregnancy who are tested for HIV. This is obtained from the antenatal register.

- v. **HIV infected in antenatal clinic:** Number of antenatal clinic pregnant women who are HIV-infected on the latest test during the pregnancy. This includes those who have been tested and found to be HIV positive and those coming for ANC with a known HIV positive status. This is obtained from the antenatal register.
- vi. **Preventive ARV prophylaxis in antenatal clinic (mother dose):** Number of pregnant women in the antenatal clinic receiving the mother dose(s) of preventive ARV prophylaxis. The prophylaxis includes HAART for prophylaxis or own treatment. This is obtained from the antenatal register.
- vii. **Preventive ARV prophylaxis in antenatal clinic (infant dose):** Number of pregnant women in the Antenatal clinic issued with the infant dose(s) of preventive ARV prophylaxis. This is obtained from the antenatal register.
- viii. **New clients in maternity clinic:** Number of pregnant women attending the Maternity clinic for the first time. This is obtained from the maternity register.
- ix. **Unknown HIV status at maternity:** Number of pregnant women admitted into the maternity with unknown HIV status. This is obtained from the maternity register.
- x. **Counselling and testing for HIV in maternity ward:** Total number of pregnant women admitted into maternity with unknown status that are counselled and tested for HIV during labour or after delivery. This is obtained from the maternity register.
- xi. **HIV Positive diagnosed in maternity ward:** Number of pregnant women admitted into maternity clinic who are diagnosed to be HIV infected. To avoid double counting, this figure includes only those who have tested positive in maternity. This is obtained from the maternity register.
- xii. **Preventive ARV prophylaxis in maternity ward (mother dose):** Number of pregnant women newly diagnosed in Maternity who have been issued with ARV prophylaxis (please note that this excludes mother who had been issued with prophylaxis in ANC and have now come to deliver). This is obtained from the maternity register.
- xiii. **Infant preventive ARV prophylaxis in maternity clinic/ ward:** Number of infants born in maternity receiving the infant preventive ARV prophylaxis in the maternity clinic (this also excludes the children whose mothers were given ARV prophylaxis at ANC so as to avoid double counting). This is obtained from the maternity register.
- xiv. **Deliveries:** Total number of pregnant women delivering at the health facility, this is stratified by the HIV status.
- xv. **Counselling on infant feeding options:** Number of mothers delivering at the health facility counselled on infant feeding options. This is obtained from the maternity register.
- xvi. **Infant testing:**
 - a. Number of infants tested for HIV at 6 weeks old.
 - b. Number of Infants tested for HIV at 9 months and 18 months
 - c. Number of infants testing HIV-positive.

This is obtained from HEI register.

xvii. **Linkages to care and treatment:**

- d. Number of HIV infected women attending antenatal clinic that are referred for HIV care and treatment or provided with care and treatment at ANC/MCH
- e. Number of HIV infected women in maternity that are referred for HIV care and treatment.
- f. Number HIV infected infants referred for HIV care and treatment.
- g. Number of HIV infected infants initiated on treatment as per the national guidelines
This is obtained from antenatal, HEI, PreART, ART and Maternity registers.

xviii. **Initiated on co-trimoxazole:**

- h. Number of HIV infected pregnant women attending antenatal clinic that has been initiated on co-trimoxazole. This is obtained from the antenatal register.
- i. Number of HIV exposed infants initiated on Cotrimoxazole at six weeks. This is obtained from the HEI register/ PreART register.

With the measurements listed above, the following performance indicators that are both global and local are calculated:

In summary the indicators are:

1. **HIV Testing and counselling**

- a. **Number and Proportion of Pregnant women with known status:** these includes those with known positive status and those getting tested within PMTCT settings (ANC, L&D, PNC)
- b. HIV Positivity at PMTCT Settings: This is the total number of pregnant women who are HIV infected at PMTCT settings, these include the known positives at entry into ANC and those newly diagnosed at ANC, L&D and Post Natal clinics (within 72 hours).
- c. Number and Proportion of Pregnant women whose partners are tested in PMTCT settings
- d. Number and Proportion of infants provided with early infant diagnosis by age one year: within 2 months, 3-8 months and at 9-12 months (confirmatory PCR) Number of HIV infected women at PMTCT Settings (Includes those known positive at entry into ANC).

2. **Provision of ARV**

- a. Proportion of HIV infected women assessed for ARV eligibility at ANC
- b. Proportion of HIV infected women who are provided with ARV prophylaxis by regimen (AZT, sdNVP, HAART)
- c. Proportion of HIV exposed infants provided with ARV Prophylaxis at PMTCT Settings

3. **Linkages to care and treatment**

- a. Proportion of HIV infected infants enrolled into care and treatment
- b. Proportion of HIV infected infants initiated on HAART

Roles and Responsibilities:

Facility:

- It is the role of every health provider to document all the services provided, the documentation can be in the clients cards or booklet or in the requisite registers. The documentation also includes commodities consumed. The documentation should use the prescribed MOH data collection tools.
- At the end of every month the health provider or records in charge is expected to compile the various service delivery reports into the facility report i.e. MOH 711 or MOH 731: the PMTCT section. The facility in charge should review and validate all submitted reports.
- The compiled MOH 711 and 731 is then sent to the province for entry into DHIS, the facility reports should be submitted to the sub national level by the 5th of the month following the reporting period.
- The facilities are expected to maintain copies of the submitted reports for data quality assurance/ audits.
- Facilities are also expected to use the generated data for decision making at the facility so as to gauge performance, improve quality of care and track progress towards achieving the set goals e.g. AOP, Performance contract, HSSF e-MTCT and others; For instance each health facility should compute transmission rates by determining the final status of all HIV exposed infants at 6 weeks, 9 months and confirmatory PCR for the antibody positive PCRs at nine months.

National and Sub National Levels:

- Quantify the required data collection and reporting tools, coordinate the procurement and distribution of the same.
- Routinely review the submitted reports for timeliness, accuracy, completeness and consistency and promptly provide feedback and address any emerging issues.
- Conduct routine supervisions to assess the filing of data collection and reporting tools, understanding of collected indicators and use of data at all levels.
- Review the data collection and reporting tools infrequently as prescribed by national and international reporting and program requirements.
- Coordinate the trainings of health workers on data collection, reporting and use.

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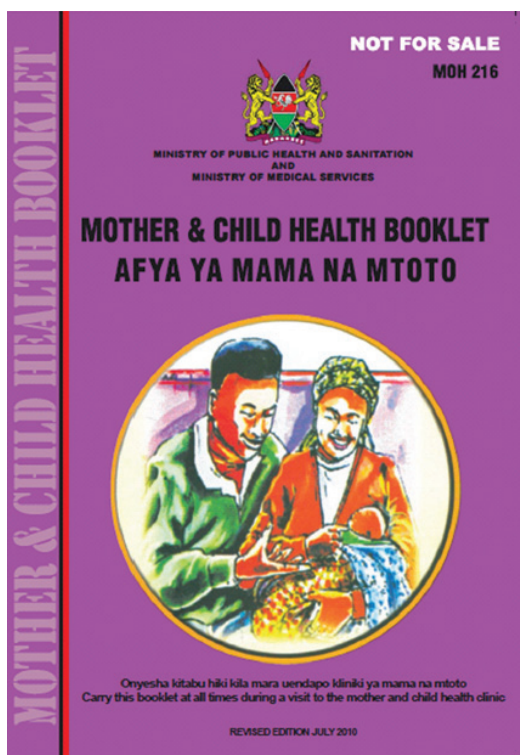
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Appendices

Appendix I

Mother and Child Health Booklet



Appendix II:

WHO Clinical Staging of HIV/AIDS for Adults and Adolescents with Confirmed HIV infection

CLINICAL STAGE 1

1. Asymptomatic.
2. Persistent generalized lymphadenopathy.

CLINICAL STAGE 2

1. Unexplained moderate weight loss (<10% of presumed or measured body weight).
2. Recurrent upper respiratory tract infections (sinusitis, tonsillitis, otitis media and pharyngitis).
3. Herpes zoster.
4. Angular cheilitis.
5. Recurrent oral ulceration.
6. Papular pruritic eruptions.
7. Seborrhoeic dermatitis.
8. Fungal nail infections.

CLINICAL STAGE 3

1. Unexplained severe weight loss (>10% of presumed or measured body weight).
2. Unexplained chronic diarrhoea for longer than one month.
3. Unexplained persistent fever (above 37.5°C intermittent or constant for longer than one month).
4. Persistent oral candidiasis.
5. Oral hairy leukoplakia.
6. Pulmonary tuberculosis.
7. Tuberculous Lymphadenopathy.
8. Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis or bacteraemia).
9. Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis.
10. Unexplained anaemia (<8g/dl), neutropaenia (<0.5 × 10⁹ per litre) and/or chronic thrombocytopenia (<50 × 10⁹ per litre).

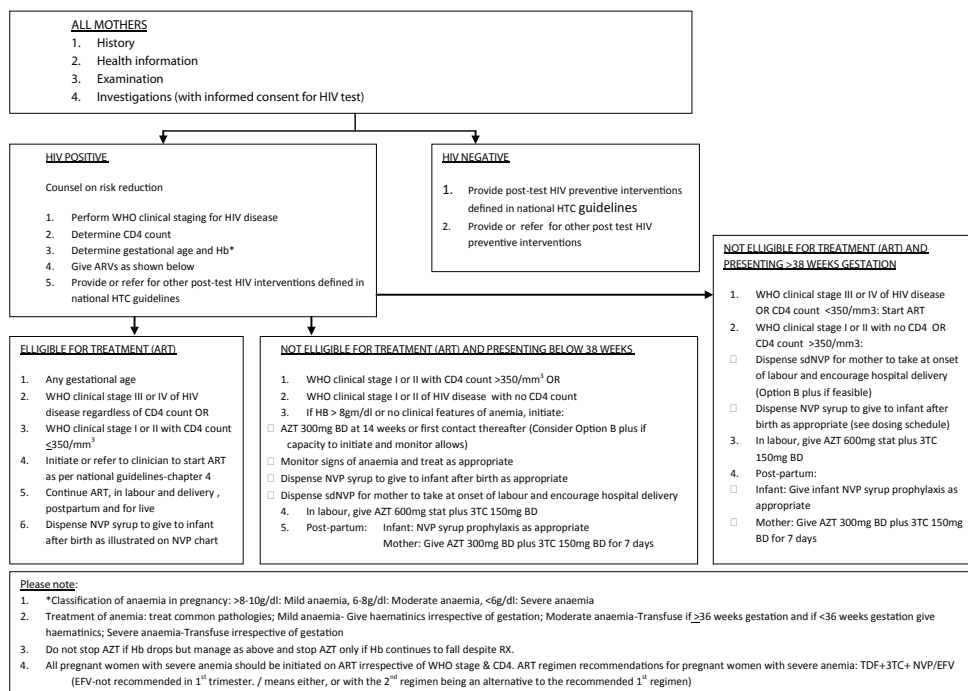
CLINICAL STAGE 4

1. HIV wasting syndrome.*
2. Pneumocystis pneumonia.
3. Recurrent severe bacterial pneumonia.
4. Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration or visceral at any site).
5. Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs).
6. Extrapulmonary tuberculosis except Tuberculous Lymph adenopathy.
7. Kaposi's sarcoma.
8. Cytomegalovirus infection (retinitis or infection of other organs)
9. Central nervous system toxoplasmosis
10. HIV encephalopathy.
11. Extrapulmonary cryptococcosis including meningitis.
12. Disseminated non-tuberculous mycobacterial infection.
13. Progressive multifocal leukoencephalopathy.
14. Chronic cryptosporidiosis.
15. Chronic isosporiasis.
16. Disseminated mycosis (extrapulmonary histoplasmosis or coccidiomycosis).
17. Recurrent septicaemia (including non-typhoidal Salmonella).
18. Lymphoma (cerebral or B-cell non-Hodgkins).
19. Invasive cervical carcinoma.
20. Atypical disseminated leishmaniasis.
21. Symptomatic HIV-associated nephropathy or symptomatic HIV-associated.
22. Cardiomyopathy.

***Please note:** Signs and symptoms of HIV wasting syndrome include: Unexplained involuntary weight loss (>10% baseline body weight) with obvious wasting of body mass index <18.5 PLUS unexplained chronic diarrhoea (loose or watery stools three or more times daily) reported for longer than one month OR reports of fever or night sweats for more than one month without other cause and lack of response to antibiotics or antimalarial agents. Malaria must be excluded in malaria prone areas.

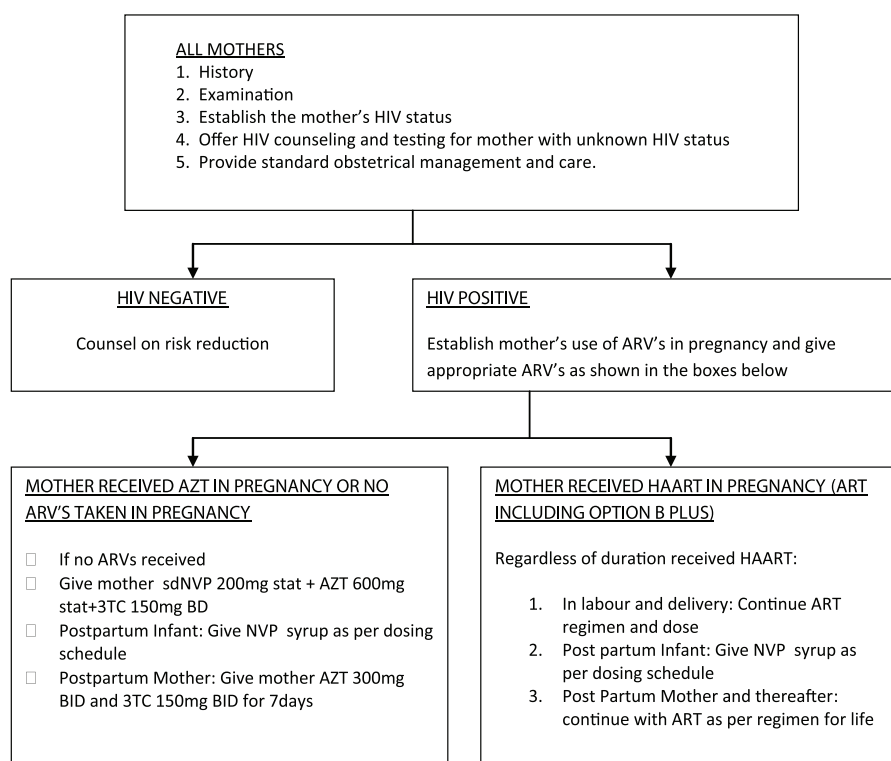
Appendix III-A:

USE OF ARVs FOR TREATMENT AND PMTCT OF HIV IN ANC



Appendix III B:

USE OF ARVs FOR PMTCT OF HIV IN LABOUR AND DELIVERY UNITS AND POSTPARTUM PERIOD



Appendix IV

Contraceptive Options for People Living With HIV

Evidence of conception has demonstrated that fertility in HIV positive women for the most part is unaffected. However, certain conditions may affect fertility such as low body mass index, AIDS and intercurrent illness, especially tuberculosis. Putting women who are HIV infected on contraceptives is one of the means of preventing mother to child transmission of HIV (PMTCT).

It is the right of HIV infected women to make their own decisions regarding reproduction. They may wish to have more babies, limit their families or avoid pregnancy altogether. The health care providers they consult should enable them to make informed choices by themselves.

The following contraceptive methods are available in Kenya: - progesterone only pills, low dose combined oral contraceptives, depot medroxyprogesterone acetate (DMPA - depo), levonorgestrel and etonogestrel implants. Emergency contraceptive pills, copper intrauterine contraceptive devices, barrier methods, female and male sterilisation are also available.

Some drugs interact with hormonal contraceptives and concurrent use should be avoided.

These drugs include:

- Protease inhibitors – Ritonavir, Nelfinavir, Lopinavir with Ritonavir.
- Non-nucleotide reverse transcriptase inhibitors (NNRTIs) – Nevirapine, Efavirenz.
- Anti-TB drugs – Rifampicin and Rifabutin.
- Other drugs – Griseofulvin, Phenobarbitone, Carbamazepine, Phenytoin.

All the above do not apply in the face of other medical conditions that are contra-indications for the various methods e.g. known cardiovascular disease, hepatic conditions, smoking, high blood pressure and thromboembolic disorders.

The following table summarises major issues regarding use of different contraceptives by HIV-positive women.

Appendix V:

Contraceptive Methods for Use in Couples and Women Living with HIV Infection

Table 10.1 Contraceptive Options for Use in Couples and Women Living with HIV Infection

METHOD	COMMENTS	USE IN HIV POSITIVE PATIENTS
Condoms	Male & female condoms available. Provide dual protection against STIs/HIV & pregnancy. Require attention & care for correct use each time. May require co-operation of partner	Can and should be used at all stages of HIV infection Can and should be used by patients on ART Correct and consistent use by HIV infected patients is recommended regardless of the use of other methods of contraception (dual contraception).
Hormonal Methods	Very effective and easy to use Suitable for short- or long-term use Reversible Associated with non-contraceptive health benefits Serious complications extremely rare	Can be used without restriction in HIV+ women not on ART Can be used without restriction in all HIV+ women for emergency contraception Some ARV drugs may reduce method effectiveness. DMPA*/Implants can however be used with ART; re-injection of DMPA should be done at 10-12 weeks If hormonal method is chosen, condoms should still be used correctly and consistently

Intrauterine Contraceptive Device	<p>Highly effective, long-term, reversible method</p> <p>Remains in place up to 12 years</p> <p>Almost 100 percent effective</p> <p>Has no effect on fertility when used by nulliparous women</p> <p>Should not be provided to women with high risk sexual lifestyle</p> <p>Bacterial STIs should be screened for and /or treated as a precaution prior to insertion of IUCD</p>	<p>Attractive method for women with HIV who desire very reliable pregnancy protection</p> <p>Can be inserted in HIV+ women who do not have WHO Stage 4 disease/ AIDS defining illness</p> <p>For women with stage 4 disease IUD can be inserted once they are on ART and have controlled symptoms of severe illness.</p>
Sterilization	<p>Good, very effective for couples or individuals who want no more children</p> <p>Safe, simple surgical procedure</p> <p>Considered permanent</p>	<p>No medical reasons to deny sterilization to clients with HIV</p> <p>Procedure may be delayed in event of acute HIV-related infection or stage 4 disease pending immune reconstitution</p> <p>Encourage condom use as well</p>

Contraceptive Methods for use in Couples and Women Living with HIV Infection

*DMPA = Depot Medroxyprogesterone Acetate (Depo-Provera)

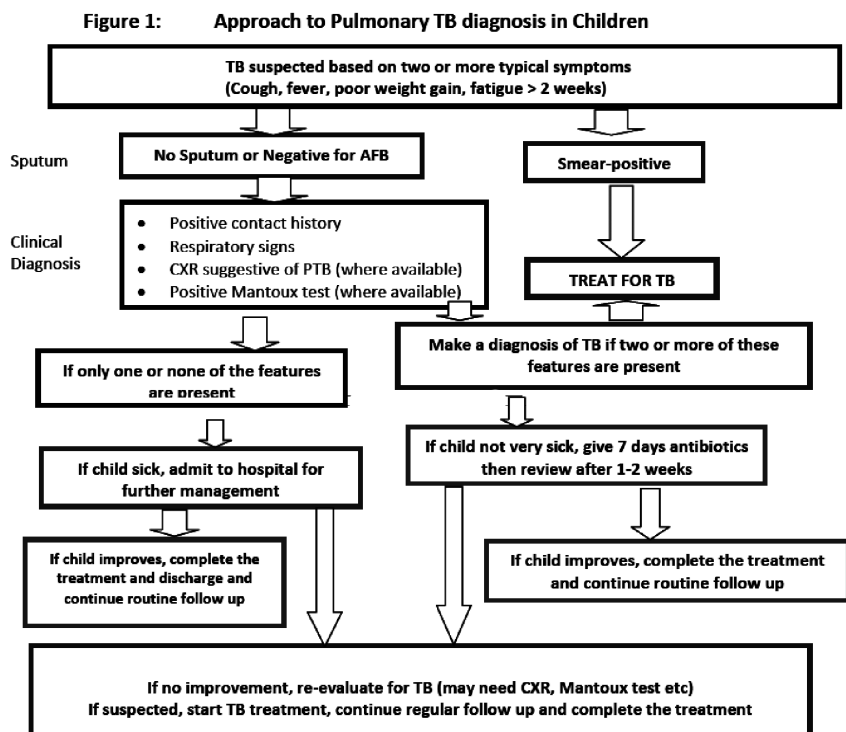
Appendix VI:

Common Adverse Effects of ARV Use During Pregnancy

Class	Adverse effects	Counselling and Follow-up Tips
Nucleoside/ Nucleotide Reverse Transcriptase Inhibitors(NRTIs)		
Zidovudine (AZT) Lamivudine (3TC) Stavudine (d4T) Abacavir (ABC) Tenofovir (TFV/TDF) Emitricitabine (FTC)	Nausea Diarrhoea Hypersensitivity (ABC) Anaemia (AZT)	May not be well-tolerated in early pregnancy when morning sickness is common May increase risk of non-adherence May have inadequate blood levels All ARVs should be discontinued and restarted when N&V is gone or effectively treated Follow-up labs: CBC, LFTs
Non- Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)		
Nevirapine Delavirdin Efavirenz (EFV) FDC TDF/FTC/EFV	Rash Elevated liver enzymes(common with NVP in high CD4 count) EFV: CNS effects (sedation, insomnia, vivid dreams, dizziness, confusion, feeling of 'disengagement' Teratogenicity	If rash in 1st 2 wks do not increase NVP dose and contact clinician Mild rash may be managed with antihistamines Avoid corticosteroids during NVP dose escalation EFV should be taken initially at bed time Avoid EFV in women of high child-bearing potential Do not operate heavy machinery.
Protease Inhibitors (PIs)		
Saquinavir (SQV) Indinavir (IDV) Ritonavir (RTV) Nelfinavir (NLF) Lopinavir/ritonavir (LPV/r) Atazanavir (ATV) Fosamprenavir Tipranavir (TPV) Darunavir (DRV)	GI intolerance Hepatotoxicity Lipodystrophy Dyslipidemias Insulin resistance Hyperglycaemia Lactic acidosis and hepatic steatosis	Monitor glucose levels Ask regularly for symptoms of hyperglycaemia Monitor hepatic transaminases (ALT and AST) particularly during the first 18 weeks of therapy, when this toxicity is most likely Take with food Antiemetics Antimotility

Appendix VII:

Diagnostic algorithm for Pulmonary TB in Children



Notes:

1. All children should be tested for HIV
2. Mantoux test should be regarded as positive as follows:
 - >5 mm diameter of induration in high-risk children (includes HIV-infected children and severely malnourished children)
 - >10 mm diameter of induration in all other children (whether they have received a BCG vaccination or not)
3. Please note that a mantoux may be negative despite the child having TB, especially in severe disseminated TB, malnutrition and HIV disease.

Score Charts/ Diagnostic Criteria for Tb in Children

Clinical diagnosis of PTB in children shall be based on the following:

Presence of 2 or more of the following symptoms

- Cough > 2 weeks
- Weight loss or poor weight gain
- Persistent fever and/or night sweats > 2 weeks
- Fatigue, reduced playfulness, less active
- PLUS
- Presence of 2 or more of the following:
 - Positive contact history
 - Respiratory signs
 - CXR suggestive of PTB (where available)
 - Positive Mantoux test (where available)

Then PTB is likely, and treatment is justified

NOTES:

The key elements to a successful diagnosis of PTB in children include:

1. Careful history taking (including history of TB contact and symptoms consistent with TB)
 - Ask for symptoms consistent with TB including chronic cough > 2 weeks, fever- body temperature of 38 °C for 14 days after common causes such as malaria and pneumonia have been excluded, weight loss or failure to thrive (also look at the growth chart), and or night sweats.
 - Enquire whether the patient has been in close contact with smear-positive pulmonary TB (usually a parent or other member of the family)
2. Clinical examination (especially growth monitoring)
Physical signs highly suggestive of extra pulmonary TB:
 - Often the main clinical finding is just failure to thrive
 - Gibbus, especially of recent onset (resulting from vertebral TB)
 - Non-painful enlarged cervical lymphadenopathy with fistula formation
3. Bacteriological diagnosis
 - a. Microscopy for acid fast bacilli
 - b. TB culture and drug susceptibility testing where possible
 - c. Histopathology depending on specimen
 - d. Xpert MTB/RIF (to be used only with sputum and sputum sediments)
 - e. Line Probe Assays (LIPA)
4. Chest radiography: This is particularly important in children with suspected PTB.
Radiological features suggestive of PTB will include,
 - a. Persistent lung opacification especially if focal enlarged hilar or subcarinal lymph nodes,
 - b. Diffuse micronodular infiltrates (miliary pattern)
 - c. Pleural effusions with apical infiltrates and cavities especially in adolescents.
 - d. The finding of marked abnormality on CXR in a child with no signs of respiratory distress (no fast breathing or chest in-drawing) highly supportive of TB
5. HIV testing
All children with suspected TB should be tested for HIV
6. Tuberculin skin testing (TST)
 - A positive TST is evidence that one is infected with MTB, but does not necessarily indicate disease

Interpretation of Tuberculin skin test: TST is regarded as positive if the induration is:

- More than 10mm in all other children, whether they received BCG vaccine or not.
- More than 10mm in all other children, whether they received BCG vaccine or not.
- More than 5mm in, HIV infected, immunocompromised, or severely malnourished.

7. Chest radiography: This is particularly important in children with suspected PTB. Radiological features suggestive of PTB will include,
- a. Persistent lung opacification especially if focal Enlarged hilar or subcarinal lymph nodes,
 - b. Diffuse micronodular infiltrates (miliary pattern)
 - c. Pleural effusions with apical infiltrates and cavities especially in adolescents.
 - d. The finding of marked abnormality on CXR in a child with no signs of respiratory distress (no fast breathing or chest in-drawing) highly supportive of TB

Appendix VIII:

MINISTRY OF HEALTH INTEGRATED MONITORING AND EVALUATION REPORT FORM MOH 731, NASCOP

Facility _____ Facility Code _____ Managing Agency (e.g GOK,Mission,Private) _____

District _____ Month _____ Year _____

N/B: Indicate N/S where there is no service and N/D where there is service but no data

2 Prevention of Mother-to-Child Transmission

2.1 Testing for HIV

		Value
Antenatal	HV02-01	
Labour and Delivery	HV02-02	
Postnatal (within 72hrs)	HV02-03	
Total Tested (PMTCT) (Sum HV02-01 to HV02-03)	HV02-04	

2.2 HIV Positive Results

Known positive status (at entry into ANC)	HV02-05	
Antenatal	HV02-06	
Labour and Delivery	HV02-07	
Postnatal (within 72hrs)	HV02-08	
Total Positive (PMTCT) (Sum HV02-05 to HV02-08)	HV02-09	
Total with known status (HV02-04 plus HV02-05)	HV02-10	

2.3 Partner Involvement

Male partners tested - (ANC/L&D)	HV02-11	
Discordant Couples	HV02-12	

2.4 Maternal Prophylaxis (at first contact only)

Prophylaxis – NVP Only	HV02-13	
Prophylaxis – (AZT + SdNVP)	HV02-14	
Prophylaxis – Interrupted HAART	HV02-15	
HAART (ART)	HV02-16	
Total PMTCT prophylaxis (Sum HV02-13 to HV02-16)	HV02-17	

2.5 Assessment for ART Eligibility in MCH (at diagnosis)

Assessed for eligibility at 1st ANC - WHO Staging done	HV02-18	
Assessed for eligibility at 1st ANC - CD4	HV02-19	
Assessed for Eligibility in ANC (Sum HV02-18 to HV02-19)	HV02-20	
Started on ART during ANC	HV02-21	

2.7 Infant Testing (Initial tests only)

PCR (within 2 months)	HV02-24	
PCR (from 3 to 8 months)	HV02-25	
Serology antibody test (from 9 to 12 months)	HV02-26	
PCR (from 9 to 12 months)	HV02-27	
Total HEI Tested by 12 months (Sum HV02-24 to HV02-26)	HV02-28	

2.8 Confirmed Infant Test Results

Positive – (within 2 months) – PCR	HV02-29	
Positive – (3 – 8 months) – PCR	HV02-30	
Positive – (9 – 12 months) – PCR	HV02-31	
Total Confirmed Positive (Sum HV02-29 to HV02-31)	HV02-32	

2.9 Infant Feeding

EBF (at 6 months)	HV02-33	
ERF (at 6 months)	HV02-34	
MF (at 6 months)	HV02-35	
Total Exposed 6 months	HV02-36	
BF (12 months)	HV02-37	
Not BF (12 months)	HV02-38	
Not Known	HV02-39	
Total Exposed 12 months (Sum HV02-37 to HV02-39)	HV02-40	

2.10 Infant ARV Prophylaxis (at first contact only)

Issued in ANC	HV02-41	
Labour and Delivery	HV02-42	
PNC (<72hrs)	HV02-43	



Prepared by:	Verified by:
(Name).....(Designation).....	(Name).....(Designation).....
(Signed).....	(Signed).....

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