FEDERAL MINISTRY OF HEALTH NIGERIA

UNITY AND FAITH PEACE AND PROGRESS

NATIONAL GUIDELINES

for

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (PMTCT)

2010

FEDERAL MINISTRY OF HEALTH

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NATIONAL GUIDELINES

FOR

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (PMTCT)

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FOREWORD

The Federal Ministry of Health initiated the National Prevention of Mother to Child Transmission (PMTCT) of HIV programme in 2001, with the aim of reducing vertical transmission of HIV. The National PMTCT Guidelines which provide the recommended standard of care for HIV positive pregnant women was first developed in 2003 and then reviewed and updated in 2005 and 2007 to reflect global trends in line with relevant scientific studies.

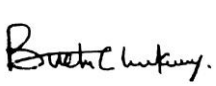
Following the release of the World Health Organisation (WHO) 2010 Guideline on "Antiretroviral Drugs for treating pregnant women and preventing HIV infections in infants (Recommendations for a Public Health Approach)" which is based on new global evidences and best practices, the National PMTCT Guidelines have once again undergone a review.

As before, the Guidelines are written for health professionals (medical and other health care providers) and managers responsible for maternal and child health services who care for women during the antenatal, labour, delivery and postpartum periods as well as their infants. Recognizing that resources and situations differ from one part of the country to the other, these guidelines could be adapted to suit local circumstances as long as the fundamental principles are preserved.

The major changes in this edition of the Guidelines include the emphasis on identifying pregnant women in need of treatment for their own illness versus those who only require prophylaxis for the current pregnancy. The drug regimen of choice for prophylaxis is now HAART with the option of the AZT-based regimen for the facilities that do not have the capacity to monitor clients on triple therapy. The Guidelines also advocate breastfeeding as the preferred infant feeding option with ARVs taken by either the mother or baby. ARV intervention is to begin as early as 14 weeks gestation and last till cessation of breastfeeding.

This review and update of the National PMTCT Guidelines has been led by the National PMTCT Task Team and coordinated by the HIV/AIDS Division of the Federal Ministry of Health. All relevant stakeholders have been involved including International Partners, Clinicians, other Government agencies and People living with the virus.

The 2010 National PMTCT Guideline is hereby recommended for use by all health care providers in health facilities throughout Nigeria. It is hoped that this will ensure standardization and implementation of quality services as we work towards the goal of elimination of mother-to-child transmission by 2015.



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Thank you for a splendid job!

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ACRONYMS

3TC	Lamivudine
ABC	Abacavir
ADR	Adverse Drug Reaction
AFASS	Affordable, Feasible, Available, Sustainable, Safe
AFB	Acid Fast Bacilli
AIDS	Acquired Immunodeficiency Syndrome
ALT	Alanine aminotransaminase
ANC	Antenatal Care /Antenatal Clinic
ARV	Antiretroviral (Antiretroviral drug)
ART	Antiretroviral Therapy
ARM	Artificial rupture of membrane
AST	Aspartate aminotransaminase
AZT	Azidothymidine (Zidovudine)
BCG	Bacillé-Calmette-Guerin
BFHI	Baby Friendly Hospital Initiative
BMS	Breast milk Substitute
CBOs	Community-Based Organisations
CCM	Country Coordinating Mechanism
CDC	Centre for Disease Control and Prevention
CD4+	Cluster for Differentiation type 4 (Antigenic marker on T-lymphocytes CD4+)
CHAI	Clinton Health Access Initiative
CMV	Cytomegalovirus
CNS	Central nervous system
CPT	Co-trimoxazole Preventive Therapy
CSF	Cerebrospinal Fluid
CSO	Civil Society Organization
CT	Computerized Tomography
CTX	Co-trimoxazole
CXR	Chest X ray
d4T	Stavudine
DBS	Dried Blood Spot
DIC	Disseminated Intravascular Coagulopathy
ddC	Zalcitabine
ddI	Didanosine
EBF	Exclusive Breastfeeding
EBV	Epstein Barr Virus
EC	Expert Client
ECG	Echocardiography
EEG	Electroencephalography
EFV	Efavirenz
EGA	Estimated Gestational Age
EID	Early Infant Diagnosis
ELISA	Enzyme-linked Immunosorbent Assay

E/U	Electrolytes and Urea
FBC	Full Blood Count
FBO	Faith-Based Organization
FDC	Fixed-Dose Combination
FMOH	Federal Ministry of Health
FP	Family Planning
FTC	Emtricitabine
FHI-GHAIN	Family Health Initiative Global HIV/AIDS Initiative in Nigeria
HAART	Highly Active Antiretroviral Therapy
HBC	Home-Based Care
HBV	Hepatitis B virus
HCT	HIV Counselling and Testing
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HIVDR	HIV Drug Resistance
HSV	Herpes Simplex Virus
IATT	Inter-agency Task Team on PMTCT
ICAP	International Centre for AIDS Care and Treatment Programme
IEC	Information, Education and Communication
IF	Infant Feeding
IFA	Immunofluorescence Assay
IgG	Immunoglobulin G
IHV-N	Institute of Human Virology Nigeria
IMAI	Integrated Management of Adolescent Illnesses
IMCI	Integrated Management of Childhood Illnesses
INH	Isoniazid
IPT	Isoniazid Preventive Therapy
IPTp	Intermittent Preventive Therapy for Malaria in pregnancy
IVF	In-Vitro Fertilization
LFT	Liver Function Test
LIP	Lymphoid Interstitial Pneumonitis
LMIS	Logistic Management Information System
LPV/r	Lopinavir/ritonavir
MAC	Mycobacterium Avium Complex
MCH	Maternal and Child Health
MDG	Millennium Development Goal
MDT	Multi-Disciplinary Team
MIS	Management Information System
MTCT	Mother-to-Child Transmission (of HIV)
MRI	Magnetic Resonance Imaging
NACA	National Agency for Control of AIDS
NASCP	National AIDS/STIs Control Programme
NEPWHAN	Network of People Living With HIV/AIDS in Nigeria
NFV	Nelfinavir
NGO	Non-Governmental Organisation

NHMIS	National Health Management Information System
NNRIMS	Nigeria National Response Information Management System
NNRTIs	Non-Nucleoside Reverse Transcriptase Inhibitors
NPC	National Population Commission
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
NSAID	Non-steroidal Anti-Inflammatory Drugs
NtRTI	Nucleotide Reverse transcriptase inhibitor
NVP	Nevirapine
OIs	Opportunistic Infections
OPV	Oral Polio Vaccine
ORT	Oral Rehydration Therapy
OVC	Orphans and Vulnerable Children
PABA	People Affected By AIDS
PCP	*Pneumocystis jirovecii* Pneumonia
PCR	Polymerase Chain Reaction
PCV	Packed Cell Volume
PEP	Post-Exposure Prophylaxis
PHC	Primary Health Care Centre
PEPFAR	President's Emergency Plan for AIDS Relief
PI	Protease Inhibitor
PITC	Provider-Initiated Testing and Counselling
PMTCT	Prevention of Mother-to-child Transmission of HIV
PLWHA (PLHIV)	People living with HIV and AIDS
RDA	Recommended Daily Allowances
RHSO	Reproductive Health Services Outlet
RNA	Ribonucleic Acid
RTV	Ritonavir
SAPC	State AIDS Programme Coordinators
SMX	Sulphamethoxazole
STIs	Sexually Transmitted Infections
TB	Tuberculosis
TDF	Tenofovir
TMP	Trimethoprim
TT	Tetanus toxoid
TBA	Traditional Birth Attendant
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VHW	Village health worker/Voluntary health worker
VL	Viral Load
VZV	Varicella Zoster Virus
WHO	World Health Organization
ZDV	Zidovudine

SECTION 1
Introduction

1.0 Magnitude of the problem of HIV and AIDS

The HIV and AIDS pandemic is one of the most serious health crises the world is facing today. A disproportionate burden has been placed on women and children, who in many settings continue to experience high rates of new HIV infections and of HIV-related illness and death. In 2009, 33.3 million individuals were living with HIV, of whom 15.7 million were women and 2.1 million were children under 15 years of age. Globally, HIV is the leading cause of death in women of reproductive age. Since nearly all HIV infections in children are acquired from their mothers, the global epidemiology of HIV in children reflects that of HIV in women. It has been estimated that, in 2009, there were 370, 000 new paediatric infections with sub-Saharan Africa accounting for about 90% of both of these figures. Nearly all such infections can be prevented by PMTCT programmes providing highly effective ART and ARV prophylaxis interventions.

Sub-Saharan Africa has continued to bear the greatest burden of the HIV and AIDS epidemic, with approximately 67.6% of the total number of people living with HIV, 69.2% of the 2.6 million of total new infections and 72.2% of the 1.8 million deaths in 2009. Over the decades, the epidemic, once dominated by infected males has become progressively feminized and in sub-Saharan Africa approximately 60% of adults living with HIV are women. Over 90% of infection in children is acquired through mother-to-child transmission (MTCT) and as more women contract the virus, the number of children infected has been growing.

Since the first case of AIDS was reported in a 13-year old girl in Nigeria in 1986, the epidemic has persisted with National HIV sero-prevalence rate of 1.8% in 1991, 5.8% in 2001and 4.4% in 2005 (see Figure 1.1). It is currently at 4.6% in 2008 antenatal survey.

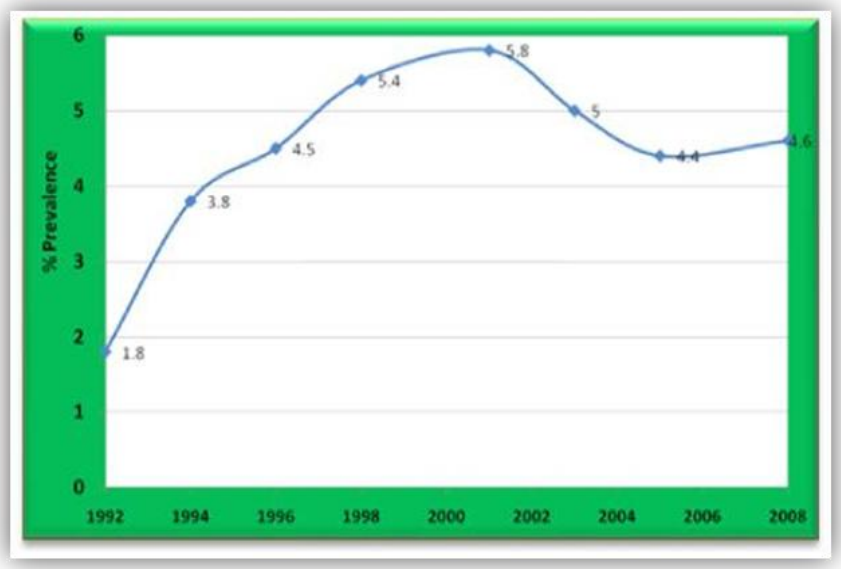

Figure 1.1 HIV Prevalence Trend in Nigeria (1991 – 2008)
Source: National HIV and AIDS Sentinel Sero-prevalence Survey, 2008

The prevalence rate in Nigerian states ranges from 1.0 to 10.6%. Seventeen states had rates above 5%. The prevalence was generally higher in urban areas except in nine states and the FCT. Among young persons, the highest prevalence of 5.6% was in the age group of 25 to 29 year olds. By the end of 2008, it was estimated that there were 2.95 million Nigerians living with HIV. New infections in adults were 323,000 while 57,000 infants were born with HIV. Heterosexual transmission accounts for nearly 80%, while MTCT and use of unsterilized sharps, infected blood and blood products accounted for 10% each.

1.1 Mother-to-Child Transmission of HIV

Most children less than 15 years living with HIV acquire the infection through mother-to-child transmission (MTCT). This can occur during pregnancy, labour and delivery or during breast-feeding. In the absence of interventions, the risk of such transmission is 30-45%.

The high burden of MTCT in sub-Saharan Africa (compared to the rest of the world) is due to higher rates of heterosexual transmission, higher prevalence of HIV in women of reproductive age, high total fertility rate, characteristically prolonged breastfeeding culture, as well as poor access to PMTCT interventions. The burden of MTCT in Nigeria as at 2009 is as shown on Table 1.1. Transmission of HIV in children has become a critical health problem that threatens to undermine the positive impact of child survival strategies in the African continent.

Table 1.1: Estimated magnitude of MTCT in Nigeria *(2009)*

Indicator	Estimate
National Median HIV prevalence (ANC)	4.6%
Estimated Number of people living with HIV	Total: 2.98 million
Annual HIV positive births	Total: 56,681
Cumulative AIDS deaths	Total: 2.99 million • Male 1.38 million • Female: 1.61 million
Annual AIDS deaths	Total: 192,000 • Male 86,178 • Female 105,822
Number requiring anti-retroviral therapy	Total 857.455 • Adult 754,375 • Children 103,080
New HIV infection	Total: 336,379 • Male 149,095 • Female 187,284
Number of children orphaned by AIDS	2,175,760

Source: FMOH (2008) ANC 2008 Report HIV estimates and projection

1.1.1 Risk factors for MTCT

The rate of Mother to Child transmission of HIV is affected by many factors. These have been grouped into viral, maternal, obstetric, foetal and breastfeeding factors (Table 1.2.).

Table 1.2: Factors associated with increased risk of MTCT

Factors	Strong Evidence	Limited Evidence
Viral	• High maternal viral load • Viral characteristics	• Viral resistance
Maternal	• Advanced disease • Immune deficiency • HIV infection acquired during pregnancy or breastfeeding • Sexually transmitted infections • Malaria	• Vitamin A deficiency • Anaemia • Chorioamnionitis • Frequent unprotected sex • Multiple sexual partners • Smoking • Alcohol • Intravenous drug abuse • Genetic (HLA subtypes, mutations of surface CD4 receptor)
Obstetric	• Vaginal delivery • Rupture of membranes for more than 4 hours • Prolonged labour	• Invasive or traumatic procedures • Instrumental deliveries • Amniocentesis • Episiotomy/genital lacerations • External cephalic version • Ante-partum/intra-partum haemorrhage
Foetal/Infant	• Prematurity • First of multiple deliveries	• Lesions of the skin and/or mucus membrane (e.g. oral thrush) • Genetic
Breastfeeding	• Mixed feeding • Breast disease (abscess/mastitis/cracked nipples) • Prolonged breastfeeding	

1.1.2 Prevention of Mother-to-Child Transmission of HIV

The risk of MTCT can be reduced to less than 2% by interventions that include the use of anti-retrovirals (ARVs) as either prophylaxis or therapy given to women in pregnancy, labour and during breastfeeding. In situations where a mother is not receiving ARVs during the breast-feeding period, the breast-fed infant should receive ARV prophylaxis until one week after cessation of all breast-feeding. Where breastfeeding is not possible however, it should be noted that the use of commercial infant formula is an alternative.

Other important measures include avoiding obstetric procedures such as chorionic villus sampling, external cephalic version, early artificial rupture of the membrane, instrumental delivery and episiotomy where possible, as well as active management of the third stage of labour and the use of elective caesarean delivery.

One of the goals of the June 2001 Declaration of Commitment of the United Nations General Assembly Special Session on HIV and AIDS (UNGASS) was to reduce the proportion of infants infected with HIV by 20% by 2005 and 50% by 2010. The Nigerian National goal for PMTCT as contained in the 2003 AIDS Policy is to reduce the transmission of the HIV through MTCT by 50% by the year 2010 and to increase access to quality HIV counselling and testing services by 50% by the same year. To achieve this goal, a comprehensive four-pronged strategy to prevent HIV infection among infants and young children is being implemented in Nigeria since 2001. The strategy includes the following elements:

- Primary prevention of HIV infection in women of reproductive age group and their partners
- Prevention of unintended pregnancies among HIV positive women
- Prevention of HIV transmission from HIV infected mothers to their infants
- Care and support for HIV infected mothers, their infants and family members.

1.2 Goal and Targets of the 2010 - 2015 National PMTCT scale up plan

Goal

The overall goal is to contribute to improved maternal health and child survival through accelerated provision of comprehensive PMTCT services.

Targets

- To provide access to at least 90% of all pregnant women to quality HIV counselling and testing by 2015
- To provide access to at least 90% of all HIV positive pregnant women to more efficacious ARV prophylaxis by 2015
- To provide access to at least 90% of HIV exposed infants to more efficacious ARV prophylaxis by 2015
- To provide access to at least 90% of HIV positive pregnant women to quality infant feeding counselling by 2015
- To provide access to at least 90% of all HIV exposed infants to early infant diagnosis services by 2015.

1.3 Comprehensive approach to primary prevention of MTCT

The United Nations' four-pronged strategy for PMTCT addresses a broad range of HIV related prevention, care, treatment and support needs of pregnant women, mother, their children and families. This comprehensive approach includes the following four elements:

A. Primary prevention of HIV infection in women of reproductive age group and their partners include the following:

- Use of the "ABC" approach to enhance safer and responsible sexual behaviour and practices. This approach involves:
  - A = Abstinence - refraining from having sexual intercourse
  - B = Be faithful - being faithful to one partner
  - C = Condom use - using condoms correctly and consistently.
- Safer and responsible sexual practices include:
  - Delaying the onset of sexual activity until marriage
  - Practicing abstinence

  - Reducing the number of sexual partners
  - Consistent and correct use of condoms.
- Provision of early diagnosis and treatment of STIs: The early diagnosis and treatment of STIs can reduce the incidence of HIV in the general population by about 40%. STI treatment services present an opportunity to provide information on HIV infection, MTCT and referral for testing and counselling.
- Making HIV testing and counselling widely available: HIV testing and counselling services need to be made available to all women of child-bearing age because PMTCT interventions depend on the woman knowing her HIV status.
- Provision of suitable counselling for women who are HIV negative: Counselling provides an opportunity for a woman who is HIV negative to better understand how to protect herself and her infant from HIV infection. It can also serve as powerful motivation to adopt safer sex practices, encourage partner testing and discuss family planning.

B. Prevention of unintended pregnancies among HIV positive women

The responsibility of the government and health services is to provide HIV positive women and their partners with comprehensive information and education about the risks associated with child bearing as part of routine public information about HIV and AIDS, to ensure that HIV positive women and their partners have informed choices of action, and to respect and support the decisions they reach. This means:

- Providing good quality, user-friendly, and easily accessible family planning services so that HIV positive women can avoid pregnancy if they choose
- Promoting condom use combined with a more effective method of contraception (dual method) for dual protection from HIV and other STIs and from unplanned pregnancies as an effective strategy to prevent HIV transmission
- Integrating dual protection messages into family planning counselling services
- Offering contraception to all HIV positive mothers in the immediate postpartum period to prevent unintended pregnancy because lactational amenorrhoea does not guarantee adequate contraception even in women who exclusively breastfeed.

C. Prevention of HIV transmission from infected mothers to their infants

- **Specific PMTCT Interventions**
  - HIV testing and counselling
  - HIV and Infant feeding counselling
  - Modification of obstetric practices
  - Administration of ARV prophylaxis to mother-child pair.

D. Provision of appropriate treatment, care and support to HIV-infected mothers, their infants and family

- **Package of services for mothers**
  - ART for women eligible for treatment
  - Co-trimoxazole prophylaxis
  - Continued infant feeding counselling and support
  - Nutritional counselling and support
  - Sexual and reproductive health services including FP

- Psychosocial support.

- **Package of services for HIV exposed children**
  - ARV prophylaxis
  - Routine immunization and growth monitoring and support
  - Co-trimoxazole prophylaxis starting at 6 weeks
  - Early HIV diagnostic testing at 6 weeks where virologic tests are available
  - Antibody tests for screening of infants and children less than 18 months where virologic tests are not available or for diagnostic testing beyond 18 months
  - Ongoing infant feeding counselling and support
  - Screening and management of tuberculosis
  - Prevention and treatment of malaria
  - Nutritional care and support
  - Psychosocial care and support
  - Antiretroviral therapy for eligible HIV infected children
  - Symptom management and palliative care if needed.

1.4 Benefits of prevention of mother to child transmission of HIV

Most children that acquire HIV through MTCT die within the first two years of life in parts of sub-Saharan Africa where PMTCT services are lacking. The increasing number of AIDS-related deaths in under-fives across sub-Saharan Africa and in Nigeria in particular is threatening to reverse the gains made on child survival programmes. The cost of care and support for HIV infected children places heavy financial burden on families, communities and the health care system. PMTCT benefits the mother, infant, family, community and the health system in the following ways.

1.4.1 Benefits to the Mother

- Identifies HIV positive mothers for targeted interventions to reduce risk of transmission of infection to their babies and to access care and support services
- Promotes positive behaviour change and reduces risk of HIV transmission
- Increases use of dual protection methods of family planning and STI prevention
- Helps to plan for the future
- Promotes infant feeding support
- Promotes access to early preventive and medical care
- Helps personal and financial decision-making.

1.4.2 Benefits to the Infant

- Decreases numbers of HIV infected infants
- Promotes early diagnosis and intervention for the HIV exposed infants
- Improves child health and survival.

1.4.3 Benefits to the Family

- Promotes communication between couples and testing of both partners
- Provides opportunity for testing other family members
- Contributes to reduction of stigma and discrimination
- Helps to plan for the future
- Provides infant feeding support.

1.4.4 Benefits to the community

- Promotes the understanding and acceptance of the HIV and AIDS epidemic and those living with HIV and AIDS
- Promotes uptake of risk reduction practices leading to reduction in the incidence of HIV
- Promotes acceptance and uptake of HIV testing and counselling
- Contributes to reduction of stigma and discrimination
- Helps to plan for the future
- Provides infant feeding support.

1.4.5 Benefits to the health system

- Decreases the disease burden on the health system
- Gives an opportunity to strengthen the health system.

1.5 Implementation Strategies for the National PMTCT Programme

The strategies to achieve the National PMTCT goal and objectives include:

- All antenatal care facilities shall offer HIV testing and counselling for all pregnant women as part of existing integrated reproductive health care services and shall include referrals for family planning counselling and other services when necessary. Testing will be offered routinely with the right to opt-out
- All maternity facilities shall provide counselling on risks associated with the possible MTCT during pregnancy, delivery and breast feeding and adequate information to limit MTCT if the mother is HIV positive, including referrals for family planning services
- All levels of government shall place the highest possible priority on ensuring nationwide access to ARVs for all HIV positive pregnant women and their babies
- All institutions offering antenatal care or child healthcare services shall direct specific attention to maintaining the nutritional status of all HIV positive pregnant women and their children
- Appropriate mechanisms shall be put in place to ensure the training of health care providers at all levels on PMTCT.

1.6 Integration of PMTCT into MCH services and Linkages with other Services

HIV prevention particularly in young women and their partners is the best way to ensure that secondary transmission to infants does not occur. The majority of HIV infections around the world are among young people. Young women account for most new infections among this age group, and the majority of women attending MCH clinics for pregnancy-related care are 15-to-24 years old. During these years, youths learn, explore and make decisions that will affect the rest of their lives. Without the information, skills and services that they need to make informed choices, young people are more likely to engage in behaviours that result in high rates of sexually transmitted infections (STIs), including HIV. It is easier to integrate PMTCT interventions into MCH settings where essential services such as syphilis screening, treatment and partner notification are already in place. Conversely, adding PMTCT interventions provide an opportunity to strengthen essential MCH services and reduce perinatal morbidity and mortality for both mother and child.

Support services for integration and linkages include:

- Provision of ARVs for women and children
- Nutrition and infant feeding counselling and support
- Integrated Management of Childhood Illnesses (IMCI)
- Clinics that target specific needs such as:
  - Family Planning services
  - Sexually Transmitted Infections (STIs)
  - Other disease specific clinics such as DOTs clinics
  - Primary Health Care clinics
  - Community support (CBOs, NGOs and FBOs)
  - Health education services e.g. for behaviour change, nutrition, hygiene, etc.
  - Infant and child welfare clinics.

1.7 Process of setting up PMTCT services

The following steps should be followed for setting up PMTCT services in a new site:

- Conduct advocacy to policy makers in the hospital to solicit their support for PMTCT
- Conduct formative research if no such study has been done in that area, so as to generate data on the knowledge, attitudes, beliefs and practices of health care providers and community members as it relates to HIV and AIDS and PMTCT. The data generated should be used to develop site-specific communication interventions. It will also form a baseline for subsequent evaluation of the programme
- Conduct an assessment to evaluate the capacity of the facility to deliver PMTCT services
- Conduct facility PMTCT sensitization workshop to raise awareness of the care providers
- Adopt the *National Standard Operating Procedure* (SOP) and set up site multidisciplinary PMTCT team with clearly defined roles and responsibilities as outlined in the SOP
- Conduct or ensure that the appropriate staff of the facility are trained on:
  - HIV Testing and Counselling (HTC)
  - PMTCT
  - Infant feeding counselling in the context of HIV
  - EID
  - Monitoring and evaluation
- Establish a sustainable supply system for ARVs, HIV test kits, EID commodities, stationery, registers, summary and request forms, and other consumables
- Develop a communication work plan
- Set up a system for monitoring and evaluation
- Establish linkages with other centres
- Develop an operations research component
- Create demand for PMTCT services through advocacy to the community, sensitizations and awareness creation activities.

1.8 Minimum Capacity Requirements for a PMTCT site

The site should:

- Have a reasonable client flow of ANC attendees
- Be providing ANC services with supervision by a trained health care provider
- Provide HCT services
- Provide delivery services with capacity for caesarean section (or by referral)
- Provide care for the newborn including ARV prophylaxis
- Offer infant feeding counselling and support
- Provide services for paediatric follow-up and early infant diagnosis of HIV (or by referral)
- Provide post-natal services
- Provide family planning services (or by referral)
- Provide cervical screening services (or by referral).

1.9 Management and Coordination of the PMTCT Programme

In order to effectively manage and coordinate PMTCT in Nigeria, the following activities and structures should be put in place:

- FMOH and Partners should facilitate reporting from the sites to the FMOH and feedback to the sites. All sites should have the national PMTCT registers and summary forms and fill them appropriately
- The teams in each site should comprise members from every relevant department and the roles and responsibilities of members of the team, especially the team leaders at the sites, should be properly defined
- The national PMTCT SOPs and flow chart should be used to guide the implementation of services at the sites
- An HIV Prevention and Control Initiative Group (HIPCIG) should be set up in each implementing institution to consist of core implementers of the ARV and the PMTCT and other HIV-related programmes to ensure better coordination, and enhance PMTCT Plus strategy. The group should meet regularly, and develop comprehensive plans and implement accordingly
- NASCP should meet with implementing partners working on PMTCT to determine the process and mechanism for collaboration.

SECTION 2
Management of HIV in Pregnant Women and PMTCT

2.0 Introduction

The entry-point for PMTCT services is through HIV testing of pregnant women attending antenatal care. In all settings, HIV testing and counselling (HTC) should be offered to all pregnant women seeking these services, and service providers should promote strategies to mobilize pregnant women and other women of reproductive age to go for testing and counselling wherever these services are accessible, including home-based testing.

2.1 HIV Testing and Counselling

HIV testing is the process that determines whether a person is infected with HIV or not. HIV counselling is the confidential dialogue between individuals and their health care providers to help clients examine their risk of acquiring or transmitting HIV infection and to make informed decisions based on information available to them.

2.1.1 Benefits of Testing and Counselling in the Antenatal Setting

These include:

- Reinforcement of safer sex practices and empowering HIV-negative pregnant women to remain negative
- Provision of opportunity for counselling on infant feeding with emphasis on exclusive breastfeeding
- Enabling HIV-infected women to access ARV prophylaxis
- Enabling women to make informed choices about future pregnancies
- Providing HIV-infected women the opportunity to seek early medical care for HIV related conditions e.g. TB
- Providing opportunity for referrals
- Providing early diagnosis, treatment and follow-up support for the exposed infant
- Providing the partners and other family members an entry point into HIV services
- Ameliorating the impact of HIV and AIDS stigma in the community
- Empowering women to take part in peer support groups
- Enabling identified HIV infected women to adopt a positive life style.

2.1.2 Challenges of Testing during the Antenatal Period

The challenges of testing during the antenatal period include:

- Limited space for counselling
- Additional workload and stress for health care providers carrying out counselling
- Stigmatization and discrimination of HIV-positive women in health facility and the community
- Frustration for care providers and mothers when ARV and other interventions are unavailable
- Creating potential for disharmony, gender violence and abandonment in the family. In practice, however violence is rarely encountered on disclosure of positive HIV status to partner.

2.1.3 Approach to HIV Testing in Pregnant Women

HIV testing of pregnant women should be accompanied by culturally acceptable counselling that covers the benefits of determining HIV status and its implications for a woman's life, pregnancy and unborn child. The elements of effective counselling are confidentiality, time, acceptance, accessibility, consistency and accuracy.

The recommended approach to testing and counselling is the routine approach (also referred to as the "opt-out" approach) where HIV testing is offered as part of routine tests in antenatal clinics, the woman has the right to refuse taking the test. Mandatory testing is not recommended.

2.1.4 Essential Components of Testing and Counselling for PMTCT

These include:

- Pre-test information
- HIV testing and same day result
- Post-test counselling
- Follow-up counselling.

2.1.4.1 Pre-test Information

Information should be provided to all clients before HIV test is done. The counsellor should explain the basic facts about HIV and AIDS, benefits of testing, MTCT and possible interventions to minimize the risk of MTCT. Couple counselling should be encouraged. These interventions may include:

- Screening for and treating STIs
- Health education on refraining from alcohol and smoking
- Practicing safer sex during pregnancy
- Re-screening in labour for women who tested HIV negative during the antenatal period
- Access to ARV prophylaxis in pregnancy and during breastfeeding for HIV positive women.

Pregnant women should be told that HIV testing is not mandatory and declining an HIV test will not jeopardize their access to antenatal care or other services. Women can always have another opportunity to test should they change their mind.

Educational materials on HIV testing and prevention of MTCT should be available for women to take home to read and also share the information with their male partners and other family members.

Group/individual health information

In antenatal clinics with a large volume of clients it may not be easy conducting individual pre-test counselling sessions. In order to minimize the time spent by clients at the centre, the counsellor could conduct group health information sessions.

The counsellor who leads a group counselling session will need to cope with the complex dynamics that may arise in a group, which include:

- Dealing with an over-assertive dominant individual
- Allowing each participant to speak
- Coping with people who become emotionally distressed in a group
- Being non-judgmental

- Refraining from lecturing the group and allowing the group to learn from each other's experience.

When requested and where feasible, pre-test information about HIV, pregnancy and MTCT should be provided in the form of individual counselling. When recommending HIV testing and counselling to patients, the health care provider should:

- Introduce self and establish rapport
- Gain the clients' confidence and assure her/them of confidentiality
- Provide more information about HIV and AIDS, transmission, HIV testing, window period and the meaning of positive and negative results
- Re-emphasize the benefits of HIV testing and PMTCT services
- Provide information on the benefits of early diagnosis of HIV for infants
- Discuss partner testing and issues regarding concordant and discordant test results
- Discuss any concern the clients may have
- Assess client's personal risks and discuss risk reduction for those seeking individual counselling
- Discuss the possible reaction of the client to positive or negative results
- Clarify that verbal informed consent is sufficient for an HIV test
- Discuss the services available in the case of either a negative or positive result including whether ARVs are available
- Discuss disclosure with partner and family
- Encourage clients to speak openly, frankly and provide an opportunity for questions to be asked
- Emphasize the availability of HIV counselling and testing in pregnancy, labour and delivery for clients that decline testing
- Summarize the reason/s why HIV testing and counselling is being recommended.

Follow-up where HIV testing is declined

Declining an HIV test should not result in reduced quality or denial of services, coercive treatment or breach of confidentiality, nor should it affect a person's access to health services that do not depend on knowledge of HIV status. For individuals declining the test the following should be considered:

- Re-offer individual counselling on the benefits of HIV testing at subsequent contacts
- Discuss and address the barriers to accepting the test and develop a plan to return for HIV test
- Discuss HIV risk reduction
- Discuss exclusive breastfeeding
- Provide take-home information and referral(s) where appropriate.

2.1.4.2 HIV Testing and Same day Result

See Section 2.2 for details of HIV testing.

HIV testing of women in labour

HIV testing in labour should be recommended to all women of unknown status and those who tested negative during pregnancy. This is because some women might not have registered in the antenatal clinic and are presenting for the first time in labour. Such women should be offered the opt-out approach and given appropriate post-test counselling in the post partum period or pre-test counselling if she had declined the test.

The following should be considered:

- Determine HIV test history
- Discuss the benefits of testing and ARV prophylaxis
- Explain the testing process
- Offer the test.

If the above is not feasible at the time the woman presents, steps should be taken to offer the test as soon as possible after delivery.

2.1.4.3 Post-test Counselling

Post-test counselling is an integral component of the HIV testing process. All individuals undergoing HIV testing must be counselled when the test results are given, regardless of the test result. Test results should be available on the same day. Same day results are recommended for all clients receiving HIV testing using rapid tests. Information, education and communication (IEC) materials on HIV and on testing should be made available to all pregnant women.

The health care provider should take the following steps in post-test counselling:

- Introduce self and establish rapport
- Assure the client of confidentiality
- Assess the readiness of the client to receive the test result.

For clients with HIV positive results:

- Disclose the result immediately, simply and clearly in a neutral manner
- Allow time for her to understand the implication of the test result *(this may require subsequent visits)*
- Determine whether she understands the meaning and implications of the test result
- Ask about her feelings and concerns and provide support in coping with emotions arising from the test result
- Discuss:
    - Disclosure of the result and address when, how and to whom
    - HIV testing for partner and other family members
    - About and inform her on availability of essential PMTCT services including ARV prophylaxis/treatment
    - The need to screen for TB, STIs and cervical cancer
    - Importance of EBF with ARVs for HIV free Survival and available support
    - The mode of delivery and the need for health facility-based delivery
    - Personal risk reduction plan
- Inform and encourage her:
    - To access family planning services considering her future fertility needs
    - To access available care and support services
    - To attend subsequent ANC visits and stress the importance of delivering in a health facility providing PMTCT services
    - On the relevant preventive health measures such as good nutrition, use of CPT, IPTp and ITN
- Discuss:
    - Available support systems at home and in the community

- Adequate maternal nutrition including iron and folic acid supplementation
- HIV testing for the infant and necessary follow-up and linkages
- The need for further investigations such as FBC, CD4 count, VL, serum chemistry, and others as the need may arise

- Summarize information and provide IEC materials.

For clients with HIV negative results:

Providing post-test counselling for HIV negative women is an opportunity to provide them with adequate information to remain negative.

- Disclose the result immediately in a neutral manner
- Discuss the meaning of a negative result; a negative result does not imply immunity against HIV for life
- Remind the client about the window period, and encourage her to repeat the test in 3-6 months
- Discuss:
  - About re-screening in labour
  - Risk reduction strategies
  - Partner HIV testing and disclosure
  - Exclusive breast-feeding.

2.1.4.4 Follow-up Counselling

Follow-up counselling is regular counselling on short or long term basis for clients living with HIV and meant to provide support for both infected mother and baby. Follow-up counselling issues include:

- Concerns about relationships: sexual and others
- Risk reduction
- Hope for survival and positive living for both baby and mother
- Referral to other care and support services for both baby and mother
- Coping with own feelings: anger, loneliness, suicidal thoughts, hopelessness and depression
- Economic empowerment, employment and other practical issues
- Partner involvement
- Disclosure
- Stigma, fear of isolation and prejudices.

2.1.5 Other Components of HIV Counselling in PMTCT

2.1.5.1 Partner notification, couple counselling and significant others

The counsellor should not disclose the result(s) without the informed consent of the client but should explore issues surrounding disclosure of an HIV result to a partner and significant others.

Partner notification helps:

- To make choices around infant feeding practices easier
- The infected partner access health care earlier
- Offers the partner opportunity to provide other psychosocial support for adherence to therapy, clinic appointments, family planning etc.

Couple counselling and testing helps:

- To address the challenges associated with disclosure

- To reduce HIV transmission from one partner to the other
- Decision-making easier about sexual behaviour and act on those decisions.

Where couples are reluctant to be tested together or men are reluctant to test with their partners, it may be appropriate to refer them elsewhere. Partner testing should be adapted to the services in the facility and can take place either in the ANC or the HTC centre.

Couple HIV counselling and testing has emerged as an important intervention aimed at preventing the transmission of HIV between individuals who are sex partners in sub-Saharan Africa. Counsellors should assist couples by:

- Providing clear and accurate prevention messages;
- Mitigating tension and diffusing blame
- Dispelling myths
- Providing tailored HIV prevention messages based on the couple's life style.

Significant Others:
Some women may wish to involve other family members such as mothers, sisters or other relatives who can take on important supportive roles.

2.1.5.2 Sharing HIV Status with Health Providers
For a pregnant woman to benefit from the many MTCT interventions, it is important that other health care providers are aware of her HIV status on a 'need to know basis'. The woman should be counselled on the benefits of such shared confidentiality and be assured that it would not result in stigma and discrimination against her.

2.1.5.3 Understanding Proposed PMTCT Interventions
For a woman to make informed decisions about her pregnancy, counsellors should present available options for treatment and care. ARV for PMTCT should be offered to all infected pregnant women. Detailed explanations, monitoring and follow-up are particularly important, since the treatment procedure is complex and involves a number of different services, including family planning and infant-feeding support.

2.1.5.4 HIV and Infant Feeding
All HIV infected mothers should be encouraged to exclusively breastfeed their babies for the first 6 months, after which complementary feeds are introduced and breastfeeding continues for up to 12 months. Breastfeeding should be accompanied with maternal ART or ARV prophylaxis and/or infant ARV prophylaxis.

If a mother had previously passed through the PMTCT programme, the reasons for the change in policy on infant feeding in the context of HIV should be explained in simple language to stress:

- Shift of emphasis to HIV-free infant survival
- Use of BMS (commercial infant formula and others) is associated with increased risk of infant morbidity and mortality
- There are many benefits to EBF
- Mother-infant pair using ARVs makes breastfeeding safe.

2.1.5.5 Risk Reduction Strategies

Counsellors should discuss:

- Safer sex practices and the women should preferably involve their partners
- Use of condoms (male and female condoms)
- Beliefs and constraints regarding the use of condoms.

2.1.5.6 Sexually Transmitted Infections (STI)

In generalized epidemics as we have in Nigeria, HIV is primarily transmitted through heterosexual sex and the presence of an STI can increase the risk of HIV acquisition or transmission including MTCT. Diagnosis of STI, partner notification and treatment should be discussed. Patients diagnosed with STI should be offered HIV testing and encouraged to discuss HIV testing and counselling with their partners.

2.1.5.7 Family Planning

Knowledge of HIV/AIDS and HIV sero-status may increase a woman's ability to make voluntary and informed decisions about the number, spacing and timing of pregnancies, including the use of contraceptive methods. It is recommended that testing and counselling be integrated into reproductive health services

Issues for discussion include:

- Contraceptive options
- Dual protection
- Dual methods
- Decisions on future fertility.

2.1.5.8 Referral for Related Health care and Social Support

Counsellors should be aware of the locally available resources in relation to a pregnant woman's on-going health and support needs. In order to provide comprehensive and long-term care, other issues that should be addressed include:

- Other children
- Responsibilities of the woman and her partner (e.g. compliance with follow-up schedules)
- Means of support
- Referral to local services and support groups.

2.1.5.9 Planning for the Future

Issues for discussion include:

- Fate and future of their children if the parents become sick or die
- Living with uncertainty
- More information on HIV and safer sex practices
- Referral for spiritual and legal support.

2.2 Clinical Evaluation in PMTCT

The goals of investigations in the PMTCT setting are to:

- Accurately detect all HIV positive pregnant women
- Detect the presence of other diseases whose presence can increase the transmission of HIV, or which are themselves transmittable from the mother to the child, or which can increase morbidity in the mother
- Determine CD4 counts for prophylactic and therapeutic purposes

- Determine viral load when available
- Detect infection status in exposed infants
- For women that will require ART, organ and system function tests should be carried out prior to and while on therapy.

2.2.1 Confidentiality Code for Laboratory tests

All HIV associated test results should:

- Be properly secured to prevent access by unauthorized individuals
- Be sealed and delivered to the clinician responsible for the client
- Not be communicated to the patient by telephone or e-mail.

2.2.2 Laboratory Diagnosis of HIV Infection in Pregnant Women

The laboratory testing for diagnosis of HIV infection is either by direct detection of the viral particles or its components or by indirect methods of detection of antibodies against the virus. The use of indirect method in adults is as reliable as direct viral detection especially where testing is done with consideration to avoid the window period after a previous exposure to a risk or source of HIV.

2.2.2.1 HIV Antibody Tests

There are 3 types of HIV antibody tests:

a) Simple or rapid tests
b) Enzyme-linked Immunosorbent Assay (ELISA) tests
c) Western Blot tests.

a.) Simple/rapid tests

These utilize whole blood or serum, do not require special equipment or highly trained staff, and are as accurate as the ELISA tests. Simple/rapid tests will usually give results in less than 30 minutes and are easy to perform. They can be performed by laboratory personnel or by other health care providers trained to use them. Linkages should be established with medical laboratory personnel to provide quality assurance.

Figure 2.1 shows the serial rapid HIV testing algorithm recommended for use in PMTCT settings. A "screening test kit" is used initially, with the use of a "confirmatory test kit" only when the result of the first test is positive. A third, or "tie-breaker" test is then required to resolve the discordance whenever the first two rapid tests differ. The result obtained by the tiebreaker kit is reported as the ultimate HIV test result. If however the screening test is negative, the test result is reported as HIV negative.

NB: *Refer to current National HTC Guidelines for details on HIV testing and counselling.*

Recommended HIV rapid antibody test kits

The following rapid antibody kit combinations shown below are recommended for use as screening, confirmatory and tiebreaker tests consecutively.

1. Screening test	Determine	Unigold	Determine
2. Confirmatory test	Unigold	Statpak	Statpak
3. Tiebreaker test	Statpak	Determine	Unigold

b.) ELISA tests

This method is the most efficient for daily testing of large numbers of samples. It however requires expensive equipment, highly trained staff, maintenance and a reliable power supply. They are used in big laboratories that are attached to tertiary institutions for blood safety and diagnosis because they are very sensitive (false negative tests are rare).

c.) Western Blot test

This is a confirmatory HIV test. It has the advantage of making diagnosis of HIV1 and HIV2. However, it is expensive and more difficult to perform.

2.2.2.2 Direct Methods of HIV Detection

These tests detect the presence of HIV components, antigens or complete virus. They include:

- **p24 antigen test**: detects the presence of p24, a viral core antigen
- **RNA PCR**: the human immunodeficiency virus is an RNA virus. RNA PCR tests detects the presence of cell-free virus (HIV RNA) in body fluids; it measures viral load (VL) or number of viral particles present in a unit of blood (ml or micro-liter)
- **DNA PCR**: detects host cell associated virus or the genetic material (DNA templates of HIV RNA duplicated for insertion into host DNA); it indicates active viral replication
- **Viral culture**: carried out to incubate and grow the virus in a medium: characterizing strains of HIV including drug resistant strains.

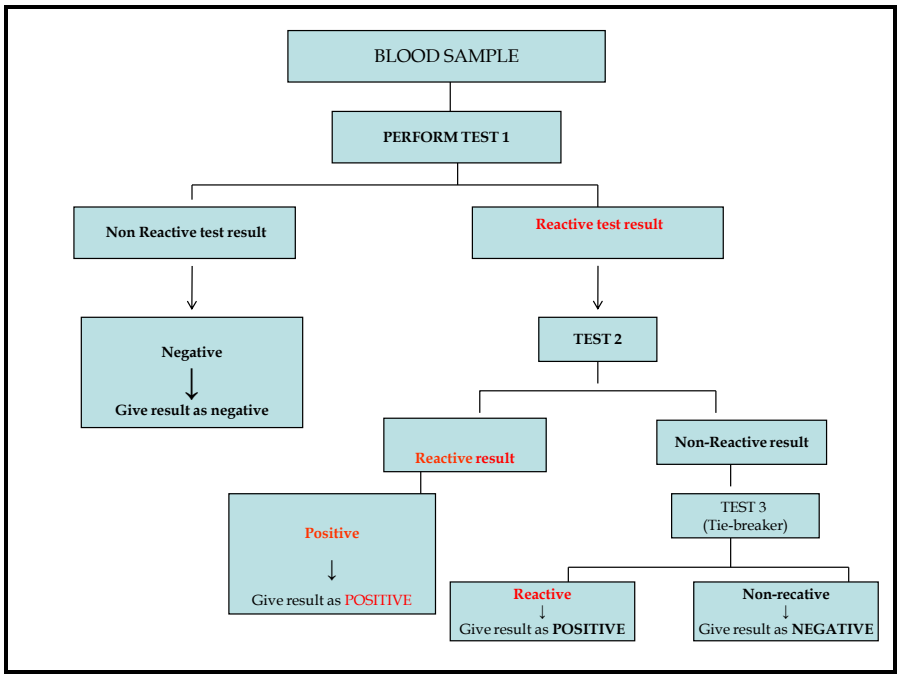

Figure 2.1 Serial Rapid HIV Testing Algorithm

2.2.3 Other Routine ANC Tests Required

Other tests for the pregnant woman include:

- Blood grouping (ABO)
- PCV
- Urinalysis
- VDRL for Syphilis

- Blood glucose
- Haemoglobin genotype
- Blood film for malaria parasites.

2.2.4 Laboratory diagnosis of HIV infection in children*

2.2.4.1 Antibody tests

Babies born to HIV-positive mothers could have some maternal antibodies to HIV in circulation, and may test positive using the available antibody tests until about the age of 18 months when the maternal antibodies completely disappear. However, antibody tests can be used to exclude HIV infection from the age of 9 months if the test result is negative and the infant has not been exposed to maternal breast milk in the 3 months preceding the test. This means that antibody testing in the child can only be reliably used to diagnose HIV infection after the age of 18 months provided the child has stopped breastfeeding at least 3 months earlier.

In a breastfed child, antibody test should be carried out at least 3 months after cessation of all breastmilk.

2.2.4.2 Polymerase Chain Reaction (PCR)

Polymerase Chain Reaction measures HIV nucleic acid (DNA and RNA), and is not affected by the maternal antibodies. If this is available, a diagnosis can be made soon after delivery (usually as early as 6 weeks after birth).

The DNA PCR is used for diagnosis in infants and can be performed on dried blood spots (DBS) samples collected on a special filter paper or fresh whole blood. These samples can be collected from infants at a PMTCT site or wherever health care providers come into contact with exposed children for transport to referral laboratories where they are analysed.

**NB: Refer to National Guidelines on Early Infant Diagnosis of HIV for details.*

2.2.5.1 Measuring Maternal Immune Status

2.2.5.1 CD4 cell count

The CD4 T lymphocyte count is used to determine the immune status of the HIV infected individual. This is necessary to determine whether treatment or prophylaxis is required. Sites offering PMTCT services that do not have this available should have a blood sample referral system with the nearest laboratory equipped to conduct the test. CD4 tests can be either manual or automated.

Manual systems

Manual tests are simple and can be performed at most laboratories with trained personnel, a microscope and the necessary test kits. They involve staining for CD4 cells and using a counting chamber to count the cells under a microscope. Manual technology is ideal for PMTCT linked sites and primary health care centres. Examples include C*ytospheres and Dynal beads.*

Automated systems

Automated tests use computerized machines (*Cyflow, Point care, Guava*) to measure CD4 count. Some of these machines also measure the CD4 percentage. They are ideal for

laboratories with a high volume of samples, a good power supply and good temperature control.

2.2.6 Screening for sexually transmitted and opportunistic infections

Where possible, there is a need to screen for certain STIs and OIs in pregnant HIV positive women as they could be transmitted to the infant thereby increasing the risk of MTCT or increase maternal morbidity. It is recommended that based on the availability of facilities, the following diseases should be screened for in the HIV positive pregnant woman.

2.2.6.1.1 Tuberculosis

Any client with a chronic cough or other symptoms suggestive of TB should be referred to the nearest national TB DOTS centre for clinical evaluation, possible chest X ray and sputum testing as appropriate. Those not screened during pregnancy should be screened after pregnancy.

2.2.6.1.2 Syphilis

Syphilis should be screened for using VDRL.

2.2.6.1.3 Hepatitis B

Mother to child transmission is the commonest cause of hepatitis B infection in children. It also increases morbidity in the HIV positive woman. It can be screened for using test kits for Hepatitis B Surface Antigen (HBsAg).

2.2.6.1.4 *Chlamydia trachomatis*

Performing culture of vaginal specimen can screen for chlamydia. Antigen screening tests for active infections and antibody tests for previous exposure are also recommended.

2.2.6.1.5 Gonorrhoea

Neissaeria gonorrhoea can be screened for using microbiological examination of endo-cervical specimen.

2.2.6.1.6 Human papilloma virus (HPV)

HPV infection is associated with HIV infection and can cause cervical cancer. Refer client as appropriate to the nearest centre for cancer screening.

2.2.6.1.7 Urinalysis for significant bacteriuria

A simple dipstick test is sufficient if the woman has significant bacteriuria, which should be treated even in the absence of symptoms.

2.2.7 Sample handling

- The critical aspect of quality assurance that guarantees reliable results
- Appropriate samples must be collected as specified by the test procedure and properly maintained throughout the duration of the assay
- Samples for long term storage should be stored frozen and thawed only when needed for assay
- Standard precautions must be used to handle blood and body fluid specimens
- The term 'universal precautions' refers to a concept of blood borne disease control which requires that all human blood and other potentially infectious materials be treated as if known to be infectious for HIV, HBV, HCV or other blood borne

pathogens, regardless of the perceived 'low risk' status of a patient or patient population
- Laboratories must have written procedures for handling spills of blood and other body fluids.

2.2.8 Transportation of samples

- There must be documented procedures detailing transportation and handling of all patient specimens to ensure that all specimens are submitted in appropriately labelled and well-constructed containers with a secure lid to prevent leakage during transport
- For assays that require cells or plasma, an adequate cold chain must be maintained to ensure sample integrity.
- For dried blood spot samples the drying and packaging procedures must be adhered to in order to prevent contamination.

2.2.9 Waste disposal

The laboratory is responsible for protecting staff against all real or potential hazards of wastes at all stages of disposal, including transportation and disposition. Such methods include:

- All infectious wastes that may be contaminated (e.g. glassware, blood collection tubes, specimens, and other solid or liquid waste or refuse) must be discarded into 'biohazard' labelled containers that do not leak and have solid, tight-fitting covers that are applied before transport from the laboratory work area for storage and disposal
- Syringes, needles, lancets, or other bloodletting devices that are capable of transmitting infection from one person to another must be used only once and then discarded
- All waste 'sharps' (e.g., needles, scalpels, glass and plastic sharps) must be discarded in puncture-resistant containers that are easily accessible, located in areas where sharps are commonly used, and that have been properly labelled to warn handlers of the potential hazard
- Shearing or breaking of contaminated sharps is completely prohibited. Bending, re-capping, or removing contaminated needles is prohibited as a general practice. Used needles should be immediately discarded un-recapped, into accessible sharps containers.

2.3 Preconception (Pre-pregnancy) care in the context of HIV

Preconception care is recognized as a critical component of health care for women of reproductive age. The main goal of preconception care is to provide services for health promotion, screening and interventions for women of reproductive age before pregnancy to reduce risk factors that might affect subsequent pregnancies. Screening for HIV infection is strongly recommended for women with unknown HIV status, who are considering pregnancy.

With the advent of ARVs, HIV infected patients are living longer, healthier lives and many now view HIV infection as a manageable chronic infection. Many HIV-affected couples desire to have children and the main challenge is planning for the best time and means to

achieve this without transmitting infection to the partners (in sero-discordant settings) or off-spring.

In the context of HIV, pre-pregnancy care provides an excellent opportunity for addressing the four elements of a comprehensive approach to PMTCT.
Specifically, it provides an opportunity:

- To provide HIV prevention messages to women of reproductive age before pregnancy
- For prevention of unintended pregnancy among women infected with HIV
- For couple testing and counselling,
- For couple education and partner disclosure of sero-status
- For promotion of adherence to interventions and follow-up

In Nigeria, as in many under-resourced countries, pre-pregnancy care is yet to attain the prominence it deserves.

Table 2.1. Minimum equipment required for a HCT centre

No.	Description of equipment	Counselling Room	Reception	Laboratory	Waiting Area
1	Steel cabinet	2	2	-	-
2	Desk/table	1	1	1	-
3	Chairs	4	2		6
4	Fans	1	1	1	1
5	Sitting benches	-	2	-	3
6	Formica-topped working table	1	-	1	-
7	Sink (or wash-hand basin)	1		1	-
8	Generator (2 KVA)	-	-	1	-
9	Refrigerators	1	-	1	-
10	Shelves	1	-	1	4
11	Lab consumables; e.g. Automated pipettes 2, Pipette tips 200, Cotton wool 4, Plastic container with cover for cotton swabs 2, Racks (2:cryo tube size), cryotubes 200, Spirit 4L, Hard-cover notebooks 6,Sodium Hypochlorite (4 litres), Lancet (3 Pkts), Plasters (3Pkts), Detergent (1Carton), Toilet soap (1 Carton).				
12	Cards for documentation/records	4000			
13	Referral forms	500			
14	HCT registers	2	2	2	
15	Waste bin	1	1	1	1
16	Latex gloves (cartons of 100)	20			
17	Protective goggles	2			
18	Disposable nylon bags (black)	300			
19	(Sharp-proof) disposable container	1		1	
20	Computer, Printer (HP Laser 1320), UPS and accessories	-	1	1	1
21	Television, DVD Player	-	-	-	1

Action steps for pre-conception care

Facilities should establish a preconception care clinic to address a wide range of concerns of couples contemplating pregnancy. Care providers in this clinic should be well trained in HIV and PMTCT related issues. This service should be part of the PMTCT package that HIV positive couples can access when they are desirous of pregnancy. This clinic should focus on the following:

- Achieving safe conception
- Family planning messages in the context of HIV
- Couple counselling and HIV testing
- Couple education
- Partner disclosure
- ART adherence promotion
- Diagnosis and treatment of OIs such as TB
- STI diagnosis and treatment
- Discordant couple management
- Management of abnormal menstruation/infertility
- Information on support groups
- Sex education.

For women with HIV infection, preconception care must focus on recommendations for safe sexual practices that prevent HIV transmission to sexual partners and protect women from acquiring potentially harmful sexually transmitted diseases or even additional strains of HIV that may be more virulent or resistant to therapy.

Women also need education about perinatal transmission risks and prevention strategies, expectations for the child's future, and where desired, effective contraception until the optimal maternal health status for pregnancy is achieved.

Appropriate therapy to maximally reduce viral load and optimize immune function before pregnancy is important. Specific counselling regarding available reproductive options that both prevent HIV exposure to uninfected partners, as well as preventing super-infection with resistant or more virulent virus should be discussed

2.3.1 Preconception Counselling Package for HIV-infected Women

The following should be included in preconception counselling for HIV-infected women:

- Selection of effective and appropriate contraceptive methods to reduce the likelihood of unintended pregnancy
- Education and counselling on perinatal transmission risks, strategies to reduce these and potential effects of HIV or treatment on pregnancy course and outcomes
- Initiation or modification of ART avoiding agents with potential teratogenicity for the developing foetus (e.g., efavirenz, hydroxyurea) and choosing agents effective in reducing MTCT, attaining a stable, maximally suppressed maternal viral load
- Evaluating and controlling for therapy-associated side effects which may adversely impact materno-fetal outcomes (e.g., hyperglycemia, anaemia, hepatic toxicity)
- Evaluation and appropriate prophylaxis for OIs and immunizations (e.g., pneumococcal, or hepatitis B vaccines) as indicated

Table 2.2 Suggested steps in preconception care in the context of HIV

Preconception counselling	Preconception counselling for couples	Exclude AIDS-defining illness using WHO criteria	Investigations
The topics to focus on are: • Achieving safe conception • Family planning messages in the context of HIV • Couple counselling and HIV testing • Couple education • Partner disclosure • ART adherence promotion • STI diagnosis and treatment • Diagnosis and treatment of OIs (e.g. TB) • Discordant couple management • Management of abnormal menstruation/infertility • Sex education • Information on support groups	The topics to focus on are: • Discussion of safer conception techniques • Discussion of risk of transmission to partner and baby • Current and future health of infected partner(s) • Infant feeding • Critical need for adherence to interventions	Patients already receiving anti-retroviral therapy: • Ensure regimen of drugs without teratogenicity effects • Ensure adequate therapy for at least 1 year with appropriate follow-up (stable viral load and CD4+ cell count)	Carry out the following: • CD4 counts • Viral load • Full blood count including platelets • Liver function tests • Hepatitis virus screening • Screen for sexually transmitted infections (Syphilis, Gonorrhoea, Chlamydia trichomoniasis) • Screen for TB • Investigate infertile couples as appropriate

- Optimization of maternal nutritional status
- Institution of the standard measures for preconception evaluation and management (e.g. assessment of reproductive and genetic disease history, screening for infectious diseases/STIs and initiation of folic acid supplementation)
- Screening for maternal psychological disorders and substance abuse
- Planning for perinatal consultation if desired or indicated.

2.4 Antenatal Care for HIV Positive Women

2.4.1 Specific Modification of Obstetric Care for HIV Positive Women

It is important that health care providers in the antenatal clinic are able to identify women who have tested positive in order to treat them appropriately. This must be done in a way that respects their privacy and rights. As part of the initial counselling, women should be told why it is important that health care providers know their HIV status. Each health facility will need to identify a way to make this available in the notes, without making it accessible to the public.

When a woman is known to be HIV positive or is diagnosed as HIV positive during pregnancy, her obstetric and medical care will need to be strengthened and modified. Post-test counselling for HIV positive pregnant women should include information on the following:

- Disclosure, partner notification and testing
- Benefits of PMTCT intervention
- ARV
- Nutrition
- Delivery
- Infant feeding
- The need for follow-up and adherence.

All HIV positive women should be given optimal health care to ensure their safe delivery. In a situation where the life of the woman is being threatened by the continuation of the pregnancy, termination of pregnancy should be in accordance with the provisions of the law.

Note

- Additional visits will not be required for obstetric reasons, although she may need to attend for further counselling sessions
- Avoid invasive procedures such as chorionic villous sampling, amniocentesis or cordocentesis
- External cephalic version (ECV) may carry a risk of HIV transmission to the foetus and should therefore be avoided
- Care should be individualized in special circumstances such as premature rupture of membranes (preterm and term) and ante-partum haemorrhage
- Use of the partograph: proper and consistent use of the partograph in monitoring the progress of labour will improve the management and reduce the risk of prolonged labour in all women
- Artificial rupture of membranes (ARM) is practiced routinely in many settings although it should be reserved for women with abnormal progress of labour. Rupture of membranes of more than four (4) hours duration is associated with an

increased risk of HIV transmission. Therefore early ARM should be reserved for those with foetal distress or abnormal progress. ARM can be done if cervical dilatation is 7 cm or more

- Instrumental delivery: forceps and vacuum delivery should be avoided as they have been shown to be associated with increased risk of MTCT. If it has to be done, vacuum with silastic cup is preferred
- Vaginal cleansing with chlorhexidine (0.25% solution) is believed to reduce the risk of puerperal and neonatal sepsis. It may also have some effect on HIV transmission where membranes are ruptured for more than 4 hours. After every vaginal examination, the birth canal is wiped with gauze or cotton wool, soaked in chlorhexidine solution. The number of vaginal examinations should be kept to a minimum
- Routine episiotomy has been shown to have no obstetric benefit; it should be used only for specific obstetric indications.

2.4.2 Initial Examination

An HIV-infected pregnant woman should have a full physical examination. This should focus on HIV related symptoms and illnesses and signs of OIs (especially tuberculosis). Special attention should be paid to the following:

- Anaemia
- Persistent diarrhoea
- Respiratory infections: TB is a common OI and other bacterial respiratory infections are common in HIV-positive women
- Oral and vaginal candidiasis
- Lymphadenopathy
- Herpes zoster (chronic/re-current) is a common presenting sign of HIV infection, occurring early in the disease, often before there is much immune suppression
- Other skin conditions such as Candidiasis, vaginal wart, etc
- Other sexually transmitted infections
- Weight gain or loss.

2.4.3 Laboratory Investigations

HIV positive pregnant women should be tested for syphilis (VDRL) and have haemoglobin or haematocrit estimation and urinalysis done. If resources permit, the following investigations may be valuable:

- Hepatitis B and C
- Full blood count (FBC)
- Blood film for malaria parasites
- Tests for sexually transmitted infections e.g. gonorrhoea and chlamydia
- Liver function test
- Renal function test
- Lipid profile
- CD4 cell counts
- Viral load.

2.4.4 Nutritional Support

All women need advice on healthy diet and may need nutritional support during pregnancy. However, HIV positive women should be advised on the following:

- Eat small but frequent meals to increase food absorption
- Ensure adequate diet by intake of energy and protein rich foods, fruits and vegetables
- Ensure micronutrient supplementation during pregnancy, which should include: iodine, zinc, calcium, magnesium, iron, folic acid, selenium and vitamins A, C, B6, B12 and D.

These micronutrients may enhance the immune status of the client. They may be found in dark green leafy vegetables, yellow and orange fruits, sweet potatoes, pumpkins, carrots, avocado and tomatoes.

2.4.5 Lifestyle and Behavioural Change

Behavioural changes that should be encouraged to reduce risk of MTCT include:

- Smoking, alcohol and recreational drug use should be discouraged
- Unprotected sex during pregnancy and breastfeeding may be associated with an increase risk of HIV transmission to the baby. Women should be encouraged to use condoms, even with their spouse or trusted partner, to protect against HIV and other STIs. Couple counselling and testing is encouraged so that both partners know if they are at risk for HIV infection with unprotected sex
- Women should be counselled on how to deal with stress and on a healthy lifestyle.

2.4.6 Treatment of Common Infections

- HIV positive women may have other sexually transmitted infections that will require treatment, e.g. syphilis and gonorrhoea
- Urinary tract infection and respiratory infections are more common in HIV positive women and may require antibiotic therapy
- Vaginal candidiasis may be recurrent and may be treated with local antifungal compounds.

2.4.7 Prophylaxis for Common Infections and Clinical Conditions

Prophylaxis in HIV positive women should include:

- Iron and folate: ARVs especially AZT predisposes patients to high risk of developing anaemia
- Multivitamin supplementation
- Tetanus toxoid immunization
- Intermittent preventive treatment (IPTp) with Sulfadoxine-pyrimethamine (SP) for malaria: 3 doses of SP are recommended for all HIV positive pregnant women, avoiding the first trimester and the last 4 weeks of gestation. Those already on co-trimoxazole prophylaxis need not have the antimalarial prophylaxis. Women sensitive to sulphur drugs should be given proguanil or other alternatives
- *Pneumocystis jirovecii pneumonia* (PCP) prophylaxis: PCP prophylaxis (Co-trimoxazole 960mg once daily) should be given to women with CD4 cell counts below 350 cells/µl).

2.5 Intrapartum care

It is important that HIV positive women are not isolated or treated differently from other women in labour. Supportive measures, empathy and caring attitudes by the health care provider are necessary to boost the morale of the client. It is known that 50–60% of MTCT and most accidental exposure to health care providers occur during this period. Therefore universal safety precautions *(Section 4*) should be applied by all health care providers on all women in labour irrespective of their HIV status.

2.5.1 Factors associated with Increased Risk of MTCT

Increased risk of MTCT is multi-factorial involving viral, maternal, placental and foetal conditions as well as the delivery process.

2.5.1.1 Viral Factors:

- Viral load; the higher the viraemia the higher the risk of transmission
- Presence of resistance to anti-retroviral drugs
- Transmission rates are higher with HIV 1 than HIV-2 infection.

2.5.1.2 Maternal Factors:

The following conditions increase MTCT.

- Low CD4 cell count
- Symptomatic disease
- Poor nutritional status
- Presence of STIs and other genital ulcers during labour.

2.5.1.3 Placental Factors:

- Placental disruption from any cause increases the chance of feto-maternal transfusion thereby increasing the risk of HIV infection
    - Antepartum haemorrhage
    - Intra partum haemorrhage
- Chorioamnionitis
- Placental malaria.

2.5.1.4 Obstetric Factors:

These include:

- Vaginal delivery with higher viral load
- Invasive obstetric procedures
    - External cephalic version
    - Foetal scalp electrodes and foetal blood sampling
    - Instrumental deliveries like vacuum extraction or forceps
- Prolonged duration of rupture of foetal membranes (PROM)- 4 hours and above)
- Prolonged labour
- Episiotomy and genital lacerations
- First born of multiple pregnancies.

2.5.1.5 Foetal Factors:

- Prematurity
- Foetal genetic characteristics.

2.5.2 Rapid HIV Testing in Labour

Health care providers should verify the HIV status of all women who are admitted to the labour ward by checking on the mother's records and/or by asking the mother whether she has been tested for HIV. The management of those who are HIV positive is discussed below.

Women of unknown HIV status and those who had tested negative earlier in pregnancy are candidates for rapid testing and counselling in labour. It is therefore recommended that routine HIV testing in labour (with right to opt-out) should be offered to them. If this is not possible during labour, the health care provider should provide testing and counselling at the earliest possible time after delivery.

2.5.3 Management of HIV Positive Women in Labour

2.5.3.1 Prophylactic ARVs

Prophylactic ARVs are recommended for all HIV positive pregnant women. The detailed recommendations are found in Section 3.

2.5.3.2 Mode of Delivery

Vaginal delivery

HIV positive women should be allowed vaginal delivery where there is no contraindication and especially those who have accessed ARV prophylaxis/therapy in the antenatal period and whose maternal viral load may be considered to be low.

(a) *Management of labour*

Labour management should follow usual obstetric guidelines. Women need not to be isolated, but labour ward staff must use universal safety precautions with all patients. *(See Table 2.5: Interventions for safe vaginal delivery)*. Analgesia should be given in labour if required and epidural analgesia is not contraindicated.

(b) *Support during labour*

Emotional support during labour is important for all women, and may be even more necessary for the HIV-infected woman concerned about her condition and risks of HIV transmission to the child. This may be made worse by fear of stigmatization and discrimination by medical staff, or because she has not disclosed her status to her partner or family members. Whenever possible, during labour, HIV positive women should have the option to have a companion of their choice who knows their HIV status and can provide supportive companionship. Where this is not possible labour ward staff must be sensitive to the fears and concerns of the HIV positive mother about her infection, and how much she had told any of her companions.

(c) **Induction of labour**

As prolonged rupture of membranes is associated with increased risk of MTCT, careful assessment of the desirability of CS rather than induction of labour is necessary. Labour could be induced with ARM, oxytocin, prostaglandins or a combination out of these. Where induction is chosen, membranes should be left intact for as long as possible. Oxytocin should not be used with intact membranes. The use of prostaglandins or its analogues can be considered.

(d) *Conduct of Delivery*

Delivery should be conducted using standard practices and aseptic techniques while avoiding unnecessary trauma or prolongation of the second stage.

Caesarean Section

HIV infection on its own is not an indication for CS. Available evidence shows that elective CS for women on ART with low VL (<1000 copies/ml) has no added advantage over vaginal delivery.

Table 2.3 Interventions for safe vaginal delivery

Interventions during labour/delivery	Care of the baby at delivery	
• Perform vaginal cleansing with warm (0.25%) chlorhexidine solution to prevent genital infections • Avoid: o Frequent vaginal examinations o Episiotomies unless absolutely necessary o Instrumental delivery unless when necessary • Clamp cord immediately after baby is delivered and avoid milking the cord • Cut cord under cover of wrapped gauze swab to avoid blood spurting.	• Wipe baby's mouth and nostrils with gauze at delivery of the head. • Handle all babies with gloves regardless of mother's HIV status until blood and secretions are washed off • Keep all babies warm soon after delivery • Wipe the baby dry with a towel or cloth to remove maternal body fluids • Where suctioning is indicated, a mechanical suction unit (at a pressure below 100mmHg) or bulb suction should be used; mouth operated suction is contraindicated • Place the baby on the mother's body for skin-to-skin contact soon after delivery.	• Help her attach and position the baby to her breast.

Elective CS should only be offered to HIV positive women before the onset of labour or rupture of membranes especially in the absence of ART or where the maternal viral load is high. Available evidence shows that when elective CS is performed before the onset of labour or rupture of membranes, it reduces the risk of MTCT by greater than 50% as compared to vaginal delivery.

Where CS is performed (elective or emergency) in HIV positive women, they should receive prophylactic antibiotics. If CS is performed after prolonged labour or prolonged rupture of membranes, longer courses of antibiotics should be considered.

2.5.3.3 Best Obstetric Practices

There should be capacity to:

- Train health care providers in safe delivery techniques and life-saving skills for mothers and infants
- Provide safe delivery kits and essential obstetric drugs
- Provide a safe delivery infrastructure with a safe water source, good drainage, electricity, delivery beds covered with waterproof material, antiseptics, gloves, and other materials required for a hygienic delivery environment
- Ensure a safe blood supply
- Provide community education about the importance of antenatal care and hospital delivery.

2.6 Post-partum Care

2.6.1 Immediate post-partum care

The post-partum period in the health facility is an opportunity to educate all patients about HIV, to provide counselling and testing if this was not carried out previously, and to reinforce the education provided during the antenatal period. This should be done in a private place so that the discussion can be confidential. Both HIV infected and uninfected mothers should receive this education and counselling before discharge. Emphasis should also be made on the importance of routine immunization and the need for good hygiene to prevent infection.

2.6.1.1 Post-partum Care for HIV negative mothers

The health care provider should:

- Reinforce and support breastfeeding
- Discuss sexual activity in the postpartum period and protection against HIV infection
- Discuss couple or partner testing and counselling
- Discuss contraception and provide condoms where appropriate
- Educate and reinforce about infant care
- Complete mother care sections on education and counselling, delivery and postnatal exam
- Schedule post-natal visits.

2.6.1.2 Post-partum care for HIV positive mothers

The health care provider should:

- Review and support infant feeding
- Discuss:

- Couple or partner testing and counselling
- Sexual activity and protection of partners against HIV infection
- Contraception and provide condoms.

- Provide the infant with ARV prophylaxis *(see Section 3)*
- Educate and reinforce on optimal infant care
- Provide adherence counselling for women that need to continue on ARV
- Discontinue ARV according to recommendations in this *Guidelines*
- Review infection prevention and discuss prompt medical attention
- Complete counselling/education for mother care and postnatal examination
- Discuss the importance of early infant diagnosis
- Schedule post-natal visits.

2.6.1.3 Mothers whose HIV status is unknown

The health care provider should:

- Provide counselling and testing soon after birth *(see section 2.1 and 2.2)*
- Commence ARV prophylaxis for infants of HIV positive mothers *(see Section 3.2)*
- Complete education and counselling as above before discharge.

In the immediate post-partum period, there is need to perform routine physical examination with particular emphasis on the vital signs, detection of anaemia, breast, abdomen and perineum (e.g. for tears, bleeding, infected lochia, etc). HIV-infected women are more prone to post-natal infections including UTI, ARI, puerperal sepsis, infected episiotomy and caesarean section wound sepsis. Therefore, health care providers should be aware of this and observe for signs of infection.

2.6.2 Breast care

(i.) For a woman who is breastfeeding:

Cracked nipples, mastitis and breast abscess increase the risk of breast milk transmission of HIV. They often result from poor attachment of the baby on the breast, candida infection, frequent washing of the nipples, and application of abrasive creams and lotions.

Measures to prevent cracked nipples include:

- Ensuring correct breastfeeding technique with proper attachment of baby on breast
- Prompt treatment of vaginal thrush or infant oral thrush
- Washing the breasts once daily and avoiding creams and lotions on the nipples.

A mother should be shown how to put a clean finger on the baby's mouth to remove a baby from the breast without traumatizing her nipples. She should also be instructed to smear her nipples with breast milk after feeds and air-dry her breasts. Women should be encouraged to seek health care promptly if they have nipple discomfort when they are breastfeeding. Baby should not be fed on a breast with mastitis or breast abscess.

(ii.) For a woman who is not breastfeeding:

She should use a comfortable brassier to limit milk production and support the breast.

2.6.3 Care of the Perineum

The health care provider should:

- Emphasize on good perineal hygiene and proper handling of body fluids
- Avoid contaminating the baby with body fluids or bedding soiled with lochia
- Disallow bed-sharing in the hospital

- Cleanse episiotomy wound with a clean material preferably sanitary pad soaked in warm saline at least once daily.

2.6.4 Contraception and Reproductive Health Care

Appropriate family planning methods should be discussed during antenatal period and again before discharge home. In those areas where prolonged exclusive breastfeeding is the norm, some women may rely on lactational amenorrhoea (LAM) as a contraceptive method, and this will be lost with changes in infant feeding. Some women may have a period of abstinence after the birth of the child, and may not wish to start contraceptive use before this. They should be given information about how and where to obtain contraception when they wish it. HIV infected couples should be advised to use condom in addition to the use of other method of contraception for dual protection.

2.6.4.1 Barrier methods

These include:

- Female condoms
- Male condoms.

These barrier methods provide both contraception and protection against HIV and other STIs (dual protection).

2.6.4.2 Hormonal contraception

These include:

- Combined oral contraceptive pills
- Progestogen-only pills
- Injectable progestogen (DMPA or noristerate/NET-EN)
- Progestogen implants (such as Implanon or Norplant)

Note: these do not protect against HIV and other STIs.

2.6.4.3 Intra-uterine contraceptive devices (IUCD)

The copper T 380-A is commonly available and can be safely used with proper patient selection.

2.6.4.4 Sterilisation

This is suitable for HIV positive women and their partners who do not wish to have more children.

2.6.4.5 Emergency contraception

This is especially important where barrier methods are being used as the primary contraceptive method, and women should be told about the possibility of using emergency contraception if the condom breaks or slips.

2.6.5 Cervical Screening

HIV-positive women have a higher risk of cervical dysplasia and malignancy. Therefore, they should have a cervical smear, if possible at a postnatal check-up and at least annually. In women with CD4+ counts below 200cells/µl or who have symptoms of AIDS, a six-monthly smear should be advised. Where these facilities are not available, such patients should be appropriately referred.

2.6.6 Follow-up

Follow-up schedule for mother-infant pair should be at 2, 4 and 6 weeks after delivery and should have:

- Post natal follow-up best provided as a comprehensive package by the child welfare provider/medical officer/paediatrician, adult HIV physician, obstetrician/ maternity care staff and family planning provider
- The postnatal period as the beginning of the on-going care and support for women with HIV infection, especially where the diagnosis was first made during pregnancy
- Information given to women on maintaining own health and how and where to seek treatment if needed
- Advice given to women on the need for OI prophylaxis and TB treatment if indicated by the clinical stage of the disease
- Link for clients to community-based support groups for on-going counselling and other support services.

2.6.7 Referrals after Postnatal Care

All HIV infected women should be referred to the adult ART clinic after postnatal visit.

2.6.8 Post Abortion Care

HIV positive women are more likely to have spontaneous abortions than their HIV negative counterparts. There may also be rare occasions where termination of pregnancy is performed for medical indications, in accordance with Nigerian laws.

In most cases, the HIV status of the woman will not be known. Health care providers should be aware of the possibility of HIV and look for clinical signs and symptoms related to HIV. Where the woman is known to be HIV-positive, consider the use of prophylactic antibiotics after uterine evacuation. Ensure that family planning and HIV counselling and related services are made available as appropriate. They should also be counselled about possible problems, such as infection or bleeding, which may occur after the procedure.

SECTION 3
The Use of Anti-Retroviral Drugs in PMTCT

3.0 Introduction

There is a significant amount of new evidence available on the effectiveness of ARV prophylaxis to prevent mother to child transmission of HIV. Particularly important are the evidences indicating the benefits of starting ARV prophylaxis earlier during pregnancy and its extended use for mothers or infants in decreasing the risk of breast milk transmission. This and the availability of new information on optimal timing for ART initiation make the revision of the *National Guidelines* imperative. Since the use of ARVs to reduce MTCT has been found to be effective in Nigeria, revision of *The Guidelines* provides an important opportunity to simplify and standardize current recommendations, and to provide updated guidance for more effective PMTCT interventions.

In addition to the criteria for initiation of ART in adults infected with HIV as outlined in the *National ART Guidelines*, pregnancy constitutes another indication for the use of ARVs for therapy or prophylaxis. Therapy is indicated as per the WHO criteria. When the mother does not meet the criteria for treatment then prophylaxis should be offered.

3.1 When to Initiate ARV Therapy or Prophylaxis

Pregnancy in the HIV positive woman is an indication for ARVs irrespective of CD4, VL or clinical stage (*see Appendix I)*. The time to commence and ARV choice depend on the clinical setting. ARVs should be provided as soon as possible with expert consultation where necessary.

3.1.1 Use of Anti-retroviral drugs for therapy

ART should be initiated in HIV positive pregnant women based on the following criteria:

a. CD4 Count ≤ 350 irrespective of WHO clinical staging
b. WHO AIDS Stages III & IV disease, irrespective of CD4 cell count.

3.1.2 Use of Anti-retroviral drugs for prophylaxis

ARV prophylaxis should be provided for HIV positive pregnant women who do not meet above criteria. They include women with WHO Stages I & II AIDS with CD4 of >350cells/ml. Table 3.1 (Section 3.3) gives criteria for ARV use in pregnant women).

3.2 Pre-treatment Evaluation

Pre-treatment evaluation tasks should include:

- Complete history and physical examination
- Review laboratory results (FBC/ESR, FBS, LFT, Serum E &U, lipids, CD and VL). WHO clinical and immunological staging of the client (see table above)
- Ensuring availability of supportive measures (nutritional and psychosocial)
- Developing patient-specific adherence strategy.

Where the patient is on AZT prophylaxis, the minimum tests to be done should include:

- Hb/PCV
- CD4 count
- Urinalysis.

3.3 Recommendations for the use of ARVs in different clinical settings

The recommendations for the use of ARVs for PMTCT in different clinical settings are shown in the following tables.

Table 3.1 Clinical Setting I: Recommendations for pregnant HIV positive women who meet WHO criteria for ART

Pregnant woman who is ART eligible, but not currently on ART	
Mother	**Infant:**
• Confirm that ART eligibility criteria are met o CD4 count is ≤350 cells/mm^3 regardless of WHO clinical stage o WHO Clinical Stage III and IV regardless of CD4 count • Initiate ART irrespective of gestational age • Include *AZT in the regimen whenever possible o Preferred regimen is AZT+3TC+(NVP or EFV**) o Alternative regimen for hepatitis B co-infection is TDF+ (3TC or FTC) + (++NVP or **EFV) • Closely monitor for hepatotoxicity and systemic toxicity ESPECIALLY women on NVP-based regimen. *Avoid AZT if haemoglobin is ≦ 8g/dl or PCV ≦ 24% **EFV-based regimen should NOT be used in the 1st trimester. Women on EFV should be counselled and offered effective contraception after delivery. Use in early pregnancy associated with congenital neural tube defect [potential risk <1%)] ***Women on AZT, 3TC and NVP and found to react to NVP in 1st trimester, stop NVP and replace with a PI (LPV/r, SQV/r, NFV or IDV/r) ++When NVP is used in women with CD4 count between 250- 350, caution should be exercised. **Previous exposure to single-dose Nevirapine** NVP resistance disappears after 6 months of stopping NVP exposure. Where ARVs are required if NVP was last used: • < 6 months ago, use PI* + 2 NRTIs • > 6 months ago, use: o NVP + 2NRTIs in 1st trimester o EFV + 2NRTIs in 2nd and 3rd trimesters (use CD4 criteria to monitor for virologic failure with alpha response#) o AZT + 3TC + ABC o AZT + 3TC + TDF #Alpha response: Check VL 1 month after starting treatment. A drop of ≥1.0 log_{10} suggests that treatment is very likely to succeed.	• All infants irrespective of type of feeding should receive daily NVP **from within 72 hours of birth to 6 weeks of age**: o For babies with weight <2,500g, give NVP 10mg or 1ml once daily o For babies with weight ≥2, 500g, give NVP 15mg or 1.5ml once daily.

Table 3.2. Clinical Setting II: Recommendations for pregnant HIV positive women who do not meet the criteria for ART

<table>
<tr><th colspan="2">Pregnant HIV positive women who do not meet the criteria for ART</th></tr>
<tr><td colspan="2">1. For facilities with capacity (on–site or by linkage) to provide and monitor triple ARV medication:</td></tr>
<tr><td><u>Mother:</u>
• Commence triple ARV prophylaxis from 14 weeks or as soon as possible when the woman presents late in pregnancy, labour or delivery. Any of the following combinations is recommended as appropriate:
o AZT + 3TC + LPV/r
o AZT + 3TC + EFV
o AZT + 3TC (or FTC) + EFV
o AZT + 3TC + ABC
o TDF + 3TC (or FTC) + EFV
• Maternal triple ARV prophylaxis should continue until 1 week after cessation of infant's exposure to breast milk
• Mothers who decide not to breastfeed should stop ARV prophylaxis 1 week after delivery.
NB: NVP should be avoided in women with CD4 count >350.</td><td><u>Infant:</u>
All infants in this clinical scenario should be given daily NVP from birth to 6 weeks of age.

Dosage of daily NVP:
From birth to 6 weeks of age
• Birth weight < 2,500g: NVP 10mg (1ml) daily
• Birth weight ≥ 2,500g: NVP 15mg (1.5ml) daily
From 6 weeks to 6 months of age:
• NVP 20mg (2ml) daily
From 6 months to 9 months of age:
• NVP 30mg (3ml) daily
From 9 months to 12 months of age:
• NVP 40mg (4ml) daily.</td></tr>
<tr><td colspan="2">2. For facilities with limited capacity (on – site or by referral) to provide and monitor triple ARV medication.</td></tr>
<tr><td><u>Mother</u>
• AZT from 14 weeks gestation.
• sd NVP at onset of labour
• AZT+3TC 12 hourly during labour and delivery
• AZT+3TC 12 hourly for 7 days postpartum
(NB: If Hb is ≤ 8g/dl (PCV ≤ 24%), avoid AZT and refer to next level of care.)</td><td><u>Infant</u>
(A) For breastfeeding infants, start daily NVP; continue until 1 week after cessation of all exposure to breast milk.
(B) For non-breastfeeding infants, give daily NVP until 6 weeks of age
(See Scenario above for NVP dosing)</td></tr>
</table>

Table 3.3. Clinical Setting III: Recommendations for pregnant HIV positive women on ART

Pregnant HIV positive women already on ART	
Mother	**Infant**
• Should continue with the ART **Zidovudine should be a component of the regimen whenever possible [avoid if haemoglobin is ≤ 8 g/dl or PCV ≤ 24%; in this case use TDF+ (3TC or FTC) + NVP as applicable]* **Efavirenz is contraindicated in the first trimester and it should be replaced with NVP or PI* **NB:** In the event of previous clinical or virologic failure on NNRTI-containing regimen use any of the following as appropriate: • PI* + 2 NRTIs • AZT + 3TC + ABC • AZT + 3TC + TDF	• All infants irrespective of feeding practice should receive daily NVP preferably within 72 hours of birth to six (6) weeks of age. *Dose*: • Birth weight < 2,500g: NVP 10mg (1ml) daily • Birth weight ≥ 2,500g: NVP 15mg (1.5ml) daily. .

Table 3.4. Clinical Setting IV: Recommendations for HIV positive women who are diagnosed or seen for the first time in labour

<table>
<tr><th colspan="2">Pregnant HIV positive women who are diagnosed or seen for the first time in labour</th></tr>
<tr><td colspan="2">1. For facilities with capacity (on–site or by linkage) to provide and monitor triple ARV medication:</td></tr>
<tr><td><u>Mother</u>
• Triple ARV prophylaxis commencing during labour and continuing until one week after cessation of all breastfeeding.
For details of regimen see clinical setting II.

NB: Assessment for eligibility for ART should be done as soon after birth as practicable.</td><td><u>Infant:</u>
• Give daily NVP from birth to six weeks of age.

Dose:
• Birth weight < 2,500g: NVP 10mg (1ml) daily
• Birth weight ≥ 2,500g: NVP 15mg (1.5ml) daily.</td></tr>
<tr><td colspan="2">2. For facilities with limited capacity (on–site or by referral) to provide and monitor triple ARV medication.</td></tr>
<tr><td><u>Mother:</u>
• Intra-partum:
o Sd NVP
o AZT + 3TC 12 hourly as soon as diagnosis is made in labour
• Post partum: AZT + 3TC 12 hourly for one week after delivery

NB:
Determine mother's ART eligibility within 5 days of delivery, and follow appropriate guidelines including referral to ART /Care programme (see Appendix I for WHO Clinical Staging).</td><td><u>Infant:</u>
If mother is breastfeeding but not yet commenced on ART:
• Give daily NVP to infants from birth until one week after cessation of all exposure to breast milk.

If mother is breastfeeding and eventually commenced on ART:
• Give daily NVP to infants from birth and continue until six weeks after maternal commencement of ART.

If mother is not breastfeeding:
• Give daily NVP to infants from birth until 6 weeks of age.
Dosage of daily NVP: (See Scenario above for NVP dosing)</td></tr>
</table>

Table 3.5. Clinical Setting V: Recommendations for pregnant HIV positive mothers who present after delivery

Pregnant HIV positive women who present after delivery	
Mother • Determine ART eligibility and follow appropriate guidelines including referral to ART/Care programme.	**Infant:** ***If mother is breastfeeding but not commenced on ART***: • Give daily NVP to infants from birth until one week after all exposure to breast milk has ended. ***If mother is breastfeeding and eventually commenced ART*** • Give daily NVP to infants from birth and continue until six weeks after maternal commencement of ART ***If mother is not breastfeeding:*** • Give daily NVP to infants from birth until 6 weeks of age. **Dosage of daily infant NVP:** Refer to doses as in scenarios above.

Table 3.6. Clinical Setting VI: Recommendations for pregnant HIV positive patients who are co-infected with tuberculosis

Pregnant HIV positive women who present with active tuberculosis	
Mother: • Treat TB first if possible • Delay ARV treatment until second trimester, if possible. The following ART regimens are recommended in decreasing order of preference: **If treatment is initiated in second trimester, use:** • EFV + 2NRTIs • AZT + 3TC + ABC • Ritonavir-boosted PI* + 2 NRTIs (change rifampin to low dose rifabutin) • AZT + 3TC + TDF *(See Tables 3.3 & 3.4 below for NRTI combinations)* **NB:** *Avoid AZT if haemoglobin is ≤8g/dl or PCV ≤24%)* **SQV/r or LPV/r.*	**Infant:** • Give daily NVP to infant from birth until six weeks of age irrespective of feeding practice • Give prophylactic INH from birth (5mg/kg once daily) until 6 months of age irrespective of feeding practice. **Dosage of NVP:** *See Clinical Scenarios above.*

Table 3.7. Clinical Setting VII: Recommendation for pregnant HIV positive women with indication for ARV use where required ARVs are not available

HIV-infected women with indication for ARV use, but required ARV drugs are not available
All efforts should be made to ensure that all pregnant women who need ARV have access to it either on site or by referral.

Table 3.8 Summary of eligibility criteria for use of ARVs in HIV positive pregnant women

Facility where CD4 count is available	
CD4 ≤350 cells/mm³	**CD4 >350 cells/mm³**
Start ART regardless of clinical stage	Start ART only if symptomatic (AIDS stage 3 or 4)
WHO Clinical stage	
Stage 1	Offer ARV prophylaxis
Stage 2	Offer ARV prophylaxis
Stage 3	Commence ART
Stage 4	Commence ART
Facility where CD4 count is not available	
Refer client or send client's specimen to the nearest centre with CD4 capability.	

Table 3.9 Nucleoside Reverse Transcriptase Inhibitors (NRTI) combinations

Choice of Regimen	ARV Combinations
Preferred	• AZT + 3TC
Alternatives	• AZT + ABC, AZT + ddI, AZT + TDF, AZT + FTC • d4T (30mg) + 3Tc, d4T + FTC, d4T + ABC, d4T + TDF • ABC + 3Tc, ABC + FTC, TDF + FTC, TDF + 3Tc.

Table 3.10 Contraindicated NRTI combinations

ARVs	Potential problems
*d4T + ddI (Use with caution if other options are unavailable)	• Increased toxicity, including neuropathy, pancreatitis and lactic acidosis. • Fatal cases of lactic acidosis with steato-hepatitis (fatty liver) have been reported in pregnant women.
AZT + d4T	Antagonistic effect; should never be used together
TDF+ ddI	Risk of early virologic failure and decline in CD4 count in patients who achieve virologic suppression
3TC + Emtricitabine	Similar drugs; no added benefit
TDF + ABC	Suboptimal effect

Table 3.11 Maternal and infant safety concerns of recommended and alternative ARVs for pregnant women and their infants

ARV	Maternal ARV intervention during pregnancy, labour, delivery and thereafter			Infant prophylaxis concerns
	Maternal concerns	Placental passage	Infant concerns	
Nucleoside and nucleotide reverse transcriptase inhibitors				
Abacavir (ABC)	Risk of hypersensitivity reaction (5-8% of non-pregnant women, rate unknown in pregnant)	Yes	Limited data available; animal studies suggest potential skeletal malformations with in-utero exposure to drug levels 35 times that of human exposure	Not recommended
Emtricitabine (FTC)	No specific concerns	Yes	No specific concerns	Not recommended
Lamivudine (3TC)	• Favourable safety profile; • Concerns of HBV flare if mother is HBV co-infected and stops 3TC	Yes	Favourable safety profile	Limited safety data available

Table 3.11 Maternal and infant safety concerns.....*cont'd*

ARV	Maternal ARV intervention during pregnancy, labour, delivery and thereafter			Infant prophylaxis concerns
	Maternal concerns	Placental passage	Infant concerns	
Nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs/ NtRTIs))				
Tenofovir (TDF)	• Risk of renal toxicity – monitor for this; • Concerns for hepatitis B flare if mother is HBV co-infected and stops TDF postpartum	Yes	• Concerns of foetal bone defects; • Potential concern of low birth weight	Not recommended
Zidovudine (AZT)	• Well tolerated; • Risk of anaemia	Yes	Favourable safety profile	• Favourable safety profile • Associated with anaemia; reversible once stopped
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)				
Efavirenz (EFV)	• Associated rash; • Neuro-psychiatric disturbances	Yes	• Potential teratogenicity risk (1 %) in 1st trimester; • Consider use after 1st trimester	Not recommended
Nevirapine (NVP)	• Potential risk of hypersensitivity reactions: rash, hepato-toxicity; • Incidence with CD4 count between 250-350 cells/mm^3 unknown but benefits may outweigh risks where ARVs are needed • Not recommended if CD4 >350/mm^3 - higher toxicity risk	Yes	Favourable safety profile	Favourable safety profile, including during extended dosing (until 6 months) in breastfed infants
Protease inhibitors (PIs)				
Lopinavir /ritonavir (LPV/r)	• Well tolerated; concern of hyper-lipidaemia, insulin resistance, hyperglycaemia and rarely diabetes mellitus	Yes (but low – 20%)	Concerns of preterm delivery	Not recommended

3.4 Post - Exposure Prophylaxis for Infants

All babies born to HIV positive mothers are exposed to the infection and must receive post-exposure prophylaxis as follows:

- Daily NVP for the first 6 weeks of life
- Refer to the specific clinical settings above to determine when to stop infant NVP prophylaxis.

3.5 Opportunistic infections

The term opportunistic infections (OIs) refer to disease conditions, which ordinarily does not occur in a person with competent immune system but occur in persons with a compromised immunity. In most cases there is a direct correlation between severity of immuno-suppression and the presentation of the associated OI. Most OIs occur when CD4 drops below 200cells/µl.

3.5.1 Common OIs in pregnancy

Pregnant women are susceptible to a wide range of OIs. These include infections due to:

- Bacteria
- Parasites
- Protozoa
- Fungi
- Viruses

They should therefore be able to access the several options for the prevention and treatment of OIs. However, in prescribing medication for pregnant HIV positive women the special precautions that guide drug use in pregnancy must be observed.

3.5.2 Prophylaxis for OIs

3.5.2.1 Co-trimoxazole Preventive Treatment (CPT)

Co-trimoxazole (TMP-SMX) preventive therapy (CPT) is used for the prevention of several secondary bacterial and parasitic infections in HIV positive individuals. It helps to prolong and improve the quality of life. It can safely be used throughout pregnancy. Its use leads to reduction in neonatal morbidity.

Although HIV positive pregnant women widely use CTX, there is no evidence of an increase in CTX-related adverse events among them compared to their non-pregnant counterparts. Since the risk of life-threatening infections among pregnant women with low CD4 count or clinical features of immunosuppression outweighs the theoretical risk of CTX-induced congenital abnormalities therefore women that fulfil the criteria for CTX prophylaxis should stay on it throughout their pregnancy:

- If a woman requires CTX prophylaxis during pregnancy, it should be started regardless of the stage of pregnancy
- If a woman living with HIV is receiving CTX prophylaxis and resides in a malarial zone, it is not necessary to give additional sulfadoxine/pyrimethamine–based IPTp for malaria
- Breastfeeding women should continue to receive CTX prophylaxis.

Indications for CTX prophylaxis

- All HIV positive pregnant women with CD4 counts ≤350cells/ml
- All HIV positive pregnant women with WHO clinical stages 2, 3 and 4 disease

- All HIV exposed infants (from six weeks of age until HIV infection is excluded).

Dose of Co-trimoxazole in CPT

a. Adults: Co-trimoxazole 960mg OD (one double strength or two single strength tablets)
b. Infants and children *(see Section 4)*.

Caution:

- CTX is contraindicated in persons with history of allergy to sulphur-containing drugs
- For patients on CPT, do not administer sulfadoxine–pyrimethamine for IPTp of malaria.

Initiation of CPT

The following steps should be taken:

- Educate on the association between OIs and HIV infection
- Take a detailed medical history and conduct a physical examination
- Search for and treat any existing opportunistic infections
- Search for contraindications to CPT such as known allergy to sulphur-containing drugs, kidney or liver disease
- Counsel patient on drug adherence and its side effects.

Discontinuation of CPT

- CPT should be discontinued in the event of severe adverse effects
- If there is a sustained rise of CD4+ count above 350 cells/µl (for 6 months)
- Children who have been confirmed to be HIV uninfected
- Hypersensitivity to CTX.

3.5.2.2 Pneumocystis Jirovecii Pneumonia (PCP)

Chemoprophylaxis for PCP should be administered to HIV positive pregnant women. CTX is the recommended prophylactic agent but the alternatives for those who do not tolerate CTX include:

- Dapsone
- Atovoquone.

3.5.2.3 Toxoplasmosis

- CTX can be administered for primary prophylaxis of toxoplasmosis as described for PCP
- Secondary prophylaxis is provided using same indications as for non-pregnant women
- HIV positive pregnant women with suspected or confirmed primary toxoplasmosis should be managed in consultation with an appropriate specialist.

3.5.2.4 Tuberculosis

- Screen all HIV positive pregnant women with a cough of more than 2 weeks for active TB
- Use the adult diagnostic evaluation methods to screen for TB disease
- Use abdominal shield when taking chest X rays to minimize foetal irradiation
- Refer to Section 3 (Table 3.6 Clinical Setting VI) for treatment of HIV/TB co-infection in pregnancy.

3.5.2.5 Syphilis

- All pregnant women should be screened for syphilis with either of VDRL/TPHA/RPR at the first prenatal visit
- Concurrent syphilis infection might increase the risk for perinatal transmission of HIV to the infant
- Treatment in pregnancy should consist of same penicillin regimen as recommended for the given disease stage among non-pregnant women. In HIV positive pregnant women, a second injection 1 week after the first should be considered
- Syphilis-exposed infants should be assessed for possible treatment (see *National STI Guidelines*).

3.5.2.6 Candidiasis

Pregnancy increases the risk for vaginal colonization with *Candida* species. Diagnosis of oro-pharyngeal, oesophageal, and vulvo-vaginal candidiasis is the same as among non-pregnant adults. Preferred treatment of oral/vaginal candida in pregnancy should be with:

- Topical agents when possible
- Single dose, episodic treatment with fluconazole is safe.

NB: *chronic use of 400 mg of fluconazole or higher doses in pregnancy can lead to 'fluconazole embryopathy'*

- Amphotericin B can be substituted for high dose fluconazole in the first trimester for invasive or refractory oesophageal candidiasis.

3.5.2.7 Bacterial Respiratory Tract Infections

- The diagnosis of bacterial respiratory tract infections among pregnant women is the same as for non-pregnant adults, with appropriate shielding of the abdomen during radiographic procedures
- Azithromycin is recommended when a macrolide is indicated in pregnancy. Beta-lactam and aminoglycosides may be used as needed.

3.5.2.8 Bacterial Enteric Infections

The diagnosis of bacterial enteric infections among pregnant women is the same as among non-pregnant women. Suitable agents for use in pregnancy include:

- Expanded spectrum cephalosporin
- CTX
- Azithromycin.

Neonatal-care providers should be informed of maternal sulpha therapy if used near delivery because of the increased risk to the newborn of hyperbilirubinaemia and kernicterus.

3.5.2.9 Malaria

- The diagnosis of malaria in HIV positive pregnant women is the same as in non-pregnant adults.
- Acute malaria infection causes a transient increase in HIV VL and chronic malaria infection is associated with:
    - Significant increases in HIV VL
    - Higher peripheral and placental VL, with increased risk of MTCT
    - Increased risk of intrauterine growth restriction, preterm birth and infant morbidity

- The incidence, severity and complications (e.g. anaemia and cerebral malaria) of malaria are increased by HIV infection
- Three doses of IPTp are recommended for all HIV positive pregnant women avoiding the first trimester and the last 4 weeks of gestation if possible. Use of this drug is contraindicated in persons with sensitivity to sulphonamides
- Women already on CTX prophylaxis need not be given additional SP prophylaxis for IPTp.

3.5.2.10 Hepatitis B

Treatment of symptomatic acute HBV infection during pregnancy should be supportive with special attention given to maintaining blood glucose levels and normal clotting status. Risk for preterm labour and delivery may be increased with acute HBV infection.

Treatment of chronic HBV infection is generally not indicated in pregnancy, but HBV positivity must be taken into account when considering therapy options for the HIV-infected pregnant woman**.** ARV regimens for use in HBV/HIV co-infected pregnant women should include lamivudine, emtricitabine or tenofovir, all of which have activity against HBV.

3.5.2.11 Fungal Infections

The opportunistic fungal infections include:

- Cryptococcosis
- Cryptosporidiosis
- Microsporidiosis
- Histoplasmosis
- Coccidioidomycosis
- Aspergillosis.

The diagnosis and treatment of fungal infections in HIV positive pregnant woman are not different from the non-pregnant woman. As with non-pregnant women, initial treatment should be supportive. Regarding antifungal use in pregnancy:

- Substitution of Amphotericin B for high dose azoles in the first trimester is recommended
- Albendazole for treatment of Microsporidiosis is contraindicated, topical fumagillin may be considered
- Use of intrathecal amphotericin may be required in the first trimester for coccidioidal meningitis; expert consultation is however recommended.

3.5.2.12 Cytomegalovirus (CMV)

The diagnosis of CMV infection in HIV positive women is the same as for non-pregnant women. Valganciclovir is the treatment of choice during pregnancy. Foetal anaemia, hydrops fetalis and foetal demise are possible complications of CMV infection in pregnancy.

3.5.2.13 Herpes Simplex Virus infections (HSV)

Diagnosis of mucocutaneous HSV infections is the same in pregnancy as among non-pregnant adults. Episodic therapy for first disease episode and for recurrences can be offered during pregnancy. Suppressive therapy is not used routinely but can be offered to pregnant women with frequent symptomatic recurrences.

Acyclovir is the first choice for therapy of HSV infections in pregnancy. Additional concerns with HSV co-infection are:

- Potential for in-utero transmission and for neonate at delivery (from maternal genital viral shedding) regardless of HIV infection
- Women with prodromal or visible HSV genital lesions at the onset of labour should be delivered by Caesarean section
- Herpetic lesions affecting the nipple are a contraindication to breastfeeding.

3.5.2.14 Varicella-Zoster Virus infection (VZV)

- Give the immunoglobulin (VZIG) to HIV positive pregnant women who have close contact with a person with active varicella **o**r herpes zoster infection as soon as possible (within 96 hours) after exposure
- Conduct VZV serology if oral acyclovir is used for post-exposure prophylaxis, so that the drug can be discontinued if the patient is positive for VZV
- Do not give the varicella vaccine to pregnant women because it is a live-attenuated vaccine which may cause true infection
- The preferred treatment of HIV positive pregnant women and their infants is as follows:
    - Oral acyclovir or valacyclovir for women who develop uncomplicated chickenpox during pregnancy
    - Hospitalization and use of intravenous acyclovir for women who exhibit signs or symptoms of VZV pneumonitis
    - Give VZIG to infants born to women who develop chickenpox within the period from 5 days before delivery to 2 days after delivery, to reduce the severity and mortality of neonatal varicella acquired during maternal viraemia
- Specific risks among HIV positive women with varicella during pregnancy have not been reported.

3.5.2.15 Human Papilloma Virus infection (HPV)

The decision about whether to treat genital warts during pregnancy should be individualized on the basis of the extent of the warts, concurrent symptoms, gestational age of the foetus, and patient preference**.** The management includes:

- Use topical treatments (such as bi-chloroacetic or tri-chloroacetic acid) and ablative therapies (i.e., laser, cryotherapy, and excision) during pregnancy
- Avoiding the use of podophyllin and podofilox during pregnancy
- Following the normal protocol for the management of labour for women with HPV infection unless extensive condylomata are present that might impede vaginal delivery or cause extensive bleeding
- Performing colposcopy and cervical biopsy of lesions suspicious for high grade disease or cancer in pregnant women with abnormal cervical cytology results
- Performing a diagnostic biopsy only if invasion is suspected

    NB: *Increased bleeding might occur with cervical biopsy during pregnancy. Endocervical curettage should not be done during pregnancy*

- Avoiding treatment for cervical intraepithelial neoplasia (CIN) during pregnancy unless in the presence of high grade disease

- Avoiding vaginal delivery for women with invasive cervical cancer; women with suspected cervical cancer should be referred to a gynaecologic oncologist for definitive diagnosis, treatment, and delivery planning
- Deliver women with CIN vaginally unless there are other contraindications to vaginal delivery
- Re-evaluate with cytology and colposcopy 6 weeks postpartum.

3.5.3 Treatment of Opportunistic Infections

The treatment of opportunistic infections is shown in the table below.

Table 3.12: Treatment of some Opportunistic Infections

Infections	Treatment
Cellulitis, folliculitis and furunculosis, and erysipelas	• Amoxicillin PO 500mg t.d.s for 7-10 days, or • Ampicillin/cloxacillin 500mg PO q.d.s for 7-10 days
Genital warts	• Cryotherapy or • Cauterization
Seborrhoeic dermatitis, dermatophytosis	• Antifungal agents like topical Whitfield's ointment, or • Gentian violet, or • Miconazole ointment
Scabies	• 20% Benzyl benzoate applied topically for 3 consecutive days, or • Permethrin creams 5% apply to total body; neck down; and wash off after 8 – 14 hours • Re-treat after 1 – 2 weeks. *NB: treat all household contacts even if asymptomatic*
Oral and Pharyngeal candidiasis	• Clotrimazole lozenges 10 mg 5 times daily until lesions resolves for 7-14 days • Nystatin 500,000 units (4-6 ml) gargled 4-5 times daily for 7–10 days
Vaginal candidiasis	• Butaconazole 2% cream od for 3 days, or • Clotrimazole 1% cream od for 7-14 days, or • Clotrimazole vaginal tab 100 mg od for 7-14 days
Bacterial respiratory infections	• Amoxicillin 500 mg 3 times daily, or • Flucloxacillin 500 mg qds times daily, or • Trimethoprim 960 mg bd for one week.

SECTION 4
Management of HIV Exposed Infants

4.0 Introduction

Transmission of HIV from mother to child accounts for about 90% of paediatric HIV infections. Expansion of PMTCT services provides opportunity for early intervention and care of the HIV exposed infants.

4.1 Immediate care of the newborn

The immediate care of the HIV exposed newborn should be according to standard practice. Regardless of the mothers' HIV status at delivery all infants should:

- Have their mouth and nostrils wiped with gauze at delivery of the head
- Be handled with latex gloves until maternal blood and secretions are washed off
- Have the cord clamped immediately after baby is delivered and avoid milking of cord
- Have the cord cut under cover of lightly-wrapped gauze swab to avoid blood spurts
- Be kept warm by placing infant on mother's body for skin to skin contact
- Be wiped dry with a towel or surgical cloth to remove maternal body fluids
- Have gentle suction if indicated using a mechanical/electrical suction unit at a pressure below 100mmHg or bulb suction. Mouth-operated suction is contraindicated
- Have Vitamin K administered, ensuring injection safety.

Mother should be supported to initiate her decided feeding practice within 30 minutes of delivery.

4.2 Prophylaxis for HIV exposed Infants

4.2.1 ARV Prophylaxis

All babies born to HIV positive mothers are exposed to infection and should receive post exposure prophylaxis as follows:

- Give daily nevirapine until six weeks of age; thereafter the duration of prophylaxis will depend on clinical settings as shown in section 3 above.

4.2.2 Prophylaxis for OIs

***Pneumocystis Jirovecii* Pneumonia (PCP)**

HIV–exposed infants should be offered CTX from 6 weeks until HIV status is determined. If the HIV status is positive, CTX should continue but if negative it should be stopped. CTX is given once daily. The recommended dose is as shown in Table 4.1.

Table 4.1 Co-trimoxazole Dosing Recommendations for Prophylaxis

Recommended dosage: Sulfadoxine/Trimetoprim	Suspension (200/40 per 5ml)	Paediatric Tab 100/20	Single strength adult tab 400/80
<6 months 100mg/20mg	2.5 mls	1 tab	¼ tab, possibly mix with feeding
6 months – 5 years 200mg/40mg	5 mls	2 tab	½ tab
6 – 14 years 400mg/80mg	10 mls	4 tab	1 tab

Tuberculosis

HIV infection increases the risk of developing tuberculosis due to immunosuppression caused by HIV. HIV positive women should be screened for TB at every visit to the heath facility. If the mother is diagnosed to have pulmonary TB and started treatment less than 2 months before delivery or diagnosed after child birth (open TB or still infectious):

- Give INH 5 mg/kg orally once daily for 6 months (1 tablet = 200 mg) to the infant
- Delay BCG until prophylaxis is completed or repeat BCG after completing course of INH
- Reassure the mother that it is safe to breastfeed the baby
- Follow up for growth monitoring, immunizations according to *National Guidelines*.

INH prophylaxis (5mg/kg/day) against TB should be given to infants of mothers with open tuberculosis if they opt to breastfeed their babies for 6 months. For such babies, INH-resistant BCG is also given.

4.3 Infant Feeding Counselling

Although HIV can be transmitted via breastfeeding, the effectiveness of ARVs to reduce transmission and the benefits of breastfeeding to reduce morbidity and mortality from other causes, justifies an approach that strongly recommends exclusive breastfeeding for the first 6 months followed by introduction of appropriate complementary feeding with continued breastfeeding to 12 months as the standard for feeding HIV exposed infants.

These *Guidelines* therefore recommend that health care providers should support HIV positive mothers to breastfeed. Both mother and infant must however, receive ARVs for prophylaxis or treatment as appropriate. This strategy likely gives infants the greatest chance of HIV-free survival.

4.3.1 Objectives of Infant Feeding Counselling Support

- To ensure survival of infants of HIV infected mothers
- To reduce the risk of HIV transmission from mothers to their infants.

Trained infant feeding counsellors are required to counsel HIV positive mothers on infant feeding methods and to support the mother. All HIV infected mothers should be provided with information and counselling on the following:

- Nutritional requirements of the child
- Standard of care for HIV-free survival
- Risks and benefits of breastfeeding
- Risks and benefits of formula-feeding
- Cost of infant formula feeding
- Increased risk of HIV transmission with mixed feeding in the first six months of life
- Child spacing
- Psychological stimulation of the child
- Social and cultural factors
- Breast problems.

4.3.2 Standard of care for HIV-exposed Infants

The recommended infant feeding method for HIV positive mothers is exclusive breastfeeding with ARV intervention. However, exclusive formula feeding while avoiding all breastmilk is supported where the former is not feasible.

Appropriate infant feeding is critical to child survival because the natural food for infants is breast milk. In the context of maternal HIV infection, infant feeding can become complex. HIV infection may be transmitted through breast milk from mother to child and the risk approaches 45% in the absence of any intervention. Not breastfeeding has the benefit of zero HIV transmission by this route but carries with it the risk of morbidity and mortality from malnutrition or diarrhoea. Given the median HIV prevalence of 4.6% in antenatal women in Nigeria, the HIV infected mothers are faced with two choices to take for the wellbeing of their infants:

a) Breast feed while receiving ARV intervention (to make breast milk safer), or
b) Avoid all breastfeeding (by resorting to replacement feeding).

Experience has shown that in real life, most Nigerian women are breastfeeding especially for lack of the wherewithal to circumvent this culturally acceptable and more convenient method of infant nutrition.

The *National Task Team on PMTCT* therefore recommends:

1. Breastfeeding for all HIV-infected mothers while receiving ARVs as ART or prophylaxis to the mother-infant pair
2. However, where this is not feasible, HIV-positive mothers will be supported to formula feed provided specific conditions are met:
   a. Safe water and sanitation are assured at the household level and in the community
   b. The mother, or other caregiver can reliably provide sufficient infant formula to support normal growth and development of the infant
   c. The mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition
   d. The mother or caregiver can, in the first six months, exclusively give infant formula
   e. The family is supportive of this practice
   f. The mother or caregiver can access health care that offers comprehensive child health services.

The health care worker shall accordingly provide unbiased support to facilitate safe and nutritious infant feeding as follows:

a) Mother receiving ART for her own disease could:
   - Exclusively breastfeed from birth
   - Introduce complementary foods at six months
   - Continue with breastfeeding till the infant reaches 12 months of age
   - The infant receives daily NVP for first 6 weeks of life only.

b) Mother receiving prophylactic ARVs beyond the postpartum period could:
   - Exclusively breastfeed from birth
   - Introduce complementary foods at six months
   - Continue with breastfeeding until the infant reaches 12 months of age
   - Continue with the ARVs until one week after cessation of all breast milk.
   - The infant receives daily NVP for the first 6 weeks of life only.

c) Mother receiving prophylactic ARVs for just one week after delivery could:
   - Exclusively breastfeed from birth
   - Introduce complementary foods at six months
   - Continue with breastfeeding for up to 12 months
   - The infant receives daily NVP until one week after cessation of all breast milk.

d) Mother who never had any previous exposure to ARVs before birth could:
   - Exclusively breastfeed from birth
   - Introduce complementary foods at six months
   - Continue breastfeeding to the end of 12 months
   - The infant receives daily NVP throughout the period until one week after cessation of all breast milk.

e) Mother receiving ART or ARVs as prophylaxis who chooses not to breast feed could:
   - Exclusive formula feeding from birth
   - Introduce complementary foods at six month of life
   - The infant receives daily NVP for the first 6 weeks of life.

4.4 HIV diagnosis in Children

Determining the status of children exposed to HIV during pregnancy, labour or breastfeeding is an important part of follow-up services in PMTCT programmes. HIV testing and counselling should therefore be recommended for all exposed infants as a routine component of the follow-up care for these children. Due to the rapid progression of immunodeficiency in children and the poor specificity of clinical signs, HIV testing and counselling should also be recommended for children presenting with suboptimal growth or malnutrition.

4.4.1 Early Infant and Child Diagnosis

In the first 18 months of life, methods of HIV testing that rely on the detection of the HIV virus or its products (virologic testing) are required for confirmatory diagnosis, as HIV antibody testing may not reliably confirm the true HIV status of the infant or child. Early diagnosis of HIV in these infants (0-12 months) and children (12-18 months) before they become ill is desirable for many reasons, including:

- Early introduction of ARV and other therapy for HIV-infected infants
- Tracking the effectiveness of the PMTCT programme
- Provides opportunity for women who continue to breastfeed an HIV-negative child to 'consider' switching to formula feeding.

Polymerase Chain Reaction (PCR)

This is the test used to measure viral nucleic acid; it is a confirmatory test that is not affected by the presence of maternal antibodies. HIV-exposed infants should be routinely tested for HIV using DNA PCR from the age of 6 weeks. DNA PCR can be done on whole blood samples collected through either phlebotomy or heel stick in tubes or on filters paper. Collection of a dried blood spot (DBS) on filter paper allows for samples to be dried and stored for extended periods at a wide range of temperatures without degradation. This method of sample collection is recommended for facilities where transportation to the appropriate testing laboratory is not readily available.

Breastfeeding infants who test negative with DNA PCR should have a repeat test 6 weeks after complete cessation of breastmilk and an antibody test at or after the age of eighteen months.

4.4.2 Diagnosis in Children above the age of 12 months

Babies born to HIV-positive mothers will have some maternal antibodies to HIV in circulation, thus all of them will test positive for HIV antibodies at birth. These maternal antibodies may persist for variable periods after infancy until when they finally disappear at 18 months. This means that a diagnosis of HIV infection using HIV antibody testing in the child can only be made after this time. In a breastfed child, antibody testing should be carried out at least three months after cessation of all breast milk.

Figure 4.2 below is a simplified chart showing the suggested testing approach for HIV exposed infants and children less than 18 months.

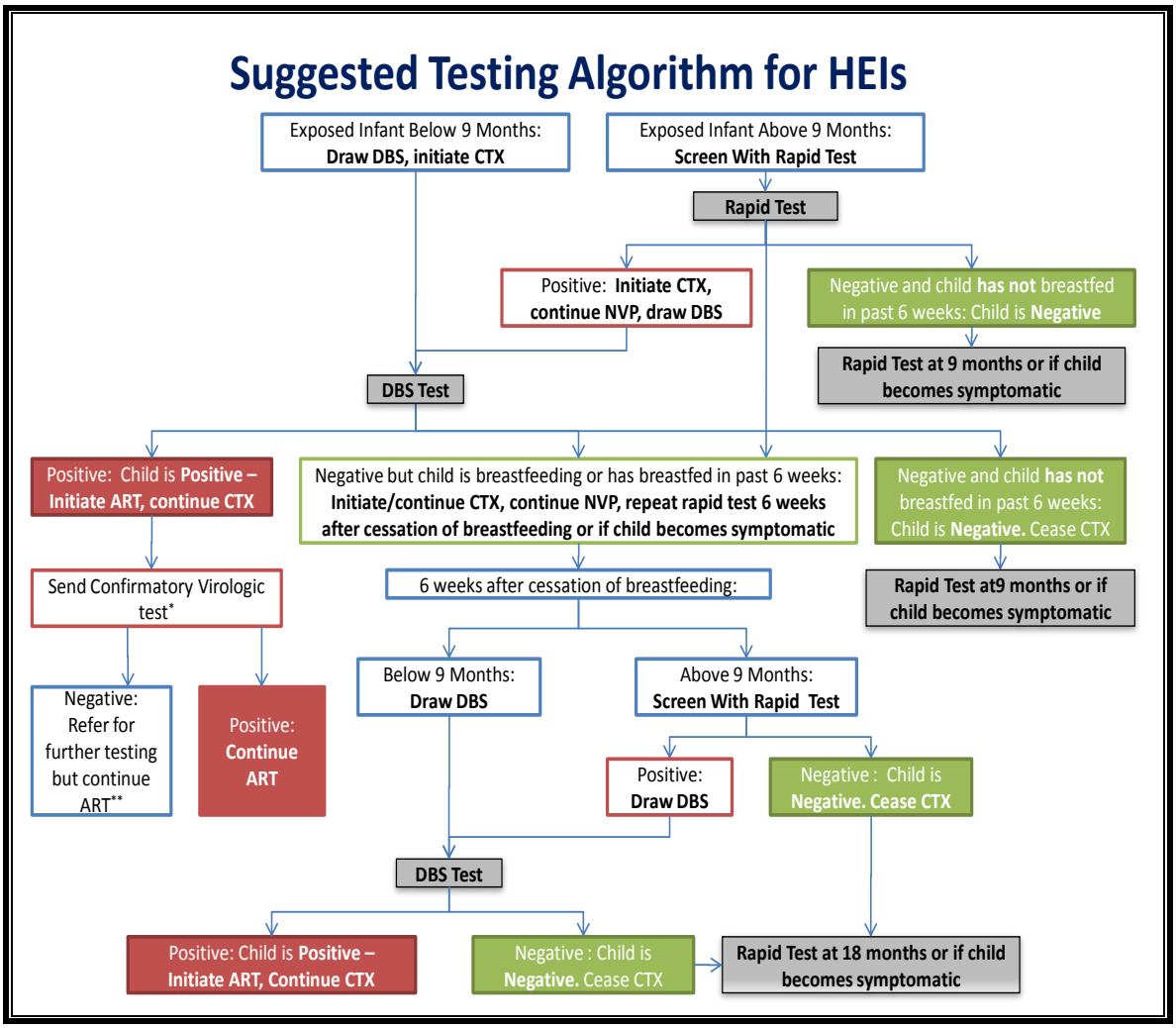

Figure 4.1: Suggested Testing Algorithm for HIV Exposed Infants and Children up to 18 Months of age

4.5 Infant Follow-up

Mothers and babies should be seen from the first few weeks following discharge. Routine follow-up should be done fortnightly for the first six weeks and monthly thereafter till at least 18 months of age. The objectives of follow-up visits include:

- To evaluate and ensure the well being of the child
- To ensure that the mother continues with her chosen infant feeding practice without difficulties
- To ensure adequate dosing and adherence to ARV prophylaxis
- To check and ensure that immunizations are given according to schedules
- To assess and manage common medical conditions
- To utilise an opportunity to screen the other siblings.

Events at 6 weeks

- Cessation of ARV prophylaxis where appropriate *(see Clinical Settings in Section 3)*
- Commencement of Co-trimoxazole prophylaxis
- Immunisations: DPT1 and OPV1
- To make early infant diagnosis (EID) by DBS sample collection for PCR
- To refer orphans and vulnerable children for appropriate support.

4.5.1 Immunizations

All children of HIV positive mothers should follow the standard immunization schedule thus:

BCG, OPV^0, HBV^0	at birth
OPV^1, DPT^1	at 6 weeks
OPV^2, DPT^2, HBV^1	at 10 weeks
OPV^3, DPT^3	at 14 weeks
Measles,	at 6 and 9 months
HBV^2, Yellow fever	at 9 months

If symptomatic do not give live vaccines: BCG, Measles, OPV and Yellow fever

4.5.2 Growth Monitoring and Promotion

It is important to monitor growth to detect failure to thrive; which is an early sign of malnutrition in formula-fed infants and it is also a sign of infections including AIDS.
Mothers should receive continued support in their chosen infant feeding method to ensure child survival and development.

- Infants should be seen regularly; anthropometric parameters should be measured serially at follow-ups (weight, length/height and occipito-frontal circumference)
- Educational, emotional and social support should be provided at these visits

4.5.3 Complementary feeding

From the age of six months, milk alone is no longer enough for adequate growth of the infant. All babies will require adequate complementary foods in addition to breast milk and breast milk substitutes. Support for infant formula between six and twelve months of age to meet milk and other nutrient need of these infants may substantially promote growth and survival.

4.5.4 Prevention and Treatment of Malaria

As is the case with all children under 5 years of age, children of HIV infected mothers should sleep under ITNs to protect them from malaria, which is a major cause of infant morbidity and mortality in Nigeria. They should be treated promptly if infant has signs of malaria *(Refer to the National guideline for the treatment and prevention of malaria)*. Co-trimoxazole prophylaxis is also protective against malaria in children**.**

4.5.5 Maternal Health

The survival of the infant is largely dependent on the mother being alive. Mothers infected with HIV need care and support. They need on going counselling to improve their nutritional status, maintain their infant feeding choice and remain relatively healthy to care for their family. The health care provider should:

- Ensure mothers understand and can practice their chosen method of infant feeding
- Ensure adequate nutrition for mothers
- Ensure adherence to follow-up schedules and ARVs.

4.5.6 Role of the Community-Based organizations

The role of the community-based organizations is vital in supporting the HIV positive mother. Community participation early in the implementation of HIV and infant feeding activities ensures sustainability and ownership of interventions and reduce stigma. Community-based organizations should therefore:

- Be encouraged to form support groups for HIV positive mothers and their families
- Support the training of lay counsellors including volunteers
- Provide care and support for HIV positive mothers, orphans and vulnerable children in their communities
- Lead advocacy and community mobilisation to create demand for PMTCT services.

4.6 Monitoring and Evaluation

Monitoring is regular tracking of key programme elements and will help to:

- Assess programme performance
- Detect and correct performance problems
- Make more efficient use of PMTCT programme resources.

The following are examples of parameters that can be monitored:

- HIV testing and counselling for pregnant women
- ARV treatment and prophylaxis to prevent MTCT
- Counselling and support for safe infant feeding practices.

Evaluation measures the changes in a situation resulting from an intervention, for example, determining the number of exposed infants who are HIV negative.

4.7 Research

Research in various areas of the PMTCT programme to strengthen implementation and improve outcome is necessary for long term success of interventions. Areas include:

- Attitude of HIV positive mothers to new recommendation on infant feeding;
- Outcome of intervention based on new recommendations;
- Determinants of PMTCT uptake;
- Impact of endemic malaria on MTCT;
- Nutritional status of HIV exposed infants.

SECTION 5
Standard Precautions

5.0 Introduction

Standard precautions are a simple set of effective precautionary practices recommended for use when caring for all patients regardless of diagnosis. They are designed to protect healthcare providers (HCP) and patients from transmission of infectious blood-borne pathogens. All biological body fluids are potentially infectious regardless of the source (patient or health care providers). HCP especially in obstetric settings can be accidentally exposed and may thereby acquire infection or transmit infection to an uninfected patient if they do not take preventive steps.

Universal precautions apply to:

- All body fluids: Transmission may occur when any of these fluids comes in contact with blood, open wounds non-intact skin and mucosal surfaces.
  - Fluids with a high risk of HIV transmission include blood and blood products, saliva, sputum, semen and vaginal secretions
  - Others like amniotic, cerebrospinal, pericardial, peritoneal, pleural and synovial fluids have poorly defined risk of transmission
  - Excretions such as urine, faeces, nasal secretions, tears, sweat and vomitus have lower risk
- All patients regardless of their infectious state or perceived risk.

It is the responsibility of the health facility to ensure that an infection prevention policy is in place and that:

- All staff routinely receive orientation on the protocols in the policy
- Necessary medications for post-exposure prophylaxis are provided
- All staff are immunised against common infectious blood-borne pathogens (e.g. Hepatitis B virus)
- On-going infection prevention education is provided for employees.

5.1 Standard recommended practices

There are 4 standard recommended practices:

- Proper hand washing
- Use of protective barriers to prevent direct contact.
- Safe handling and disposal of sharps and solid wastes (including placenta)
- Safe decontamination of instruments and other contaminated equipment.

5.2 Additional Important Precautions in Obstetric Practice

- Reduce needle stick injuries by safe handling of needles:
  - Use a needle holder during surgical procedures
  - Avoid recapping of all needles
  - Place needles and other sharps in the appropriate containers.
- Wash hands with soap and water immediately after contact with blood and body fluids
- Wear suitable gloves when anticipating exposure to blood and other body fluids
- Cover broken skin or open wound with waterproof dressing

- Wear an impermeable plastic apron for delivery
- Wear an eye shield for operation or assisting at Caesarean section and for suturing episiotomies
- Wear double gloves for all surgical operations
- Use an appropriate sized needle (21G, 4cm, curved) for the repair of episiotomies
- Pass all sharp instruments onto a receiver, rather than hand-to-hand for all surgical operations
- Use elbow length gloves for manual removal of placenta
- Use mechanical or bulb suction when indicated for newborn infants. Manual mucus extractor with non–return valves and mouth-to-mouth suction are contraindicated
- Disinfect and dispose of solid waste such as blood-soaked dressings, pads, and placenta safely.

Remember:

- Ensure the use of universal precautions in routine practice for all patients
- Report all cases of occupational exposure
- Avail yourself of post exposure prophylaxis (PEP) when required.

5.3 Management of Occupational Exposure

5.3.1 Steps to take following a needle-stick injury or mucosal exposure

In the event of an injury with a sharp object such as a needle or scalpel that has been used on a patient or when a splash of blood or secretions occurs over a mucosal surface, the following steps should be followed:

- Wash exposed area immediately with soap and running water or antiseptic solutions such as polyhexidine 2%, or glutaryladehyde 70%
- After a splash to the eye or any other mucous surface, irrigate/rinse the exposed area immediately with water (preferably running water) or normal saline
- Do not squeeze or rub the injury site
- Report the exposure to a senior member of staff, supervisor or the PEP officer immediately
- Evaluate the exposed person's eligibility for PEP.

5.3.2 Evaluation for post-exposure prophylaxis

Evaluating exposed person's eligibility for HIV post-exposure prophylaxis involves assessing the following:

- The nature and risk of the exposure
- Timing of the potential exposure
- The exposed person's HIV status
- The HIV status of the source of exposure.

5.3.3 Determination of Risk and ARV drugs for PEP

The exposure should be classified as 'low risk' or 'high risk' for HIV infection as in Table 5.1.

Immediately after exposure all exposed individuals should take PEP according to the estimated risk:

- Persons with low risk should take 2-drug ARV combination

- Persons with high risk should take a 3-drug ARV combination
- Where the risk cannot be ascertained, a 2-drug combination should be used

If the preferred regimen cannot be located rapidly it is better to administer an alternative regimen than to wait.

Table 5.1 Determination of Risk of HIV Exposure

Low Risk	High Risk
• Solid needle • Superficial exposure on intact skin • Small volume (drops of blood) on mucous membrane or non-intact skin exposures • Asymptomatic source or persons with viral load <1500 copies/ml	• Large bore needle, deep injury, visible blood on device, needle in patient artery/vein • Large volume (major blood splash on mucous membrane or non-intact skin exposures) • Symptomatic source or patient in acute sero-conversion or with high viral load

5.3.4 Actions to take following HIV testing in PEP

All persons exposed to body fluids should be counselled and tested for HIV; the subsequent actions that should be taken depend on the results of the HIV tests and Table 7.2 gives an outline of investigations at baseline and subsequent follow-up:

Table 5.2 Recommended Schedule of Investigations Following Exposure

Period	Recommended Investigations
Baseline	- HIV screening - Full blood count - Liver function test - Renal function test
Two weeks	- Full blood count - Liver function test - Renal function test
Six weeks	- HIV screening
Three months	- HIV screening
Six months	- HIV screening

- If the source person is HIV negative:
  - No PEP is necessary for the exposed person unless there is suspicion that the source is newly infected and in the "window period" of sero-negativity
- If the exposed person is HIV positive, infection is not due to the exposure being evaluated:
  - No PEP is necessary
  - The exposed person should be referred for further counselling and evaluation for ART eligibility, care and support services
- If the exposed person is HIV negative and the source patient is HIV positive:

- Give ARVs for a period of four weeks, depending on the assessed risk, as shown in Table 7.3
- Repeat HIV test at 3 and 6 months after the initial test
- Should the health care provider seroconvert during this period, provide appropriate care – counselling, evaluation for commencement of ART for HIV disease or refer for further management

- If it is not possible to determine the HIV status of the source patient:
  - Assume that the source patient is positive and proceed according to guidelines above.

Table 5.3 Recommended Drug Combinations for PEP

Recommended 2-Drug Combinations	Recommended 3-Drug Combinations
• TDF (300mg once daily) + 3TC or FTC (300mg once daily) • AZT (300 mg twice daily) + 3TC (150 mg twice daily) or CBV 450 mg twice daily. • d4T (30 mg twice daily) + 3TC (150 mg twice daily)	• Any of the 2-drug combinations at same dosage plus a PI or EFV (avoid EFV use in pregnancy) • Preferred combination is: o 2NRTIs + LPV/r 400mg/100mg twice daily o EFV (600 mg once daily) may be used as an alternative if NNRTI resistance is not suspected in source patient NB: NVP should never be used for PEP - as the risk of fatal hepatotoxicity outweighs that of HIV infection. NFV (1250 mg twice daily) may be used as the PI alternative.

The chosen regimen is continued for 28 days or until a negative result of HIV tests for the source patient become available. In areas of high HIV incidence, a significant number of HIV positive individuals may be in the "window period" of acute infection but test antibody negative. A high level of suspicion for acute HIV infection should therefore be maintained in such situations and PEP continued even if the HIV rapid test is negative.

5.3.5 Post-sexual exposure prophylaxis

The presumed benefits of PEP following occupational exposure to ARV have been extrapolated to other types of HIV exposure, including sexual assault. Where sexual exposure has occurred involving a person with HIV positive or unknown status, initiation of PEP as soon as possible after the exposure is likely to protect the exposed person and reduce the chances of HIV transmission.

Although a definitive statement of benefit cannot be made regarding PEP after sexual assault, the possibility of HIV exposure from the assault should be assessed at the time of the post assault examination. The possible benefit of PEP in preventing HIV infection also should be discussed with the assault victim if a risk exists for HIV exposure from the assault.

Factors that impact on the medical recommendation for PEP and victim's acceptance of the recommendation include:

- The likelihood of the assailant having HIV
- Any exposure characteristics that might increase the risk for HIV transmission
- The time elapsed after the event
- The potential benefits and risks of PEP to the victim.

Determination of assailant's HIV status at the time of the assault examination may sometimes be impossible. Therefore, the health-care provider should enquire about:

- Any available information concerning HIV-risk behaviour of the assailant(s), e.g. a man who has had sex with other men and injecting-drug or crack cocaine users
- Local epidemiology of HIV/AIDS
- Exposure characteristics of the assault.

When an assailant's HIV status is unknown, factors that should be considered in determining the likelihood of HIV transmission include:

- Whether:
  - Vaginal or anal penetration occurred
  - Ejaculation occurred on mucous membranes
  - Multiple assailants were involved
  - Mucosal lesions are present in the assailant or victim
- Other characteristics of the assault, victim, or assailant that might increase risk for HIV transmission.

If PEP is offered, the following information should be discussed with the assault victim:

- The necessity of early initiation of PEP to optimize potential benefits (as soon as possible after and up to 72 hours after the assault)
- The proven benefit and known toxicities of ARVs
- The benefit of adherence to recommended dosing
- The close follow-up that will be necessary
- The need for immediate review for emergency (post coital) contraception and STI management as indicated.

In post-sexual assault prophylaxis, ARVs should be administered as in the case of occupational exposure to HIV (*see Table 5.3)*. The decision on the use of two-drug or three-drug regimen should rest with the physician who will normally be guided by circumstances of the assault.

As with all cases of sexual assault it is important to arrange for on-going counselling and support for the victim.

5.3.6 Follow-up

HIV serology and other relevant laboratory investigations should be repeated at 6 weeks, 3 months and 6 months *(see Table 5.2)*.

- If taking PEP, the victim should be monitored for ARV drug toxicity
- If the victim is found to be HIV positive at any time after exposure, he/she should be referred to the ART clinic for evaluation to commence therapy for HIV disease.

SECTION 6
Community-Based PMTCT Services

6.0 Introduction

Community-based PMTCT is the provision of PMTCT services by formal (trained health personnel) or informal care providers such as traditional birth attendants (TBAs), volunteer health workers (VHWs), family members and other stakeholders outside the hospital settings usually within communities. Community-based HIV programs include those that provide services for children orphaned or made vulnerable by HIV, home-based care (HBC) and support services for people living with HIV, as well as prevention programs for the general population, the youth and high-risk groups. These services serve to complement those offered at health facilities.

The uptake of PMTCT services in Nigeria remains notably low despite significant advances in HIV/AIDS treatment and care. Studies have shown that TBAs lack adequate knowledge on issues relating to reproductive health, STIs and HIV/AIDS. It therefore becomes pertinent to train the informal cadre of community health resource persons to ensure a HIV/AIDS-free future generation. Community collaborative work aims at improving referral practices between TBAs and PHCs and induces self-referrals to skilled healthcare providers.

A skilled healthcare provider is "an accredited health professional—such as a doctor, midwife or nurse—who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the immediate post-partum period, and in the identification, management, and referral of complications in women and newborn infants" (WHO, 2008). TBAs, trained or untrained do not belong in the category of skilled health care providers. In this context, the term TBA refers to traditional, independent (of the health system), non-formally trained and community-based providers of care during pregnancy, childbirth, and the postnatal period.

Training Community Health Extension Workers (CHEWs), VHWs and TBAs equips them with knowledge and skills on key preventive health services messages for pregnant women and on recognition of need for referral to other levels of care for PMTCT services. Community PMTCT seeks to promote increased community participation including that of male partners and community health care providers for support and delivery of PMTCT services.

6.1 Goals of Community PMTCT

These include:

- To increase early regular ANC attendance and promote health facility delivery by all pregnant women
- To promote PMTCT service uptake in communities through communication that addresses socio-cultural issues surrounding pregnancy, child birth and sexuality
- To strengthen community-based structures to support post-natal care for all mothers and their babies including HIV positive mothers and their children.

Among the barriers limiting access to PMTCT services in Nigeria is the weak community component to link the mostly rural population to services that are exclusively facility-

based. There is growing evidence that community-based interventions are effective in addressing barriers to PMTCT uptake. Findings from countrywide surveys (NDHS) in Nigeria have revealed facts that must be taken into consideration in the effort to achieve the goals of Community PMTCT programmes. Some of these findings include:

- The higher burden of the HIV epidemic, which is also on the increase in rural areas where two-thirds of Nigerian population lives (NPC 2006), with median sero-prevalence of 3.7% and 4.1% in 2005 and 2008 respectively.
- Poor knowledge of MTCT
  - In 2003 46% of women and 56% of men knew that MTCT could occur through breastfeeding while in 2008 this knowledge has not significantly improved (52% of women and 59% of men)
  - By 2008, knowledge on effect of ART on reduction of MTCT has remained limited to only 28% of women and 39% of men
  - Knowledge of MTCT increases with level of education and wealth quintile, and it is higher in urban areas than in rural areas.
- Poor utilization of ANC services amongst pregnant women aged 15-49 years
  - Utilization of skilled ANC services is higher in urban than rural areas – 84% versus 46%
  - While 58% received ANC from a skilled provider during their last pregnancy, 36% had no ANC from any provider and 3% received ANC from a traditional birth attendant
  - While 16% made their first ANC visit in the first trimester, 45% made it within the first 6 months and 15% between the 6th or 7th months of pregnancy.
- Poor utilization of maternity services
  - While 62% of women deliver at home, 35% deliver at health facilities; about 20% deliver in public sector facilities and 15% in private sector facilities
  - Women in urban areas are more than twice as likely to deliver in a health facility (60% versus 25%)
  - Predictors of home deliveries among others include poor maternal education, low socioeconomic status, poor health infrastructure including difficulty with transportation and cultural practices
  - Mothers, TBAs, relatives, religious groups, etc deliver most women in the community.
- Poor Contraceptive Prevalence Rate (CPR) - a proxy for preventing unintended pregnancies among HIV positive women
  - Only 15% for all methods and 10% for modern methods; CPR among urban women is three times that of women in rural areas (26% versus 9% respectively).

In order to reach out and encourage women to promptly utilize ANC services there is a need to:

- Mobilise and build capacity of community structures

- Embark on community advocacy and sensitization to promote delivery under skilled supervision
- Devise strategies to ensure delivery of accessible and effective PMTCT services with continuity of care for HIV positive mothers and their families
- Ensure appropriate counselling support on infant feeding and availability of Early Infant Diagnosis (EID) facilities for HIV exposed children and their mothers
- Adopt a broad-based multidisciplinary approach that includes strengthening both public and private health systems as well as community-based support networks.

6.2 Elements of Community-Based PMTCT Services

6.2.1 Advocacy

Advocacy for Community PMTCT will involve:

- Collaboration with National Primary Health Care Development Agency (NPHCDA) to strengthen existing community-based structures e.g. Village Health Committees (VHC) and Community Development Associations to sensitize community members on MCH and PMTCT in order to promote sustainability
- Sensitization of Community Development Committees, PLHIV Support groups, CBO, FBO, TBAs/VHWs and Community leaders for involvement in PMTCT
- Involvement of State Ministries of Health and Local Government health authorities in programme implementation
- Community mobilization for support of community-based services.

6.2.2 Community Awareness and Participation

Community awareness for the benefits of PMTCT can help orient members of the community and create demand, leading to patronage. This can be achieved through:

- Sensitization of community-based organizations to support public messages that highlight the national PMTCT plan
- Sensitization of community members on the importance of HCT and PMTCT
- Developing a network of community organizations to participate in community HIV awareness programs and fostering community dialogue to promote MCH/PMTCT *(See Figure 6.1 below).*
- Identifying and building capacity of Community care clusters which will be supervised by Village Health Committees or Community Development associations
- Community care clusters
  - Develop coordinated plan for integration of facility-based and community based PMTCT
  - Provide care and support for HIV positive pregnant women.

6.2.3 Prevention

The prevention element of Community-based PMTCT can be achieved through:

- HIV risk assessment and prevention counselling
- Provision of HTC through outreach programmes
- Provision of family-centred index testing in homes or by referrals to health facilities
- Encouraging partner testing and disclosure to family members
- Encouraging the utilization of services for prevention for positives

- Distribution of PMTCT IEC materials
- Provision of family planning counselling and supplies
- Promotion of access to PHC services including immunization and child welfare services
- Promotion to improve access to and utilization of EID services and increased monitoring of HIV exposed babies using community resource persons
- Counselling and support for safe infant feeding to promote HIV free survival.

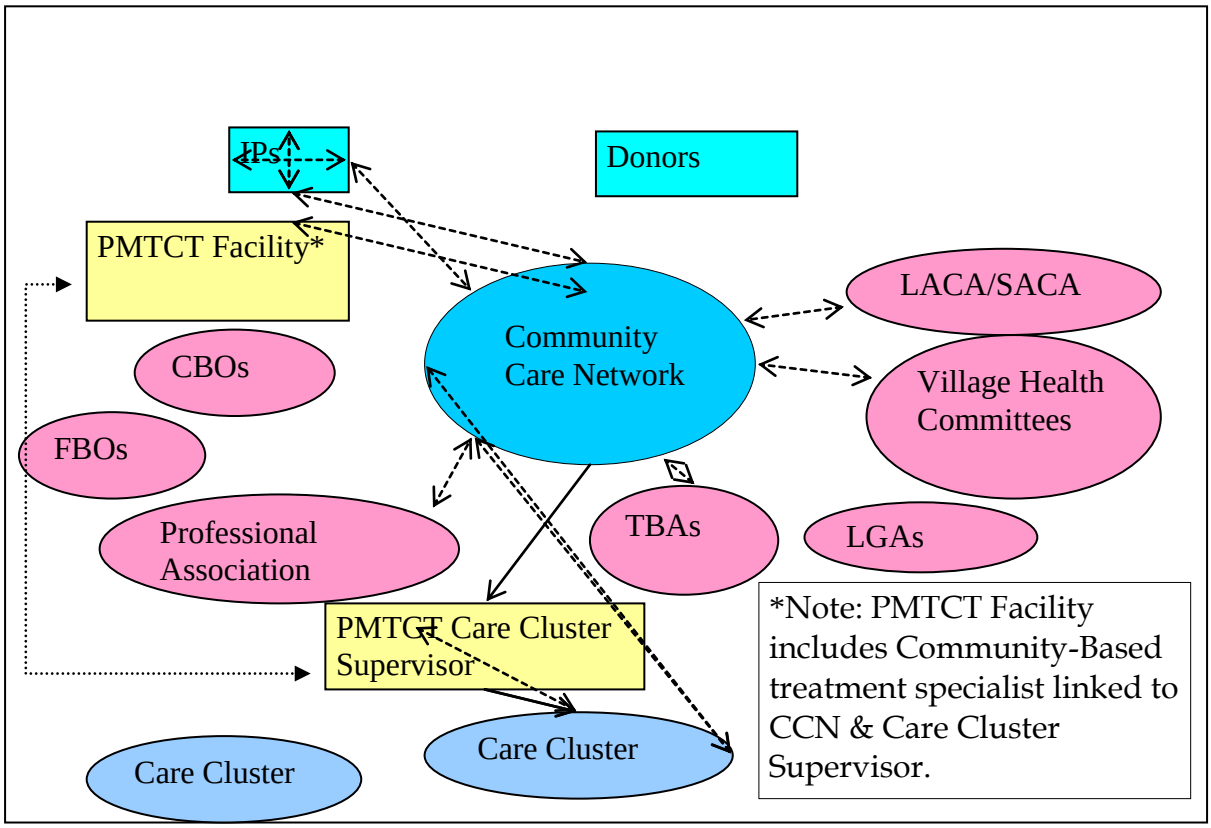

Figure 6.1: Formation of Community Care Network

6.2.4 Care and Support

Community-based PMTCT services should have access to available care and support services by linkages to health facilities. Comprehensive PMTCT facilities should be encouraged to form Community Care Networks (CCNs) to mobilize broad-based community support for PMTCT, strengthen referral linkages between the target health facility and the local community, and enhance capacities for community-based care of HIV Positive pregnant and lactating women and their families. These services are initiated or provided outside health facilities through the following methods:

- Referral from outreaches by CHEWS/TBAs (Community resource persons), religious groups, mothers, and relatives to facilities providing PMTCT services
- Involvement of facility and community-based support groups in the provision of services
- Strengthen community capacity to maintain a continuum of care to HIV Positive women, their infants and families
- Referral of home deliveries to health facilities

- Nutritional care and support at family level
- Home-based care and support including follow-up of HIV exposed babies
- Promote male involvement in MCH/PMTCT.

6.2.5 Partnership, Networking and Coordination

These elements can be achieved through:

- Establishing linkages with facility-based PMTCT centres to enhance coordination in programme implementation
- Conducting community mapping of resources, identify referral trigger factors, develop referral directories and support documentation of referral processes
- Establishing and strengthening of comprehensive referral network systems and coordination of two-way referrals between community and health facilities
- Promoting:
  - Integration of PMTCT into reproductive health, MCH and other programs
  - Integration of reproductive health into MCH/ANC services e.g. STI intervention, screening of latent syphilis infections
  - Public-private partnership through provision of services in private hospitals and providing resources to support PMTCT services
  - Partnership with Community Development Committees, CBO, FBO and other networks involved in community-based PMTCT
  - Partnership with community to provide human resources for health in MCH/ PMTCT.
- Identification of and collaboration with relevant sectors for community empowerment and economic strengthening activities to reduce gender inequalities as well as increase women's access to assets
- Collaborative coordination of community-based services by FMOH, NPHCDA, SMOH, LGA and partners.

6.3 Strategies for Effective Community-Based PMTCT Programme

6.3.1 Formation of support groups for HIV positive pregnant women *(Mother to Mother Care Model)*

- Encouraging HIV positive pregnant women to join facility-based support groups of HIV positive women
- Provision of facility support for support group members for their activities – meetings, default tracking home visits for mothers and exposed infants
- Training of support group members to serve as peer educators to one another so that they all stay linked into care and treatment
- Establishing processes for transition from facility-based support group for HIV positive pregnant women to community-based or facility-based support group for PLHIV after conclusion of PMTCT services.

6.3.2 Partnerships with community-based caregivers

- Advocacy and mobilization of community leaders, youth groups, market unions and women groups on safe motherhood initiative

- Capacity building and training of Community Development Committees, Village Health Committees, CBO, FBO and Peer Educators on HCT and PMTCT
- Providing nutritional support where feasible or by linkages to wrap-around nutrition programs
- Linkages of PHCs, CBOs, FBOs and support groups to TBA/ VHWs/ basic midwives with community orientation
- Actively link CBOs to health facilities with active referral of HIV positive pregnant women or pregnant women of unknown HIV status and their infants back to the facilities.

6.3.3 Targeted interventions for community Midwives, CHEWs, VHWs and TBAs

The majority of traditional birth attendants are neither trained nor registered yet they conduct numerous deliveries in their communities. The effort to involve this cadre of VHWs requires:

- Training them to recognise 'danger signs' during pregnancy and labour and rewarding them for referring women with such signs to health facilities
- Using them as 'health scouts' who identify pregnant women and nursing mothers in the community and direct them to the health facilities for appropriate care including PMTCT services
- Reducing their involvement in deliveries
- Providing opportunity for their transition into new roles for community care
- Identifying eligible TBAs through:
  - Focus group discussions (FGDs) around health facilities
  - Interviewing both health care providers and antenatal clients
- Set defined criteria for selection of TBAs to involve in community based PMTCT which could include:
  - Membership of an association
  - Be a respected person in the community
  - Capable of being trainable
  - Should be working in the communities where the PMTCT sites are located
  - Should be ready to refer pregnant women to access PMTCT services.
- Organisation of community resource persons (TBAs, VHWs, CHEWs etc) into community care clusters in order to provide adherence support, psychosocial and spiritual support for HIV positive women and their families
- Intensive organization, mobilization, basic training, and support for basic midwives and TBAs/VHWs
- Basic HIV and AIDS training should include:
  - Basic facts on HIV/AIDS
  - Basic PMTCT
  - Universal safety precautions
  - HIV counselling and rapid HIV testing
  - Prompt referral of HIV positive pregnant women to health facilities to ensure linkage of both women and their infants into care and treatment.

6.3.4 Role of HCT in Community PMTCT

HCT serves as an important entry point to Community PMTCT. For remote/rural hard-to-reach communities outreach campaigns or stand-alone HCT remains a practical option. PITC for pregnant women should be encouraged in these communities. HIV positive clients should be referred to the nearest health facility offering PMTCT. Such women and their infants should be linked to care and treatment at the first postnatal visit.

6.3.5 Expanding PMTCT services to PHC at Local Government level

- Increase access to PMTCT services to primary healthcare (PHC) facilities
- Develop capacity of PHC workers to provide PMTCT services
- Promote community participation in the provision of PMTCT services.

6.3.6 Interventions for private facilities with ANC and MCH services

- Encourage Public/Private partnership in the implementation of services
- Develop capacity of private practitioners in the implementation of PMTCT services
- Provide access to HIV testing and counselling for pregnant and nursing mothers.

6.3.7 Increasing partners utilisation and support for PMTCT

- Promote male involvement using town hall meetings, male interest groups and community forums using role models and male gatekeepers
- Distribution of IEC materials targeted at men
- Advocacy and promotion of couple counselling and testing
- Provision of Life skills education for male youths that is gender specific and focused on male behaviour change.

6.3.8 Roles of relevant stakeholders in PMTCT services provision

6.3.8.1 Roles of Policy makers and Federal Government

The role of policy makers include:

- Provision of strategic direction
- Formulation of policies that would promote scale up of PMTCT services without compromising quality
- Strengthen capacity to achieve full coverage of PMTCT services in line with strategic direction
- Development of strategic policy documents and guidelines
- Strengthen national technical working groups and national management of PMTCT
- Promote a harmonized, strategic approach to donor and implementation support
- Convene annual, national PMTCT meetings to review progress and challenges, and define key goals and decisions for the coming year
- Support improved programme data monitoring and modelling of coverage, need and impact
- Support integration of PMTCT with MCH and RH programmes
- Promote joint planning and accountability
  Support health systems strengthening and sustainability.

6.3.8.2 Roles of State Governments and SMOH

The role of the State Ministries of Health and other State Government agencies in monitoring and providing direction on HIV/AIDS programs with particular reference to PMTCT and MNCH (e.g. SACA, SAPC etc.) will include the following:

- Provision of funding for implementation, monitoring and supervision of PMTCT activities in the state
- Provision of waiver of ANC and delivery fees in public health facilities
- Provision of framework for linkages of private hospitals to Government facilities in provision of PMTCT services
- Support rapid implementation of new policies and guidance
- Provision of funding for training and capacity building of community level PMTCT structures (LG level, Ward level etc.)
- Enforcement of regulation of TBA activities and enforcement of reporting of women in labour beyond 12 hours in private hospitals, homes and outside health facilities to state level regulatory bodies.

6.3.8.3 Roles of Local Governments

The primary role of the Local Government is to promote and support implementation of HIV prevention, care and treatment services within maternal, newborn and child health and reproductive health programmes at PHCs.

Other roles of LG include:

- Provision of human resources in PHCs by recruitment of CHEWs, Clinical Officers, Community Health Officers and Retired Midwives etc.
- Training of Community Resources Persons (CORPS)
- Refurbishment, rehabilitating and equipping of PHCs
- Revitalising and strengthening Ward Development Committees and Community Development Committees
- Collaboration with National Youth Service Scheme and other Volunteers schemes to provide skilled healthcare workers to support PHCs
- Potential areas of support for integration of health services and involvement in HIV prevention, care and treatment services include Global fund, GAVI, UN agencies, DFID, NHIS/MDG grants, MSS Scheme etc.

6.3.8.4 Roles of TBAs

- Provision of counselling and information on PMTCT to pregnant women and their families
- Refer all pregnant women to PMTCT Sites for HCT
- Assist health care providers and other stakeholders in community mobilisation
- Collaborate with community-based organization and other CORPs in providing psychosocial support, treatment preparedness, adherence monitoring, home visits etc. to pregnant women and nursing mothers.

6.3.8.5 Roles of Health facilities

The roles of tertiary facilities include:

- Initiating and strengthening linkages with CBOs to provide care and support
- Collaboration with State Government structures to implement PMTCT guidelines

- Provision of male friendly services for partners (evening and weekend HCT)
- Coordination of community referral linkages
- Convening monthly/quarterly review meetings with collaborating organisations.

Specific roles for PHCs include:

- Active participation in provision of PMTCT services such as HCT in ANC
- Provision of basic routine laboratory investigations for HIV Positive women
- Provision of refill of ARVs for women receiving PMTCT prophylaxis
- Referrals to secondary facilities for other services
- Supervision of CORPs in home visits to HIV Positive pregnant and nursing mothers.

Specific roles for private hospitals:

- Ensuring local linkages to government hospitals for provision of HCT in ANC
- Referral to secondary facilities for routine investigations and initiation of ARV treatment.

Specific roles for State Government hospitals:

- Initiate linkages with private hospitals and CBOs for provision of HCT in Antenatal clinics
- Monitoring of collaborating health facilities
- Recruitment of Community-based Treatment Specialists and CORPs
- Training of Community Resource persons
- Provision of EID services by DBS.

6.3.8.6 Role of Community Gate keepers and Religious leaders

- Support and encourage Community and Ward Development Committees in awareness creation on PMTCT
- Promotion of male involvement in ANC/MCH e.g. by active participation in town hall meetings for male focused groups and use of peer educators
- Promotion of community dialogue on PMTCT, ANC attendance and delivery in health facilities.

6.3.8.7 Role of Nursing and Midwifery Council

- Ensure update of in-service and continued education curriculum for training of nurses and midwives with current information on HIV prevention, care and treatment
- Advocacy for implementation of policies that support reliable and equitable access for all women.

6.3.8.8 Role of Community Health Practitioners Board

- Ensure update of in-service and continued education curriculum for training of community health care providers with current information on HIV prevention, care and treatment
- Regulation of activities of community health care providers at PHC level
- Support the provision of community mobilisation and community care activities by community health care providers.

6.3.8.9 Roles of Male Partners and Family members

The role of the male partner in reproductive health cannot be over emphasized:

- Financial provision and final decision making on ANC utilization, delivery location and services and infant feeding practices
- Acceptance and support to facilitate access to ANC and PMTCT services and support for infant feeding that promote HIV-free survival of infant and good health outcomes for mother
- Partners make themselves available and access HCT.
- Acceptance and consistent practice of safer sex practices and appropriate family planning methods

6.3.9.10 Corporate Private Organisations and other stakeholders

- Support for implementation of *National PMTCT Guidelines*
- Provision of additional resources for PMTCT implementation, monitoring and supervision
- Support for workplace committees to provide information on PMTCT to staff and their families.

6.4 Establishment of Community-Based PMTCT Services

6.4.1 Principles for the Establishment of Services

The following principles should be considered in establishing Community-based PMTCT

- Evidence-based Community interventions models
- Appropriate PMTCT services
- Appropriate resources
- Community participation
- Appropriate networking and linkages to facilities and other services.

6.4.2 Steps for Establishment of Community-Based PMTCT

- Advocacy to Community leaders, groups and members
- Strengthen Village Health Committees and set up Community care networks (CCN)
- Train CCN members and community resource persons
- Conduct situation analysis and needs assessment
- Development of Action Plan on PMTCT in line with *National PMTCT Guidelines*
- Implementation of programme activities
- Monitoring and evaluation.

6.5 Community Involvement and Support for PMTCT

A core element of PMTCT should be a two-way communication between programme staff and community members. Community knowledge and perspectives must be gathered and shared in order for programme managers to design effective services and messages for the PMTCT. In addition, health services should maintain dialogue with the community to keep members informed about the purpose and availability of programme services and to monitor acceptability and impact of the programme within the community.

Community participation is a crucial component for not only its sustainability but acceptance as well. It can be utilized to implement effective strategies to reduce stigma.

6.5.1 Strategies for Ensuring Community Involvement and Support

- Explore community norms and values

- Assess and use existing community resources, including sources of social influence
- Work through social networks
- Foster family and social support
- Harness the collective power of women as agents of change in the community
- Create synergy between clinic and community-based sources of information and services
- Address the broader context within which community involvement is promoted.

6.5.2 Male Involvement in PMTCT

The burden of HIV prevention should not be placed solely on women's shoulders. Opportunities to reach out to, motivate and support men and efforts to change behaviour should be explored. The following should be done to enhance male involvement:

- Promote discussion of reproductive health and PMTCT behaviours at home
- Encourage women to attend ANC with their partners at the first sign of pregnancy and book appointments and participate in women health education sessions
- Promote couple counselling by encouraging male partners to visit the Health facility with wife for HIV Counselling and testing
- Encourage sharing of results by couples or partners
- Promote cooperation in the use of condoms
- Educate men on pregnancy and lactation so that they can support their partners
- Provide support on eating nutritionally adequate diet during pregnancy and lactation
- Discuss feeding choices with partners, spouses, and health professionals and support agreed choices
- Promote discussion of the role of men in PMTCT and infant and young child feeding in formal and informal gatherings such as PTA meetings and club events
- Encourage women to join father/mother support groups
- Encourage the establishment of new men's support groups
- Encourage HCT for other family members including other wives in polygamous settings
- Encourage male partners to support HIV positive partners in coping with HIV infection and adherence to ARV therapy
- Encourage partners to provide financial support for transportation to clinic visits.

6.5.3 Establish Community Motivators to Promote HIV Prevention Behaviours

Community motivators are members of the community that are held in high esteem. They are able to mobilize and motivate members of the community to seek appropriate healthcare services. These motivators could include health care givers, community leaders and members, father-mother support groups, religious leaders, peer educators, CBOs, FBOs and CSOs. The establishment of motivators could help increase the number of the following:

- ANC attendees
- People who go for HIV testing and counselling, disclose their results to their partners and cooperate to take needed actions
- Young unmarried people who abstain from sex or delay it until they are married
- Couples and young people who stay faithful to one sexual partner

- People who use condoms during casual sex or while pregnant or breastfeeding.
- HIV-negative women and women of unknown HIV status who breastfeed their babies exclusively for the first 6 months of life
- HIV-positive couples who go for counselling at health facilities on how to feed their babies during the first months of life
- People and groups that provide support to HIV-positive people, breastfeeding support to nursing mothers, and support consistent abstinence, fidelity and condom use.

6.5.4 Steps for Planning Motivational Activities

Planning of motivational activities starts with the community motivator and ends with planning at the health centre level through the following stages:

- The community motivator prepares an individual activity plan
- The plan is shared during meetings with community
- Community motivators' plans are discussed during these meetings
- During ward health committee (WHC) meetings, leaders should incorporate these plans into Ward health plan
- Representatives of the various ward committees meet with heath centre representatives and consolidate the plans into one health centre plan.

6.5.5 Monitoring and Evaluation

Information systems exist to track program and organizational efficiency and health information systems (HIS) for facility-based HIV programs have been strengthened considerably. However, development of information systems for community-based HIV programs has lagged behind.

Community-based programs often have multi-component service areas and differ in both capacity and resources. This peculiarity, coupled with lack of streamlined indicators, often constitutes a large burden for community health care providers in terms of data to collect. Information systems for community-based HIV programs also face the same challenges as facility-based programs and their needs are thus more diverse.

Monitoring and Evaluation (M&E) is crucial at each stage of the project:

- To identify weaknesses in implementation
- To improve coverage where necessary.

PMTCT monitoring and evaluation has the potential to be the cornerstone of health systems strengthening and of evidence-based implementation and scale-up of services. In Nigeria, well-designed and well-conducted M & E could help to identify and correct potential problems on a continuous basis and can provide feedback to strengthen the planning, design and implementation of public health intervention programs.

It is therefore recommended that M & E for establishing an effective community-based PMTCT program:

- The best evidence-based practices from existing community-based PMTCT programs should be replicated
- M & E tools should be refined with inputs from feedback during pre-test of the final tools in the effort to scale up

- Mapping of data-flow from the community level to donor level should be carried out
- A critical minimum of indicators that can be captured by community-based information systems should be defined
- Guidelines that outline clear roles for community workers and volunteers (PAVs, CHWs and TBAs) should be provided
- Responsible people for collecting and using data should be identified at all levels of the monitoring framework
- A process to facilitate feedback to communities and community-based programs should be initiated and sustained
- Documentation should be made of available linkages across other programs/sectors such as OVC, EID, ART, Social Welfare, Income generating activities, etc. for referrals.

A rapid assessment tool should be used to conduct barrier analysis; this can be used to identify the peculiar behavioural determinants. This information will then be used to develop more effective behaviour change communication messages and activities.

Data quality improvements and verification checklists (DQA) should be used quarterly to verify the quality of data collected from the community care clusters.

A list of other tools required to monitor the community based PMTCT program should include:

- Referral card
- IEC distribution monitoring tool
- CHW activity report
- Community activity register
- Community resource persons meeting report
- Service provision tool
- Community Palliative Care Register
- Household visit tool
- Support to Community service providers monitoring tool (PAVs, CHWs and TBAs).

Illustrative indicators should include:

- Number of pregnant women visited at home; Number of CHVs, TBAs and PAVs providing home visits
- Number of persons mobilized to receive HCT services as a component of PMTCT
- Number of pregnant women referred to facilities to receive PMTCT services.

Data on Early Infant Diagnosis serves as a key program element and impact indicator. Scaling up EID will require addressing barriers such as:

- Problems related to timely testing
- Delivery of results
- Prompt initiation of treatment for infants testing positive.

Effective infant feeding support is a current gap and efforts should be made to track strategies to reduce this gap using *Mother-to-Mother mentoring*.

SECTION 7
Communication for PMTCT

7.0 Introduction

Communication is a process of transmitting and receiving information on a particular issue between two or more people (sender and receiver), through a channel (medium), aimed at reaching mutual understanding. This can be verbal or non-verbal, intentional or unintentional, uses a mutually understood code (language of interaction) and usually involves a feedback process.

7.1 Communication Gaps in PMTCT

Communication for PMTCT should be preceded by careful identification of gaps in view of the huge role of communication interventions. This can be achieved through PMTCT research (formative, participatory rapid appraisal, knowledge, attitudes, behaviour and practice) studies using qualitative and quantitative methods. Based on available research and anecdotal evidence, the problems, needs and challenges that require communication interventions include, but are not limited to, the following:

- Inadequate knowledge of issues related to PMTCT (e.g. basic information about HIV and AIDS, benefits of HTC, risks associated with mixed infant feeding)
- Cultural and/or religious barriers to the promotion of and support for modern family planning methods, especially condom use
- Poor understanding among stakeholders of their roles and responsibilities in support of PMTCT
- Inadequate demand for PMTCT services
- Stigma and discrimination against PLHIV
- Community support structures for PLHIV
- Inadequate knowledge and skills among health care providers on interpersonal communication and counselling
- Lack of or inadequate community dialogue and participation
- Male dominance in decision making and health seeking behaviour at household level
- Lack of male involvement
- Negative attitudes and behaviour of service providers to clients
- Lack of a forum for health care providers to discuss PMTCT issues (e.g., operational safety, Post Exposure Prophylaxis, welfare).

7.2 Goal and Objectives of Communication for PMTCT

Goal:

To reduce the spread and impact of HIV transmission among women of reproductive age, their babies and families through strategic communication interventions.

Objectives:

- To create awareness and increase knowledge on PMTCT and HIV and AIDS, including understanding the benefits of knowing one's HIV status and importance of post-natal care and follow-up

- To positively influence attitudes, norms, values and behaviour regarding PMTCT issues, including HTC, infant feeding and community care and support
- To create demand for PMTCT services, using appropriate multimedia approaches and channels
- To create a supportive environment (especially community structures) for clients on the PMTCT programme and families affected by HIV and AIDS
- To increase support of traditional, religious and political leaders for the PMTCT programme
- To improve health care providers' capacity and skills to provide high quality PMTCT services
- To facilitate the generation of political will, provision of adequate funds and a favourable legislative environment for PMTCT and PLHIV, through targeted advocacy to all tiers of government
- To enhance strong and sustainable partnerships through awareness creation and capacity building for civil society organisations and the private sector to respond to HIV and AIDS and PMTCT.

7.3 Priority Audiences

To ensure effective communication programming for PMTCT, it is most important to decide on the priority target audiences to be addressed in relation to the gaps identified. The socio-economic and demographic characteristics of the audiences should also be considered. The key audiences would include the following:

- Policy makers (executive, legislative and judicial arms of government; hospital management, heads of health training institutions, regulatory institutions and other decision makers)
- Community leaders (religious, traditional, heads of community networks, e.g. community/village development associations
- Household heads
- Men and women of reproductive age
- PLHIV
- CBOs, NGOs, FBOs, Support Groups of PLHIV
- Health service providers
- The private sector, including pharmaceutical companies
- Development partners and the donor community
- Mass media.

7.4 Desired Behaviour Changes

It is expected that the priority audiences shall be motivated, influenced and persuaded through a careful selection of communication activities to adopt and maintain desirable changes in behaviour that will enhance the achievement of the objectives of communication for PMTCT. The desirable behaviours for each category of audiences listed below are not exhaustive.

7.4.1 Policy Makers

- Provide an enabling environment (policy, economic, social, legal) in support of PMTCT
- Seek technical information and guidance, as may be required, to increase understanding of issues and guide decision-taking and pronouncements
- Provide information on and define roles and responsibility in support of PMTCT
- Participate actively at advocacy and mobilization events for PMTCT
- Provide an enabling environment (policy, economic, social, and legal) for the reduction of stigma and discrimination against PLHIV.

7.4.2 Community Leaders (Traditional, Religious and heads of CDAs/VDAs)

- Promote PMTCT, especially HTC, through public statements, activities and actions
- Encourage and support community dialogue/participation in support of PMTCT
- Support and promote use of modern family planning methods, including condom
- Seek information on roles and responsibility in support of PMTCT
- Participate actively at advocacy and mobilization events for PMTCT
- Accept and care for PLHIV at family and community settings
- Increase involvement of women in decision making at all settings
- Promote male involvement in family health issues, including PMTCT.

7.4.3 Men and Women of reproductive age *(particularly the pregnant)*

- Increase personal risk perception
- Seek counselling and testing services at health facilities managed by trained service providers
- Increase utilization of PMTCT services
- Promote PMTCT among peers, colleagues
- Increase involvement of women in decision making at all settings
- Encourage and support partners/relations to attend antenatal care, including PMTCT services
- Ensure adherence to the infant feeding choice, while avoiding mixed feeding
- Men are strongly encouraged to attend ANC services (including PMTCT) with partners.

7.4.4 People Living With HIV Break the silence, address denial and seek necessary counselling and non-counselling services

- Join support groups
- Utilise PMTCT and other services and advocate for their use among pregnant women
- Increase self-efficacy for stigma reduction, and other positive living attributes
- Advocate for the *Greater Meaningful Involvement of Persons Living with HIV and AIDS* (G/MIPA) in programming.

7.4.5 Civil Society groups (CBOs, NGOs, FBOs, Support Groups)

- Increase community mobilization for HIV/AIDS and PMTCT
- Organise and coordinate community response to MTCT
- Seek information on roles and responsibility in support of PMTCT

- Participate actively at advocacy and mobilization events
- Organise and conduct events that encourage community dialogue on HIV/AIDS and PMTCT
- Support the fight against stigma and discrimination
- Advocate for greater funding and better legislation in support of PMTCT.

7.4.6 Health Care Providers

- Continue to improve knowledge and skills on PMTCT, especially on counselling, other service provision, universal precautions, interpersonal communication and human relations and ARV practices
- Participate actively in the *Health care provider Interactive Forum*
- Effectively coordinate the *ANC Interactive Forum*
- Encourage antenatal attendance among pregnant women
- Provide friendly and confidential services based on improved knowledge and skills
- Provide services in non-discriminatory/non-stigmatising manner.

7.4.7 The Mass Media

- Provide adequate publicity on all PMTCT-related activities
- Improve knowledge and skills on HIV and AIDS to ensure accurate information, proper use of language, analysis and presentation
- Support monitoring visits to PMTCT sites
- Actively participate in advocacy and mobilisation for PMTCT
- Produce human interest stories that encourage access and utilisation of services and discourage stigma and discrimination
- Facilitate provision of free airtime and print space for PMTCT issues and events.

7.4.8 Development Partners and Donors

- Strengthen partnership with government and other stakeholders in ensuring proper planning, implementation, monitoring and evaluation of PMTCT programmes
- Sustain provision of financial, technical and logistic support for the PMTCT programme.

7.4.9 The Private Sector

- Strengthen partnership with government and other stakeholders in provision of financial and logistic support for the PMTCT programme
- Collaborate with stakeholders in PMTCT awareness campaigns e.g. free text messages by GSM companies, advertorials promoting PMTCT in newspapers
- Provision of free/subsidised drugs and commodities e.g. by pharmaceuticals
- Actively participate in advocacy and mobilisation for PMTCT.

7.5 Key Messages for PMTCT Communication

The messages are to influence and motivate the audiences to adopt the desired behaviour for PMTCT. The key messages, which reflect the desired behaviour changes for each of the priority audiences, are contained in the *PMTCT Communication Matrix* at the end of this section. It should be noted that the messages are not exhaustive. Messages should be creatively applied to different situations.

7.6 Channels/Media

The mass media are most valuable for awareness creation, and contribute to behaviour change. In order to achieve maximum desired effect in the choice of media and the design of communication support materials, it is most important to consider the following:

- Careful selection of media based on the characteristics of the priority audiences, the issues, problems and needs to be addressed
- Careful selection of lead and support media in appropriate mix for each audience
- Interpersonal Communication (IPC), aided by communication support materials, is the cornerstone of the communication intervention for PMTCT, because of the challenge of low literacy, diversity of language, need for persuasion, credibility and integrity of message sources (e.g. health care providers, health educators, traditional leaders, religious leaders, teachers, civil society personnel). One-on-one communication invariably holds the key to stimulating demand for PMTCT services as well as strengthening positive behaviours toward PLHIV
- Communication materials in both print and electronic formats should be prepared based on audience research
- Draft communication support materials must be pre-tested with priority audiences to adequately reflect, among others, the characteristics of:
    - Relevance
    - Comprehension
    - Appropriateness
    - Acceptance (text, language, illustration) and sensitivity to culture
    - Religion and values of the audiences.

7.7 Monitoring and Evaluation of Communication PMTCT Interventions

Communication interventions should be monitored and evaluated to ensure that activities are implemented according to plan and to determine level of success achieved in the objectives set for communication. Effective monitoring and evaluation requires setting and application of indicators that will be based on the communication objectives.

Table 7.1: The PMTCT Communication Matrix

Communication Gap	Priority Audience	Desired Behaviour Change	Key Messages	Channels/ Media
a) Poor knowledge of issues related to PMTCT (Basic information about HIV & AIDS, benefits of VCT, risk associated with mixed infant feeding etc) b) Misconception about PMTCT services	1. Policy makers	Provide enabling environment (policy, economic, social, legal) in support of PMTCT	Enactment and support for implementation of policies and laws will promote PMTCT	• Advocacy visits, meetings and advocacy packages • Mass media advocacy
	2. Community leaders: (Traditional religious, CDA/CDC Chairs, etc)	• Promote PMTCT through public statements • Encourage and support community dialogue/ participation in support of PMTCT • Encourage ANC attendance by women (and men) in the community	• Utilizing PMTCT services reduces the risk of MTCT • Community dialogue and mobilization activities increases awareness and creates the demand for PMTCT services • Adequate knowledge on HIV and AIDS helps in appropriate self risk-assessment.	• Advocacy visits & meetings • Community dialogue sessions
	3. NGOs, CBOs, FBOs,	• Increase community mobilization for PMTCT • Organise and coordinate community response to MTCT • Increased personal risk perception	• Knowledge of HIV status and utilization of PMTCT services helps in protecting you and your family from the infection • MTCT is Mother to Child Transmission of HIV. • It is possible for an infected mother to have an HIV negative baby	• Training workshops seminars, rallies, community theatre, networking meetings, community and peer dialogue sessions • Communication support materials (print and electronic)

Communication Gap	Priority Audience	Desired Behaviour Change	Key Messages	Channels/ Media
	4. Men and women of child bearing age, particularly pregnant women	• Increased demand for counselling and testing services • Increased utilization of PMTCT services	Utilizing PMTCT services reduces the risk of MTCT	• Inter-personal communication media (drama, songs, story telling, poetry), group dialogue (eg, age grade meetings), health education, sermons in religious gatherings, ANC interactive forum • Inter-personal communication (IPC) training
	5. Health Care Providers	• Promote PMTCT • Provide friendly and confidential services as well as accurate information, based on improved knowledge and skills	Friendly attitudes and disposition by service providers encourage clients' utilization of PMTCT services	• Health care providers interactive forum • Job aids • Communication support materials (print and electronic)
	6. PLHIV	• Join support groups of PLHIV • Utilise PMTCT services • Increase self-efficacy for stigma reduction, and other positive living attributes	• Support groups are very good sources of information and psycho-social support for PMTCT • Utilizing PMTCT services reduces the risk of MTCT • A confident and positive attitude prolongs your life	• Training workshops and seminars • Life-skills building workshops

Communication Gap	Priority Audience	Desired Behaviour Change	Key Messages	Channels/Media
	7. Mass Media	• Increased coverage of PMTCT • Advocacy for PMTCT	• Knowledge is power • Journalists have a role to empower the people with correct and complete information on PMTCT	• Training workshops, seminars and conferences • Support materials
c) Cultural and/or religious barriers to the promotion and support for modern family planning methods, including condom	Community leaders (Traditional, religious, etc)	Support and promote use of modern family planning methods, including condom	Modern family planning methods including condom help to prevent the spread of MTCT	• Advocacy visits, meetings • Sensitisation meetings • Communication support materials • Inter-personal communication media (as above)
d) Stigma and discrimination against PLHIV	Policy makers	Provide enabling environment that reduces stigma and discrimination against PLHIV	Enact and support implementation of policies that reduce stigma and discrimination against PLHIV	• Advocacy visits, meetings • Sensitisation meetings
	Health Care Providers	Provide services in non-discriminatory/ non-stigmatising manner	Friendly attitudes and disposition by service providers reduces stigma and discrimination against PLHIV	Inter-personal communication (IPC) training
	• Community Leaders • Family Members	Acceptance and care for PLHIV at family and community settings	• PLHIV are our brothers/sisters • We should accept and care for them so they can contribute positively to the community • God commands us to be our brother's keeper	• Communication support materials (print and electronic) • Advocacy visits, meetings • Sensitisation meetings

Communication Gap	Priority Audience	Desired Behaviour Change	Key Messages	Channels/ Media
	PLHIV	• Positive attitude to life • Compliance with medical, nutritional, psycho-social prescriptions and counselling • Promotion of PMTCT and other modes of prevention, mitigation, care and support	• Living positively is healthy and reduces stigma and discrimination • Denial kills. Join a support group	• Inter-personal communication media (as above) • Inter-personal communication (IPC) training • Communication support materials (print and electronic) • Regular group dialogue
e) Lack of or inadequate community dialogue and participation	Community Leaders; NGO, FBOs, CBOs and Support groups	• Seek information on roles and responsibility in support of PMTCT • Participate actively at advocacy and mobilization events for PMTCT • Organise and conduct events that encourage community dialogue on PMTCT	• A community that talks together and works together can solve problems together • Community leaders and CSOs have a responsibility to ensure their communities participate actively in PMTCT	• Advocacy and sensitisation meetings • Seminars and workshops, community and peer dialogue
f) Male dominance in decision making and health seeking behaviour at house hold level	Men; Community Leaders (traditional, religious, VDA/VDC heads)	• Increase involvement of women in decision making at all settings • Encourage and support partners/relations to attend ante-natal care including PMTCT services	• Women are good planners and managers • When women are part of decision making, the health and social status of the family improves • Support from relations increase utilization of PMTCT services	• Advocacy and sensitisation meetings • Inter-personal communication media (as above) • Communication support materials

Communication Gap	Priority Audience	Desired Behaviour Change	Key Messages	Channels/Media
g) Lack of male partner involvement	Men, traditional, religious and VDC/VDA leaders	• Encourage wife/partner to go for ante natal care • Attend ante-natal clinic with partners	• Marriage is for love and having children involves husband and wife • Following your wife to the ANC, will increase the family bond required for the welfare of the child • Encourage your wife to access PMTCT services and protect your child from HIV	• Inter-personal communication media (as above), community and peer dialogue, religious gatherings • Communication support materials
h) Negative attitudes and behaviour of service providers to clients	Health Service Providers (Doctors, Nurses, Counsellors, Social workers, Lab. Technicians etc)	Friendly and confidential services based on improved knowledge and skills	• Earn your clients respect and confidence • Provide pregnant women with friendly and confidential services • Help prevent MTCT	• Inter-personal communication (IPC) training • Health care providers interactive forum • Communication support materials (print and electronic)

SECTION 8
Monitoring and Evaluation for PMTCT

8.0 Introduction

Monitoring and Evaluation (M&E) is an essential component of PMTCT activities. The overall purpose of monitoring and evaluation is to measure programme effectiveness at all levels and guide toward achieving goals and set strategic objectives. Information obtained from M&E can be used to demonstrate to the programme planners and policy makers that the programme efforts had measurable impacts on the expected outcome.

Monitoring is a continuous (routine) process used to verify step-by-step progress of the PMTCT programme at various levels to see whether activities are being implemented as planned, ensuring accountability, and identifying successes and challenges related to the intervention activities. It also provides resources for evidence-based planning through timely feedback to relevant authorities. Monitoring is best carried out using well-defined simple indicators meant to measure the input, process, outputs and outcome of the intervention programme.

Evaluation is carried out periodically to determine and document the extent to which results are attributable to the intervention programme measured through the outcome and impact indicators. It is concerned with identifying reasons for success and failure of a programme. It addresses future options, challenges, strategies and priorities for the continuous process of development.

Monitoring and Evaluation involves the collection, collation, analysing, report writing and feedback on various thematic activities. The Monitoring and evaluation feedback provides information for informed policy development, guidelines and implementation of the programme.

8.1 Monitoring and Evaluation Activities

The FMOH/NASCP maintains the central PMTCT Monitoring Information System (MIS) database and provides technical assistance to the States and PMTCT sites for continuous monitoring of the PMTCT program. It has the responsibility of coordinating the adaptation, development and review of the tools, indicators and guidelines that guides the collection of the PMTCT data at various levels. PMTCT data reporting is done in accordance with the National M & E information flow.

8.1.1 Service and Data Quality Activities

The Federal Ministry of Health will provide all PMTCT sites with the following National monitoring and evaluation tools:

- PMTCT registers *(see Annexes)*
- PMTCT Summary forms *(see Annexes)*
- Standard Operating Procedure (PMTCT SOP)
- Guidelines and Training Manuals.

For proper completion of the registers and forms at the sites, the Federal Ministry of Health and other stakeholders shall provide trainings at all levels (national, zonal, states, health facilities) on appropriate data collection and reporting system which feed into the National

PMTCT-MIS system. *The current registers and forms are undergoing a process of review which will be finalised in 2011.*
Essential quality assurance, quality control and quality improvement mechanisms will be developed and disseminated to PMTCT Service site coordinators and other staff as part of the site activation process.

It is anticipated that PMTCT site coordinators will:

- Utilize the commodities and training manuals provided
- Conduct further staff orientation and trainings
- Ensure an internal routine check of the registers being completed by the site team at all relevant point of services (i.e. ANC and Labour/Delivery, Postnatal including Paediatric wards)
- Provide regular supportive supervision and mentoring to the site staff completing the registers and monthly summary forms.

Using a standardized data quality checklist, a systematic plan for periodic external data quality assurance (DQA) check will be conducted by the Federal/State/Local Government Ministry of Health and other stakeholders. This will ensure data availability, consistency and validity.

The on-site activities during DQA should include:

- Check for the availability of the PMTCT registers and monthly summary forms *(see Annexes)*
- Review of site registers and summary forms for completeness and accuracy
- Availability and use of guidelines and SOP
- Patient and data flow.

The FMOH or SMOH in collaboration with relevant stakeholders should conduct monitoring and supervisory visits quarterly and DQA at least twice every year. At each of the visits, onsite mentoring and supportive guidance should be provided. At the end of the M & E visits, feedback should be provided to the PMTCT site coordinator and the entire site team.

8.1.2 Evaluation Activities
Process and outcome evaluations will be periodically conducted during the national scale up of PMTCT services to all the levels of health care. The result of the evaluation will be used to ensure both the ease and efficiency of scale-up, as well as to assess current programme success and inform future revisions of the *National PMTCT Guidelines* and *Strategic Plan*.

- Process evaluations will be conducted periodically to assess the quality of PMTCT implementation in all settings
- Outcome evaluations will be conducted periodically to assess short-term outcomes of the programme (PMTCT uptake service elements - HTC for ANC clients, ARV utilization, uptake of mothers' infant feeding choice, and number of infections averted in infants).

- Evaluation of content will include periodic reviews of the *National PMTCT Guidelines* and *National Strategic Plan*
- Evaluations of scope and area of coverage will focus on geographical distribution of PMTCT sites to ensure equity
- Evaluation of quality of implementation will focus on the ability of all PMTCT sites to meet the minimum service delivery and reporting requirements.

The overarching purposes of process evaluation are to guide programmatic implementation and aid in appropriate redirection of human resources and commodities to meet the national targets. These evaluation activities will be conducted by the FMOH/NASCP in collaboration with other stakeholders and implementing partners.

Targeted evaluations (TE) and other operational research (OR) including complex analysis of the routine PMTCT data will be used to periodically evaluate the effectiveness of PMTCT Services and intervention outputs, outcomes and impact in Nigeria. Some of the areas of interest includes but not limited to:

- Coverage and access analysis of PMTCT services in States in Nigeria
- Effectiveness of ARV prophylaxis for PMTCT
- Behaviour change impact of PMTCT programme on women and men of reproductive age.

8.2 National PMTCT Indicators

The National PMTCT indicators are used to assess the successes of preventing mother to child transmission of HIV in Nigeria. The national indicators help to demonstrate if the programme goal and objectives are being met. It also supports global indicator reporting.

The indicators are outlined under the following two categories.

8.2.1 Geographic Coverage and Access Indicators

- Number of health facilities providing and reporting PMTCT Services
- Number of LGAs reporting PMTCT Services
- Number of States reporting PMTCT services
- Number of health facilities providing and reporting EID services
- Number of LGAs reporting EID services
- Number of States reporting EID services
- Percentage of ANC attendees who received pre-test information during their first ANC visit
- Percentage of pregnant women tested for HIV (during ANC and labour) and received their results
- Percentage of HIV positive women who received ARVs to reduce the risk of mother -to – child transmission of HIV
- Percentage of infants born to HIV – infected mothers who are infected.

8.2.2 PMTCT Service Output Indicators

- Number of new ANC attendees
- Number of pregnant women receiving pre-test Information on HIV

- Number of pregnant women who had HIV testing at ANC
- Number of pregnant women testing HIV positive at antenatal clinic
- Number of HIV positive pregnant women who had CD4 cell count
- Number of pregnant women who were Counselled, HIV Tested and received HIV result
- Number of HIV positive pregnant women counselled on infant feeding
- Number of HIV positive pregnant women counselled on Family Planning
- Number of HIV positive pregnant women who agree to partner notification
- Number of pre-test counselled partners of HIV positive women who accept an HIV test
- Number of partners of HIV positive women who were counselled tested and received result
- Sero-discordant rate among HIV positive pregnant women and their partners who were HIV tested
- Number of pregnant women delivering at reporting facilities who are HIV-positive.
- Number of HIV positive pregnant women who received single regimen (AZT) prophylaxis for PMTCT
- Number of HIV positive pregnant women who received triple regimen prophylaxis for PMTCT
- Number of HIV positive pregnant women who received single dose NVP in Labour for PMTCT
- Number of HIV exposed children delivered alive
- Number of HIV exposed children who received NVP prophylaxis for PMTCT
- Number of HIV exposed babies with HIV negative status (after 6 weeks, 3 months, or 18 months of life).

8.3 National PMTCT Data Collection and Reporting Tools

In order to collect PMTCT indicator data and monitor service delivery, a set of seven PMTCT registers and monthly summary forms were developed to capture appropriate care delivery information.

The registers are:

- General Antenatal Clinic Register
- ANC HIV Testing and Counselling Register
- Partner Register
- Delivery Register
- Maternal Follow-up Register
- Child Follow-up Register
- PMTCT ARV Drug Register
- ANC Counselling & Testing Monthly summary form
- Delivery Monthly summary form
- Child Follow-up Monthly Summary form

These tools capture PMTCT specific information on the services provided to women attending ANC at different point of service delivery. The registers ensure that health care providers provide the women attending ANC and their family appropriate PMTCT services they require. Comprehensive instructions describing how to complete the registers are provided to instruct service providers on the appropriate methods for completing them.

8.4 Supportive Supervision

There should be instituted local, state and national M & E supportive supervision for all PMTCT sites in Nigeria. This ensures that data collected on PMTCT program in Nigeria are valid, consistent, accurate, timely and reliable for informed programme decision-making and National Policies on PMTCT.

A fully and functionally developed system to periodically monitor the quality of PMTCT services and data will be instituted by all local programs and monitored by external resource persons (designated as Site Support Supervisors) at the LGAs, State, and national level. During each on-site supportive supervision visit, the developed *National PMTCT Service and Data Quality Assurance Tool (SOP and Checklist)* will be applied to review the services and data collection process. This in-depth review will ensure identification of inconsistencies in data collection, collation and transmission to the next level of data flow and serve as opportunity for on-site capacity building process for the service providers.

To ensure the effectiveness of this supportive supervision, relevant cadre of health care providers and M & E specialists should be identified and trained on how to provide supportive supervision to PMTCT sites within their locality. At the state and LGA levels, the *State AIDS Program Coordinator* and *LGA Department of Health HIV/AIDS Focal Person* should be identified.

8.4.1 Guide on Supportive Supervision

Supportive Supervision is a helping process and not an inspection. The purpose of the supervision visit is to provide assistance and support to health care providers
This may include:

- Helping health care providers solve problems
- Working with health care providers to assess and to improve the quality of the service they provide
- Providing on the spot training where needed
- Arranging for longer-term training when needed
- Communicating messages from local Health Management Team (HMT) to the health care providers
- Communicating issues and concerns from health facility to the LGA, State HMT
- Helping to strengthen links between the health facility and the community
- Bringing necessary stationery, drugs, equipment, and supplies to the health facility at each visit.

8.4.2 Preparing for the Supportive Supervision Visit

- Schedule your visit in accordance with established monthly and annual supervision plan; avoid surprise visits
- Review the work plan for the health unit to be visited – objectives & targets
- Review of statistics for health facility/ unit to be visited
- Review report of last supervision visit. Note the problems identified at that visit which you should follow-up at this visit
- Note issues or changes in procedures which you will need to communicate to health facility personnel or which will require special attention during the visit
- Think about the supplies and equipment you may need to deliver to the health facility on your visit.

8.5 Data Reporting and Information flow

- Health facilities are to summarize all information in the PMTCT registers into the summary forms at the end of every month. The summary forms will be checked and signed by the supervisor before they are submitted to the M & E unit of the LGA health office
- The Local Government M & E officer will now summarize all the data from all the facilities within the LGA and send a copy of the report to the State Ministry of Health (SMOH)
- SMOH will summarize the data from the LGAs, provide feedback and send a copy of the report to the FMOH
- FMOH will:
  - Analyse all data from the States, write report and provide feedback to all levels
  - Share the report with Implementing partners and other stakeholders at national levels including National Agency for Control of AIDS (NACA).
- Implementing partners supporting PMTCT services at various levels are to key into this information flow and strengthen the LGAs and State monitoring mechanism.

SECTION 9
Logistics and Distribution

9.0 Introduction

Logistics refers to all the processes involved in the selection, forecasting, procurement, financing, inventory control, warehousing and distribution of medicines and health commodities. *Distribution* is the process where medicines and health commodities move in a safe swift manner (within a defined frame work) to the end users. Establishing and maintaining functional distribution networks is integral to the success of the programme.

The HIV/AIDS commodity supply chain management (logistics) system is essential if the control of HIV epidemic is to be achieved. Securing a dependable, regular supply of HIV test kits, reagents, ARVs and drugs for treatment of opportunistic infections, to service delivery points (SDPs) is pivotal to the success of the treatment programme since any interruption of supplies will endanger the lives of the patients as a result of emergence of drug resistant viruses among other consequences.

9.1 Purpose and Activities of Logistic and Distribution

The purpose of a logistic system is to get the right quantities of the right goods to the right place at the right time in the right condition at the right cost. Logistics and distribution constitute a supply chain management system that involves all activities that move supplies from the source to the end user.

Issues of logistics and distribution must therefore take account of several factors:

- Source(s) of funds for the implementation of the logistics programme
- Scope of the programme
- Effective forecasting/quantification
- Effective procurement
- Warehousing
- Distribution and distribution channels
- Effective coordination of logistics process to avoid stock-out
- Rational use of resources and supplies
- Coordination between levels (FMOH, SMOH, LGAs, SDPs)
- Supportive supervision to ensure adherence at the SDPs
- Inventory management for adequate and accurate record keeping
- Monitoring and evaluation
- Feedback mechanism.

9.2 Commodities for PMTCT

The commodities for PMTCT programme comprise essentially of:

- ARVs
- HIV test kits/reagents
- Drugs for opportunistic infections
- Family planning items
- Cervical cancer screening items

- STI screening kits
- EID items
- Laboratory items and other consumables.

A functional commodity procurement and supply chain committee comprising of appropriate stakeholders should be established at all levels. The roles of a *PMTCT Procurement and Supply Chain Committee* include the following:

- **Selection**
  Selection of PMTCT of HIV commodities depends on factors such as the pattern of prevalent opportunistic infections, capacity to diagnose and handle the diseases and availability of finances.

- **Forecasting and procurement**
  The process of determining those quantities to procure is what is called forecasting. Forecasting is usually done at project level and covers a period of more than one year with information on consumption pattern.

- **Distribution and storage**
  The commodities distribution process begins when the commodities are sent from the manufacturers or suppliers and ends when the commodity consumption information is sent to the Central Medical Store.

- **Ensuring rational consumption**
  Rational use of the commodities requires that PLHIV receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for the adequate period of time, at the lowest cost to them and their community.

- **Management support**
  The PMTCT commodity logistics management cycle is driven by factors that must be in place for the system to operate smoothly which include competent human resources, sufficient finances to fund the activities and purchase the commodities, a functional logistics management information system that provides vital information for planning, and managerial support in form of supervision and evaluation.

9.3 Logistics Management Information System

One of the primary components of any logistics system is a functional Logistics Management Information System (LMIS) that ensures availability of timely and accurate data for decision-making. These essential data must be collected for every product, at every level, all the time.

The three essential data elements include:

- **Stock on Hand**: Describes the quantities of usable stock of PMTCT commodities available at a particular point in time
- **Consumption pattern:** Describes the quantity of PMTCT commodities used during the report and order cycle
- **Losses/adjustments:** Losses include the quantity of PMTCT commodities removed from the distribution system for any reason other than usage (e.g. losses, expiry,

and damage). Adjustments may include receipt or issue of supplies to/from one facility to another that is not their usual supplier (e.g. a transfer).

In order to collect and report the above-mentioned data items, a number of forms were designed for the management of these commodities.

The LMIS forms include:

a. Inventory Control Card
b. Daily Consumption Record
c. Record for Returning/Transferring Commodities
d. Combined Report, Requisition and Issue Form.

a. Inventory Control Card

Inventory Control Cards track the quantity of PMTCT commodities in a facility's storage area. This record collects two essential data items, stock on hand and losses/adjustment data. The Inventory Control Card should be kept in a facility's storage area.

b. Daily Consumption Record for PMTCT commodities

This record collects the number of PMTCT of HIV commodities that have been used in the facility over a defined period of time and should be kept with the person(s) who dispenses. This information is called the Dispensed-to-user data.

c. Record for Returning/Transferring Commodities

This is used in the event that PMTCT commodities may be required to be returned to the Central Medical Stores or transferred to another facility at the same level for various reasons ranging from expiry, damage, change in the treatment guidelines, or over-stock.

d. Combined Report – Requisition and Issue Form (PMTCT commodities)

This captures all the information that is collected on the Inventory Control Card and the Daily Consumption Record for ARV drugs/ test kits. The report is used to calculate the facility order quantities, and to monitor whether the facilities are maintaining stock according to plan, i.e. no overstock, shortages, or stock outs.

9.4 Sourcing for Funds

- The Federal Government (FMOH), State Governments (SMOHs), Local Government Councils, (LGCs) should make adequate and effective budgetary provisions for sustainable implementation of the HIV and AIDS programmes which include the HCT, ARV and the PMTCT, programmes
- Government should also provide HIV/AIDS (HCT, ARV and PMTCT) programmes with funds derived from dedicated taxes, as is the case with the Education Tax Funds (ETF) in order to ensure adequacy of funding of these programmes
- All funds budgeted, including grants and donations, should be directed towards the realization of the logistic goal.

9.5 Needs Forecasting

In order to ensure that commodities for sustainable PMTCT programme implementation are available in adequate quantities, forecasting of needs must be carried out systematically:

- Personnel responsible for forecasting must be adequately knowledgeable about the process through proper training
- Adequate data and information on the extent of coverage of the programme must as much as possible be available and accessible
  Forecasting should be based on a simple, reproducible and evidence-based systematic and scientific approach
- A logistics information system or database should be regularly updated through information generation from regular monitoring and evaluation activities at programmatic and warehousing levels.

9.6 Procurement of PMTCT Commodities

An effective procurement process would invariably lead to availability of good quality commodities at favourable economic rates. This can be ensured through:

- Consolidated procurement of PMTCT commodities carried out centrally in order to benefit from the economy of scales
- Careful identification of commodities with appropriate specifications determined according to needs and situational specificity
- Competitive bidding of procurements to attract many prospective suppliers
- Procurement of commodities from reputable sources and preferably primary manufacturers with guarantee on product quality
- Where necessary, negotiation of prices based on a sound knowledge of prices
- Inclusion of buffer stock of not less than 3 months of quantified needs for procurement with consideration of expiry dates
- Ensuring destination delivery of commodities procured to designated facilities
- Provision for direct emergency procurement of commodities when the need arises
- Seeking appropriate exemptions including duty and ports charges for commodities
- Accelerating commodity registration by NAFDAC/appropriate authority
- Encouraging local production of required PMTCT supplies.

9.7 Warehousing and Distribution

- There should be adequate coordination with the facilities and distribution agents appointed to promote best distribution practices
- All procured commodities must be stored with storage requirements fulfilled at both the central storage depot and at the facility level
- Storage facilities must be secured with enough burglary and other security fittings
- All statutory inventory records of stored commodities must be maintained and transmitted periodically to all relevant implementing agencies
- All procured commodities should be distributed or delivered directly to the facilities with only the buffer stock being maintained in the central storage depot
- Monitoring of the inventory level of commodities at the facility level should be done on a quarterly basis in order to avoid overstock and stock out
- All relevant supply chain management functions geared towards ensuring commodity security should be put in place.

9.8 Rational Use of Commodities

- The use of commodities should be based on prescriptions generated from the appropriately designated health officials
- The end users of the commodities especially the ARVs should be counselled on the need for adherence and should demonstrate their commitment in this regard before starting treatment
- For PMTCT programme, the use of ARVs must be according to the appropriate timing for their use
- Supportive supervision should be enhanced to ensure timely and efficient requisition, issue and reporting system
- Inventory records on logistics information management system should be maintained
- Supplies of commodities should not exceed one month's requirement
- Efforts should be made to ensure that recipients of ARVs and other commodities are not engaged in multiple registrations in the programme
- Adequate data on reported Adverse Drug Reactions should be maintained at each facility
- Appropriate training of personnel on supply management should be encouraged.

9.9 Monitoring and Evaluation

- Quarterly monitoring and evaluation of PMTCT commodities supply chain management between central depot and facilities must be encouraged
- A simple but effective reporting system should be developed for facility reporting on the supply situation
- LMIS should be developed and maintained at all levels
- A two-way information flow must be instituted to ensure effective information and data exchange
- All records of transactions involving the commodities irrespective of whether it has to do with supplies, rational use or even adverse drug reactions (ADRs) should be appropriately maintained
- A national committee should be established to review cases of ADRs, adherence and treatment failures on monthly basis
- Second line ARVs and OIs should be procured and stored as required
- The procurement and supply chain management committee should qualitatively and quantitatively analyse service delivery to end-users
- Quarterly and annual supply chain management appraisal of the PMTCT programme should be done.

9.10 Feedback Mechanism

- A functional LMIS that ensure availability of timely and accurate data management for decision making should be put in place
- All facilities and participants on the programme should receive regular feedbacks from the centre

- Such feedbacks should clearly illustrate areas of strengths and weaknesses
- Suggestions on improvements or processes review should be clearly spelt out
- Regular review meetings to discuss issues arising should be encouraged in order to strengthen programme implementation
- Regular communication and dissemination of stock status to the relevant stakeholders to ensure that information collected are used for decision-making.

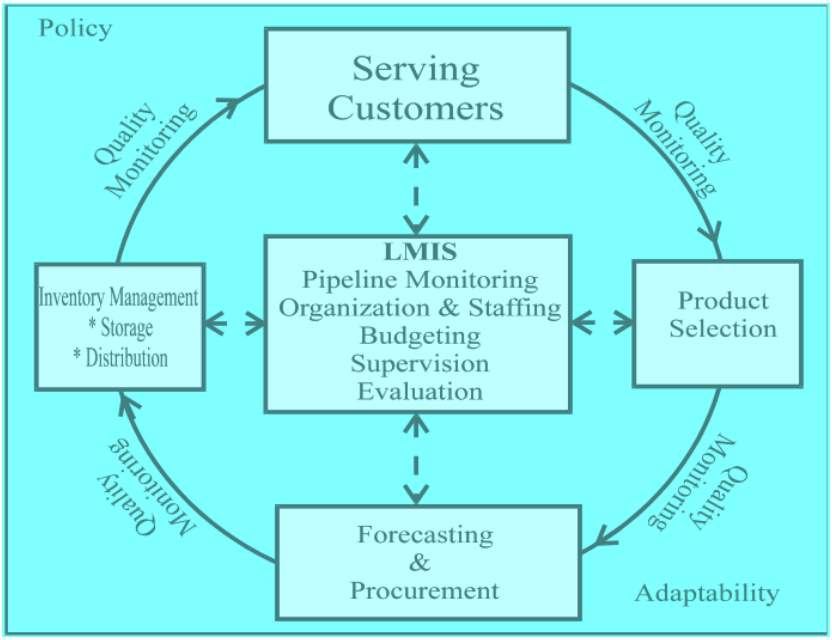

Figure 9.1: The HIV Commodities Logistics Cycle

Annex 1: WHO Clinical Staging of HIV/AIDS for Adults and Adolescents with confirmed HIV Infection

Clinical Stage 1 (*Performance scale 1: asymptomatic, normal activity)*

- Asymptomatic
- Generalized lymphadenopathy

Clinical Stage 2 (*and/or performance scale 2: symptomatic, normal activity)*

- Weight loss, <10% of body weight
- Minor mucocutaneous manifestations (seborrhoeic dermatitis, fungal nail infections, recurrent oral ulcerations and angular cheilitis)
- Herpes zoster within the last five year
- Recurrent upper respiratory tract infection (i.e. bacterial sinusitis).

Clinical Stage 3 (a*nd/or performance scale 3: bedridden <50% of the day during last month)*

- Weight loss of >10% of body weight
- Unexplained chronic diarrhoea lasting >1 month
- Oral candidiasis (thrush)
- Oral hairy leukoplakia
- Pulmonary tuberculosis within the past year
- Severe bacterial infections (i.e. pneumonia, pyomyositis).

Clinical Stage 4 (*and/or performance scale 4: bedridden>50% of the day during last month)*

- HIV wasting syndrome
- *Pneumocystis carinii* pneumonia
- Toxoplasmosis of the brain
- Cryptococcus, extra-pulmonary
- Cytomegalovirus disease of an organ other than liver, spleen or lymph node e.g. retinitis
- Herpes simplex virus infection, mucocutaneous or visceral, lasting >1 month
- Progressive multifocal leuco-encephalopathy
- Any disseminated endemic mycosis
- Candidiasis of esophagus, trachea and bronchi
- Lymphoma
- Kaposi's sarcoma
- HIV encephalopathy
- Extra-pulmonary tuberculosis

NB: Assessment of body weight in pregnant women need to consider expected weight gain of pregnancy; if suspected, use conditions whose presence is not dependent on body weight

Annex 2: General ANC Register

Hospital Name: _____ Centre No: _____ Month: _____ Year: 201__

Please enter only new ANC attendees

S/N	Date dd/mm/yy	Hospital Reg. No.	ANC No.	Name	Address	Source of Referral	Age	LMP dd/mm/yy	GA weeks	Gravida	Parity

Annex 3: ANC Counselling and Testing Register

Hospital Name: _____ Centre No: _____ Month: _____Year: 201___

Enter for the women who received HIV pre-test counselling (include group or individual counselling)

PMTCT TESTING AND COUNSELING REGISTER

S/N	Date dd/mm/yy	ANC No: (If applicable)	CT No. (If applicable)	Time of HIV Testing				Woman had Pre-Test information		Woman Accepted HIV Test		Woman's HIV Test Result		Post Test Counseling/Received result		Infant Feeding Counseling		Referred for ARV		Agreed to Partner Notification	
				Previously Known HIV+ result (Enter Date)	ANC	L&D	Post partum (<72hrs)	Yes	No	Yes	No	Pos	Neg	Yes	No	Yes	No	Yes	No	Yes	No

Annex 4: PMTCT ARV Register

Hospital Name: _____	Centre No: _____	Month: _____Year: 20___

Enter Only for all HIV Positive Women

S/N	Date	Hospital Reg. No.	ANC No.	Time of HIV Diagnosis			ARV Regimen Enter drug regimen codes							Completed Course of ARV		Child Given sDNVP	Child Given ZDV for 6 weeks		
				Past	ANC	Labour	1st Trimester	2nd Trimester	28 -33 Weeks	34 - 37 Weeks	38 - 40 Weeks	40 Weeks plus	In Labour	Yes	No	Within 72 Hrs of life	2 weeks	4 weeks	6 weeks

DRUG CODES: 1a – ZDV; 1b – sd NVP; 1c Triple Regimen

Annex 5: PMTCT Partner Register

Hospital Name: _____	Centre No: _____	Month: _____Year: 201___

Enter for the partners of women who test positive for HIV

S/N	Date dd/mm/yy	HCT Reg. No.	ANC Ref No.	Hospital Reg. No.	Partner Age	Pre-test Counselled				Partner Accepts HIV Test	HIV Test Result			Partner Is Sero discordant	Post-test Counselled		Referred To		
																	FP	ARV	Other specify
						Y	N	Y	N	Pos	Neg	Ind	Y	N	Y	N			

Annex 6: PMTCT Delivery Register

Hospital Name: _____ Centre No: _____ Month: _____Year: 200__

Enter only for all HIV Positive women

Date of Delivery dd/mm/yy	Hos Re§g. No	ANC No.	New Client		Time of HIV Diagnosis			ARV Therapy							ROM Delivery Interval		Mode of Delivery				GA (wks)	Episiotomy		Vaginal Tear		Feeding Choice		Maternal Outcome		Child Given NVP			Child Status		
								In ANC			In Labour																								
			Y	N	Past	ANC	Labo	Tripl		ZDV	Triple 1			Sd-NVP	< 4 hr	≥ 4 hr	Vag	Elect.	Emer	Other		Y	N	Y	N	EBF	EBM	Other	Alive	Dead	Y	N	SB	NND	Alive

Annex 7: Monthly ANC Testing and Counselling Summary Form

Facility Name:	Month of Report:	Centre No.:
Type of Facility:	Year of Report:	State:
City/Town:		

Enter Summary Data from General ANC, ANC Counselling & Testing and Partner Registers

	Variables	Number
	General ANC Register	
1.	New ANC clients	
	ANC Counselling and Testing Register	
2.	Group pre-test counselled	
3.	Individual pre-test counselled	
4.	Accepted HIV test	
5.A.	HIV test result ---- Positive	
5.B.	HIV test result ---- Negative	
5.C.	HIV test result ---- Indeterminate	
6.A.	Post-test counselled ---- Positive	
6.B.	Post-test counselled ---- Negative	
7.	Counselled on infant feeding	
8.A.	ARV therapy received ---- Triple therapy	
8.B	ARV therapy received ----	
8.C.	ARV therapy received ---- ZDV alone	
9.	Agreed to partner notification	
	Partner Register	
10.	Partners pre-test counselled	
11.	Partners accepted HIV test	
12.A.	Partners HIV test result ---- Positive	
12.B.	Partners HIV test result ---- Negative	
13.	Partners post-test counselled	

Completed by:		Date completed:	
Verified by:		Date verified:	

Annex 8: Monthly Delivery Summary Form

Facility Name:	Month of Report:	Centre No.:
Type of Facility:	Year of Report:	State:
City/Town:		

Enter Summary Data from both Facility and PMTCT delivery Registers

	Variables	Number
	Facility Delivery Register	
1.	Total deliveries	
	PMTCT Delivery Register	
2.A.	Number of new clients not previously booked at ANC	
2.B.	Number of HIV-positive women	
2.C.	Number of deliveries from HIV-positive women	
3.A.	Time of HIV diagnosis ---- Past	
3.B.	Time of HIV diagnosis ---- ANC	
3.C.	Time of HIV diagnosis ---- Labour / Delivery	
4.A.	ARV therapy in ANC ---- Triple therapy	
.		
4.C.	ARV therapy in ANC ---- ZDV alone	
5.A.	ARV therapy in Labour ---- Triple therapy	
.		
5.D.	ARV therapy in Labour ---- sd-NVP	
6.A.	Feeding choice ---- Exclusive breast feeding	
6.B.	Feeding choice ---- Exclusive breast milk substitute	
6.C.	Feeding choice ---- Mixed feeding	
7.	Child given NVP	
8.A.	Child status --- SB (Still birth)	
8.B.	Child status --- NND (Neonatal death)	
8.C.	Child status --- (Alive)	

Completed by:		Date completed:	
Verified by:		Date verified:	

Annex 9: Maternal Follow-up Register

Hospital Name: _____ Centre No: _____ Month: _____Year: 201___

Enter only for HIV Positive women

Family Planning (FP): **1 = None 3 = Condoms 5 = IUD 2 = Hormonal 4 = Abstinence 6 = Other**

Infant Feeding (IF): **1 = Excl. BF 3 = Mixed Feeding 2 = Excl. BMS 4 = Other, specify**

Date (dd/mm/yy)	Hospital Reg. No	ANC No.	Counselled for FP		FP Method Used (Code 1 – 6)	Counselled for Infant Feeding		IF Method at Present (code 1 – 4)	Partner HIV Status Known		Woman Referred to		
			Y	N		Y	N		Y	N	ARV	Pap S.	Other (specify)

Annex 10: Child Follow-up Register

CHILD FOLLOW-UP REGISTER

ENTER ONLY FOR HIV EXPOSED CHILDREN

	Mother's Information			Child Information									# Feeding		Rapid Test	1st PCR				2nd PCR					Rapid Test	ART Referal	Child Outcome								
(AA)	(BB)	(CC)	(DD)	(EE)	(FF)	(GG)	(HH)	(II)	(JJ)	(KK)	(LL)	(MM)	(NN)	(OO)	(PP)	(QQ)	(RR)	(SS)	(TT)	(UU)	(VV)	(WW)	(XX)	(YY)	(ZZ)	(AAA)	At 6 months			At 12 months			At 18 months		
Date (dd/mm/yy)	Reg. No.	Address & GSM No.	ARV*	Reg. No.	DOB (dd/mm /yy)	If Twins 1st	If Twins 2nd	Sex M	Sex F	Birth Wt (Kg)	**ARV	Age CTX Initiated (mo.)	Ever Breastfed (Y/N)	Feeding Option in 1st 3 Mo.	RT Result (Pos/Neg /NA)	Date Sample Sent (dd/mm/y	Date Result Received at facility (dd/mm/yy)	Result (Pos/Neg)	Date Caregiver Given Result (dd/mm/yy)	## Reason for 2nd PCR	Date Sample Sent (dd/mm/yy	Date Result Received (dd/mm/yy)	Result (Pos/ Neg)	Date Caregiver Given Result (dd/mm/yy)	RT Result at 18 mo. (Pos/Neg/NA)	Date Refered to ART (dd/mm/yy)	Well	Sick	Dead	Well	Sick	Dead	Well	Sick	Dead

* Mother's ARV Legend (D)
1 = sdNVP + Cbvr in LABOUR + Cbvr for 7 day) I only
2 = AZT in preg + TLE above
3 = AZT+sdNVP
4 = AZT+3TC only
5 = AZT+3TC+sdNVP
6 = HAART (ART)
7 = None

** Infant's ARV Legend (L)
1 = daily NVP
2 = NVP and AZT
3 = AZT only
4 = None

# Feeding Option in First 3 Months Legend (O)
1 = Exclusive Breast Feeding (EBF)
2 = Commercial Infant Formula
3 = Mixed Feeding (MF)

Reason for 2nd PCR Legend (U)
1 = Confirm Positive PCR
2 = Infants with Signs and Symptoms of HIV
3 = Follow-Up for Breastfed Child
4 = Previous Indeterminate Test
5 = Test -ve @ 9 mths with rapid test kit

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