POLICY and GUIDELINES FOR THE IMPLEMENTATION OF THE PMTCT PROGRAMME

National Department of Health

11 FEBRUARY 2008

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FOREWORD

After much discussion between policy makers and scientists, the Department of Health introduced the prevention of mother-to-child transmission of HIV (PMTCT) programme in 2001. The programme was first piloted to explore the impact of the use of nevirapine both with respect to its side effects as well as the operational requirements of the programme. The Department had concerns about the use of monotherapy and the possibility of resistance to a single drug as well as the lack of clarity on infant feeding options. The presentations by the scientific community also suggested that the use of monotherapy needed further research. But whilst these discussions were taking place, the Constitutional Court ordered otherwise, in 2002, – the implication of which resulted in the expansion of the Niverapine use without adequate requisite preparations.

The primary aim of the PMTCT programme was to decrease the number of HIV infected babies born to HIV positive mothers. Primary prevention of HIV infection particularly among women of childbearing age has always been the backbone of the programme. A comprehensive package of interventions were developed and implemented, including routinely offered voluntary counselling and testing (VCT), counselling on infant feeding practices, safe non-invasive obstetric procedures, single dose nevirapine (sdNVP) and the provision of infant formula feeding. Even then we realized that unless the health system as a whole was strengthened, the PMTCT programme will not succeed. In addition steps were taken to integrate the programme into the health system, including the integration of PMTCT indicators into the district health system, training of health workers as well as the allocation of financial resources for the programme.

Evaluation of the PMTCT programme in 2005 in three sites found that the impact of the programme depended on the degree of inequities in the health system as well as breastfeeding practices. This means that just providing nevirapine was not sufficient to improve outcomes for both mothers and babies. Research and operational data also appears to suggest that resistance to monotherapy has become a major issue – as was feared before the programme was expanded.

Recent research and advice from experts now suggests that dual therapy is indicated. After consultation between the Department of Health and experts it has been decided that the PMTCT guidelines should be revised and that dual therapy, using nevirapine and AZT should be used instead of nevirapine only for the prevention of the transmission of HIV from mother to child. Given the complexities of prescribing antiretrovirals especially to children it has been decided that only registered health professionals, in line with the relevant legislation and regulations, should be allowed to prescribe AZT. It should be noted that this has not been an easy decision given the lack of unequivocal scientific data and programme evidence on safety and effectiveness.

This programme must be seen as part of the comprehensive approach to the challenges presented by the HIV. It is also critical that as we implement these revised guidelines that we provide the highest possible quality of care to both mothers and infants.

It is important to record that the comprehensive HIV and AIDS programme had its genesis in the Partnership Against AIDS that was launched in 1998 by then Deputy President Mbeki as well as the work done by the South African National AIDS Council which was established in 2000 first under the chairpersonship of the then Deputy President of the country, Mr Jacob Zuma and most recently the current Deputy President Ms Phumzile Mlambo-Ngcuka.

Government is committed to the implementation of the comprehensive National Strategic Plan for HIV and AIDS and STIs. As well we shall continue to search for safer and more practical approaches to address the challenge of HIV and AIDS. The South African public is urged to continue to assist the government in preventing the spread of HIV and to ensure that those infected and affected continue to be respected and supported to the best of our ability.

MTshabalala

Dr Manto Tshabalala-Msimang MP

MINISTER OF HEALTH

Date: 10th February, 2008

ACKNOWLEDGEMENTS

The development of this document would not have been possible without the participation of experts in the consultations that led to the formulation of the guidelines. Thanks go to all who took the time and effort, be it through drafting sections or reading and commenting several times to improve the quality of the document. Special thanks go to the members of the PMTCT Guidelines task team including the following organizations and/or individuals: National Department of Health - Cluster: Maternal, Child and Women's Health; Cluster: HIV & AIDS and STIs; Cluster Health Information, Evaluation and Research; Cluster: Pharmaceutical Policy and Planning; Cluster: Medicines Regulatory Authority; Provincial Departments of Health; Wits Paediatric HIV Clinic; Medicines Control Council (MCC); Medical Research Council (MRC); University of KwaZulu-Natal; Witwatersrand University; National Essential Drug List Committee (NEDLC); Peri-natal HIV Research Unit (PHRU); Reproductive Health and HIV Research Unit (RHRU); Centers for Disease Control (CDC); United Nations Children's Fund (UNICEF); United Nations Development Programme (UNDP); Absolute Return to Kids (ARK); Elizabeth Glazer Paediatric AIDS Foundation.

Mr TD Mseleku
DIRECTOR-GENERAL: HEALTH
Date: 2008-02-13

ABBREVIATIONS and ACRONYMS

3TC	Lamivudine
AFASS	Affordable, Feasible, Accessible, Safe and Sustainable
ANC	Antenatal Care
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
AZT	Zidovudine
BF	Baby Friendly
BFHI	Baby Friendly Hospital Initiative
BBA	Born Before Arrival (to delivery unit)
CBO	Community-Based Organisation
CCMT	Comprehensive Care Management and Treatment for HIV and AIDS
CDC	Centers for Disease Control
CF	Complementary Feeding
CTX	Cotrimoxazole
DIO	District Information Officer
DNA PCR	DNA-based Polymerase Chain Reaction Test
DOTS	Directly Observed Treatment Short-course
d4T	Stavudine
ECD	Early Childhood Development
EBF	Exclusive Breastfeeding
EFF	Exclusive Formula Feeding
EFV	Efavirenz
ELISA	Enzyme-linked Immunosorbent Assay
EPI	Expanded Programme on Immunisation
FBO	Faith-Based Organization
FIO	Facility Information Officer
FP	Family Planning
HAART	Highly Active Antiretroviral Therapy
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
IDU	Intravenous Drug Use
IMCI	Integrated Management of Childhood Illness

INP	Integrated Nutrition Programme
Kaletra®	Lopinovir/ritonavir
MOU	Memorandum of Understanding
MTCT	Mother-to-Child Transmission of HIV
NGO	Non-Government Organisation
NHA	National Health Act
NHC	National Health Council
NSP	National Strategic Plan
NVP	Nevirapine
O & G	Obstetrics and Gynaecology
OVC	Orphans and Vulnerable children
OVG	Orphans & Vulnerable Groups
p24	protein 24
PCP	*Pneumocystis jiroveci* pneumonia (formerly *Pneumocystis carinii* pneumonia*)*
PEP	Post-Exposure Prophylaxis
PMTCT	Prevention of Mother-to-Child Transmission of HIV
PNC	Postnatal Care
RtHC	Road to Health Card
sdNVP	Single-Dose Nevirapine
SADHS	South Africa Demographic and Health Survey
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VCT	Voluntary Counselling and Testing
WHA	World Health Assembly
WHO	World Health Organisation

DEFINITIONS

Breast milk substitute

Any food or drink marketed or otherwise representing a partial or total replacement for breast milk, whether or not suitable for that purpose.

Commercial infant formula

Commercial formula refers to a commercial product that meets the applicable Codex standard for infant formula, follow-up formula and infant or follow-up formula for special dietary or medical purposes.

Complementary foods

Complementary foods means any foodstuff, whether in solid or semi-solid form, given to an infant after the age of 6 months as part of the transitional process during which an infant learns to eat food appropriate for his or her developmental stage while continuing to breastfeed or be fed with commercial formula.

Cup feeding

The act of feeding an infant or child using a cup, regardless of what the cup contains.

Exclusive breastfeeding or exclusive breast milk feeding

An infant receives only breast milk and no other liquids or solids, not even water, but may receive drops or syrups consisting of vitamins, mineral supplements or medicines that are deemed necessary and essential for the child. When expressed milk is given, the preferred term is breast milk feeding.

Exclusive formula feeding

Feeding infants who are receiving no breast milk, with a diet that provides adequate nutrients until the age at which they can be fully fed family foods. During the first 6 months of life, formula feeding should be with a suitable commercial formula. After 6 months complementary foods should be introduced.

Health care personnel

Health care providers and health care workers.

Health care provider

Any person providing health services in terms of any law, including in terms of the:

- Allied Health Professions Act, 1982 (Act No.63 of 1982)
- Health Professions Act, 1974 (Act No. 56 of 1974)
- Nursing Act, 2005 (Act No. 33 of 2005)
- Pharmacy Act, 1974 (Act No. 53 of 1974) and
- Dental Technicians Act, 1978 (Act No. 19 of 1979)

Health care worker

Any person who is involved in the provision of health services to a user, but does not include a health care provider. This includes lay counsellors and community caregivers.

HIV-exposed

Infant born to an HIV-positive woman

HIV-negative

Refers to people who have taken an HIV test with a negative result and who know their result.

HIV-positive

Refers to people who have taken an HIV test whose results have been confirmed positive and who know their result

HIV status unknown

Refers to people who have not taken an HIV test or who do not know the result of their test.

Infant

A person from birth to 12 months of age.

Micronutrients

Micronutrients are natural substances found in small amounts in food (vitamins and minerals) as compared with macronutrients (e.g. protein, fats and carbohydrates), which are found in larger amounts.

Micronutrient malnutrition

A term used to refer to diseases caused by a deficiency of vitamins or minerals.

Mixed feeding

Breastfeeding as well as giving other milks (including commercial formula or home –prepared milk), foods or liquids.

Mother-to-child transmission

Transmission of HIV from an HIV-positive woman during pregnancy, delivery or breastfeeding to her child. The term is used because the immediate source of the infection is the mother, and does not imply blame on the mother.

Nutritional status

The nutritional status of a person as determined by anthropometric measures (height, weight, circumference etc.), biochemical measures of nutrients, or their by-products in blood and urine, a physical (clinical) examination and a dietary assessment and analysis.

Nutritional supplements

Food- and/or nutrient supplements given in addition to food available at home.

Routine offer of counselling and testing

HIV-testing should be routinely offered to all ANC clients. Health care personnel give group information and individually offer HIV-testing. At this stage the patient / client always has the option to decline this. The patient/client receives post-refusal counselling or post-test counselling.

Safe infant feeding

Feeding practices that would lead to a healthy, well-grown, able live, HIV-free child who has no underlying morbidity.

WHO clinical staging of HIV & AIDS for adults and adolescents with confirmed HIV infection

Stage I.

- Asymptomatic
- Persistent generalized lymphadenopathy (PGL)

Stage II

- Unexplained moderate weight loss <10% of presumed or measured body weight
- Recurrent respiratory tract infections (e.g. bacterial sinusitis) (URTI) and/or performance Scale 2: symptomatic, normal activity.
- Herpes zoster within the last five years
- Angular cheilitis
- Recurrent oral ulceration
- Papular pruritic eruptions
- Seborrhoeic dermatitis
- Fungal nail infections

Stage III

- Unexplained severe weight loss >10% of presumed or measured body weight
- Unexplained Chronic diarrhoea >one month
- Unexplained persistent fever (above 37.5ºC intermittent or constant) >one month
- Persistent oral candidaisis
- Oral hairy leukoplakia
- Pulmonary TB
- Severe bacterial infections (pneumonia, empyema, pyomyositis, bone or joint infections, meningitis or bacteraemia)
- Acute necrotizing ulcerative stomatitis, giingivitis or periodontitis
- Unexplained anaemia (<8g/dl), Neutropaenia (<0.5 x 10^9 per litre) and/or chronic thrombocytopaenia (<50 x 10^9 per litre)

Stage IV

- HIV wasting syndrome
- Pneumocystis pneumonia
- Recurrent severe bacterial pneumonia
- Chronic herpes simplex infection (orolabial, genital or anorectal of >1 months duration or visceral at any site)
- Oesophagael candidiasis (or candidiasis of trachea, bronchi or lungs)
- Extrapulmonary tuberculosis
- Kaposis sarcoma\ Cytomegalovirus infection other than liver, spleen or lymph node (CMV)
- CNS toxoplasmosis (Toxo)
- HIV encephalopathy (ADC)
- Cryptococcosis – non pulmonary
- Disseminated mycosis (i.e. histoplasmosis, coccidiomycosis)
- Progressive multifocal leucoencephalopathy (PML)
- Cryptosporidiosis plus diarrhoea >one month
- Chronic Isosporiasis plus diarrhoea
- Herpes simplex infection; visceral or >one month mucocutaneous (HSV)
- Atypical mycobacteriosis disseminated (MOTT)
- Atypical disseminated leishmeniasis
- Non-typhoidal Salmonella septicaemia
- Extra-pulmonary tuberculosis (ETB)
- Lymphoma
- Kaposi's sarcoma (KS)
- Invasive cervical carcinoma and/or performance
- Symptomatic HIV-associated nephropathy or symptomatic HIV-associated cardiomyopathy

EXECUTIVE SUMMARY

This is an update of the National PMTCT policy and guideline. The South African PMTCT programme, conceptualized in 2000, has been implemented at pilot sites since 2001, and nationally since 2002. This policy document seeks to provide continued guidance towards successful reduction of mother to child transmission, building on work done in the past decade. Since the initiation in 2001 there have been some advances in knowledge, although much is still unknown.

Since inception, PMTCT services are offered in all public hospitals and in more than 90% of primary health care centres. During the 2005/06 financial year 70% of ANC attendees were counselled and tested for HIV of whom 26% tested positive. About 60% of pregnant women who tested HIV positive received Nevirapine. South Africa has the largest PMTCT programme in Africa.

Various studies that have been conducted on the programme suggest that the transmission rates range from 10 to about 30 percent and are even lower in the Western Cape where coverage of target population is above 90% since dual therapy was introduced. A report on the evaluation of the National programme should be released before the end of 2008.

In line with the International standards for a comprehensive strategy, the PMTCT policy recognises that in order to prevent HIV among women and children, the four elements of PMTCT are integral: -

- Primary prevention of HIV especially among women of childbearing age;
- Preventing unintended pregnancies among women living with HIV
- Preventing HIV transmission from a woman living with HIV to her infant; and
- Providing appropriate treatment, care and support to women living with HIV and their children and families.

The National PMTCT programme aims to: -

- Ensure primary prevention of HIV especially among women of childbearing age.

- Integrate PMTCT interventions into routine maternal, child and women's health services.

The specific interventions of the PMTCT programme include:

- **Primary prevention** of HIV especially among women of child-bearing age. :
- **Integrating PMTCT interventions** into routine maternal and child health as well as general HIV care, treatment and support services
- **Providing an expanded package** of PMTCT services, including:
    - Promoting the acceptability of voluntary counselling and testing services in the context of PMTCT in facilities offering routine antenatal care.
    - Promoting routine offer of voluntary counselling and testing.
    - Involvement of the partner and the family in order to ensure a comprehensive approach.
    - Providing appropriate regimens to prevent mother-to-child transmission of HIV according to the risk profile based on the HIV test, CD4 cell count and clinical staging.
    - Providing other appropriate treatment, such as for Opportunistic Infections (OI) management, nutritional support and anti-retroviral therapy, depending on CD4 cell count, nutritional status and clinical stage.
    - Providing psychosocial support to HIV positive pregnant women.
    - Providing quality, objective and individualized counselling on safe infant feeding practices (as defined in this document) for HIV positive women in health facilities offering routine ANC services, through trained feeding lay counsellors and health care professionals.
    - Strengthening obstetric practices which reduce PMTCT.
    - Improving follow-up care for HIV positive women and their infants.
    - Encouraging and supporting safe infant feeding.
    - Providing infant formula for at least 6-months for women who meet the AFASS criteria and who opt to exclusively formula feed.
    - Providing nutritional counselling and support for women who choose to exclusively breastfeed.
    - Integrating the follow-up of infants born to HIV positive women into routine child health services and the Integrated Management of

Childhood Illness (IMCI) Strategy.

- Early infant HIV testing using HIV PCR at 6 weeks of age (integrated with the EPI 6-week visit) irrespective of feeding option.
- Repeat HIV test for HIV-negative infants at 6 weeks after cessation of breastfeeding.

- **Ensuring an uninterrupted supply of test kits, drugs, infant formula and other consumables** in a timely and continuous manner; this includes developing a sustainable system for the procurement of all commodities.
- **Establishing management mechanisms** to facilitate programme implementation at all levels of the health care and social development delivery system.
- **Capacity building** of existing health care personnel on routine empowerment of women of child bearing age on PMTCT, voluntary counselling and testing, CD4 cell testing and interpretation, clinical staging, TB screening, cotrimoxazole prophylaxis, OI management, STI's treatment regimens, including issuing and dispensing drugs and toxicity monitoring, routine care of HIV-positive women, infant feeding and routine follow-up of HIV-exposed infants; capacity within larger, better-resourced centres and provinces should contribute towards identification of social problems and social safety networks in an area.

  Larger, well-resourced centres should take on a mentoring and supportive role and assist smaller, less resourced centres with implementation.
- **Encouraging appropriate managed public-private partnerships** (PPP) to strengthen services and accelerate implementation of PMCT services, with the emphasis on quality, standards and reporting.
- **Participation of civil society** including CBOs, NGOs, FBOs and treatment advocacy and literacy groups to accelerate and facilitate community and social mobilization - a key component in the implementation of this programme.
- **Developing a comprehensive integrated communication strategy** that includes:
  - The use of mass media campaigns to ensure effective and widespread dissemination of information around the benefits of the PMTCT programme especially to women of child bearing age

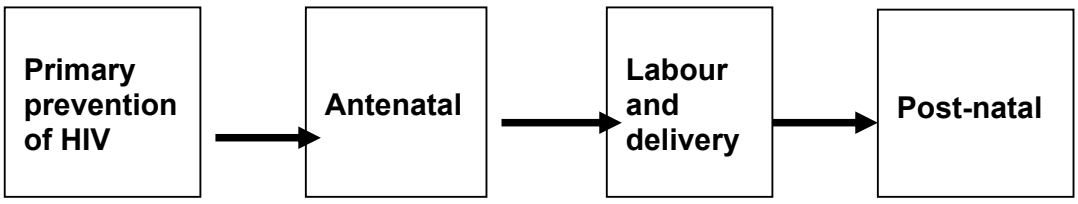
- Effective comprehensive communication methods
- Strengthen the community- based household and door-to door activities to educate and enhance utilization rates and effectiveness of program

- **Strengthening a comprehensive integrated** monitoring, research and evaluation **strategy and system**

Monitoring and evaluation of the PMTCT programme is essential. Minimum national set of indicators for the PMTCT programme have been developed that should be collected at the different stages of the programme implementation process.

THE FOUR STAGES OF PMTCT INTERVENTION OUTLINED IN THE GUIDELINE ARE AS FOLLOWS:

Figure 1: Four stages of PMTCT



Stage 1: Primary prevention of HIV and MTCT

Goal: Reduce prevalence of HIV among women of child bearing age

Objectives:

- Implement targeted HIV prevention programmes for women of child bearing age
- Strengthen prevention of unintended pregnancies among women living with HIV
- Support the implementation of women empowerment programmes and fight against gender based violence

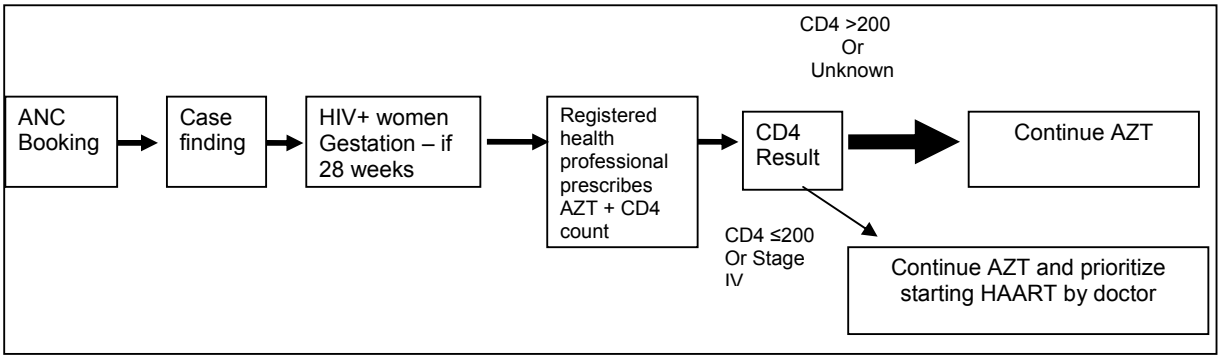
Stage 2: Antenatal care

Goal: To increase coverage of target population (HIV + PREGNANT WOMEN)

Objectives:

- Identify pregnant women who are HIV positive
- Ensure HIV-positive pregnant women enrol in the PMTCT programme
- Do a CD4 count on all HIV-positive pregnant women
- Assess according to the WHO clinical staging guideline.
- Encourage repeat HIV testing not later than 34 weeks during pregnancy
- Primary prevention counselling and support for HIV negative pregnant women
- Positive prevention counselling
- Encourage the involvement of the family
- Provide individualized psychosocial support
- Screen HIV-positive women for TB
- AZT prescribed by a registered health professional (in line with the relevant legislation and regulations) from 28 weeks gestation
- HAART for pregnant women with indications for such treatment.
- Other relevant non-HIV services
- Safe infant feeding counselling
- Provide nutrition support according to the South African National Guidelines on Nutrition for People Living with HIV, AIDS, TB and other Chronic Debilitating Conditions of 2007.

Figure 2: ARV- based activities at the Antenatal Clinic



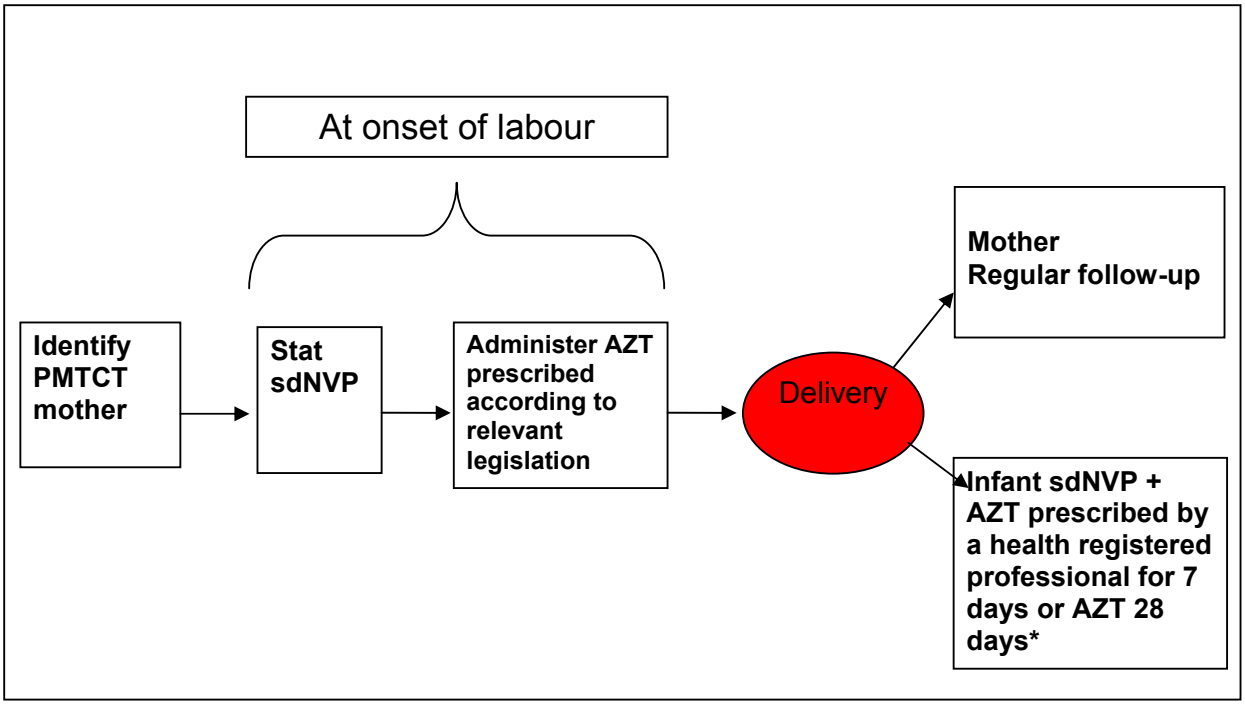
Stage 3: Labour and delivery

GOAL: Minimize the risk of MTCT of HIV during labour and delivery

Objectives:

- Identify women who are HIV positive
- Administer stat dose of NVP in 1st stage of labour
- Registered health professional, in line with the relevant legislation and regulations, to prescribe AZT according to protocol
- Avoid invasive obstetric practices and implement evidence-based Obstetric interventions recommended to reduce MTCT during labour and delivery
- Provide psychosocial support
- Counsel on safe infant feeding and confirm choice of infant feeding

Figure 3: ARV interventions during labour and delivery



***Indications for 28day AZT to infant**:

1. Mother received <4 weeks of AZT during pregnancy
2. Mother received <4 weeks of HAART or
3. Mothers who received only sdNVP
4. Mother did not receive any ARVs during pregnancy (unbooked mothers / who have not taken any ARVs during pregnancy and labour

Ongoing assistance (post labour)

- **Feeding choices**

Before the infant attaches to the breast, health personnel should confirm the mother's infant feeding choice and assist the mother accordingly.

- **Registration of birth**

New mothers should be assisted with registration of birth and assessment of social conditions for further management.

Stage 4: Postnatal follow-up of mother and infant

Goal: Reduce the risk of postnatal transmission of HIV

Objectives:

- HIV diagnosis – PCR at six weeks
- Identify all HIV infected infants that are eligible for HAART and initiate such therapy according to guidelines
- Ensure safe infant feeding practices for all infants and monitor weight gain and growth
- Cotrimoxazole for HIV exposed babies and HIV positive babies
- Clinically assess all mothers for anaemia and send blood specimen for haemoglobin measurement if pale
- Treat anaemia in consultation with a doctor trained in HIV & AIDS
- Assess and treat symptoms and signs of postnatal infection
- Keep mothers healthy

Figure 4: Postnatal PMTCT intervention for infants that are exclusively formula fed

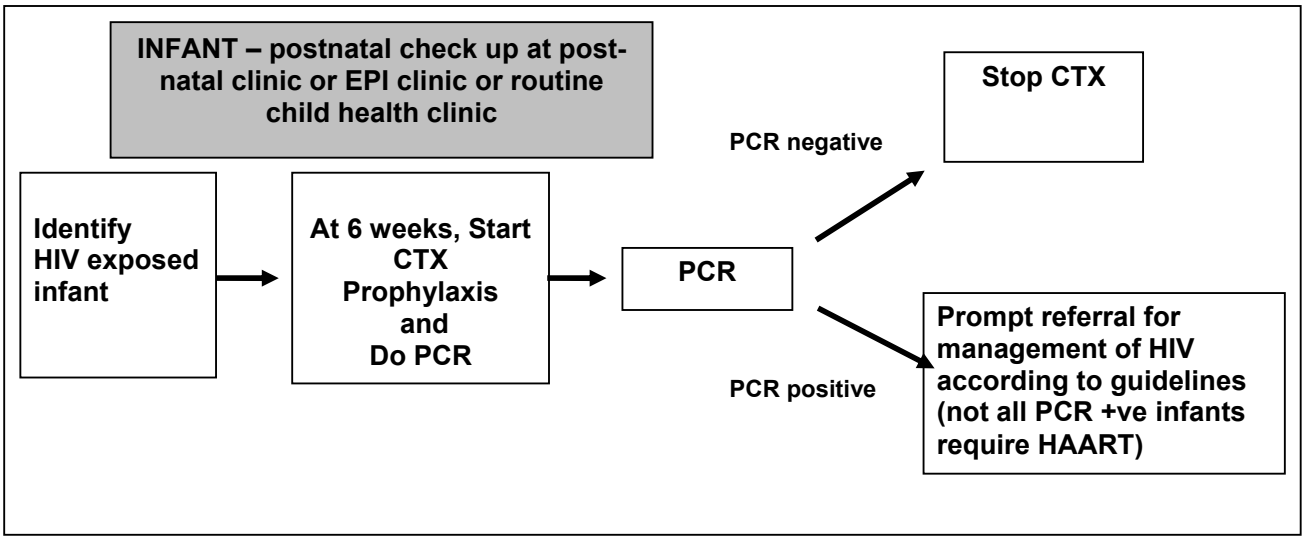


Figure 5: Postnatal PMTCT intervention for infants that are exclusively breastfed

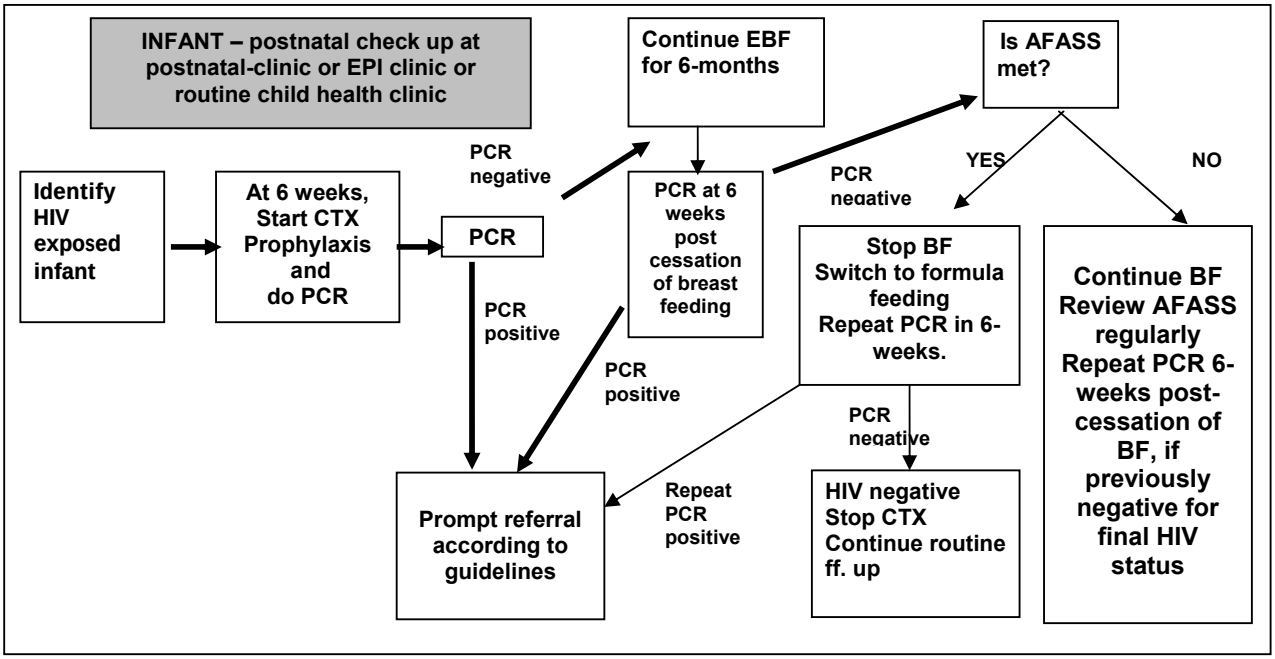
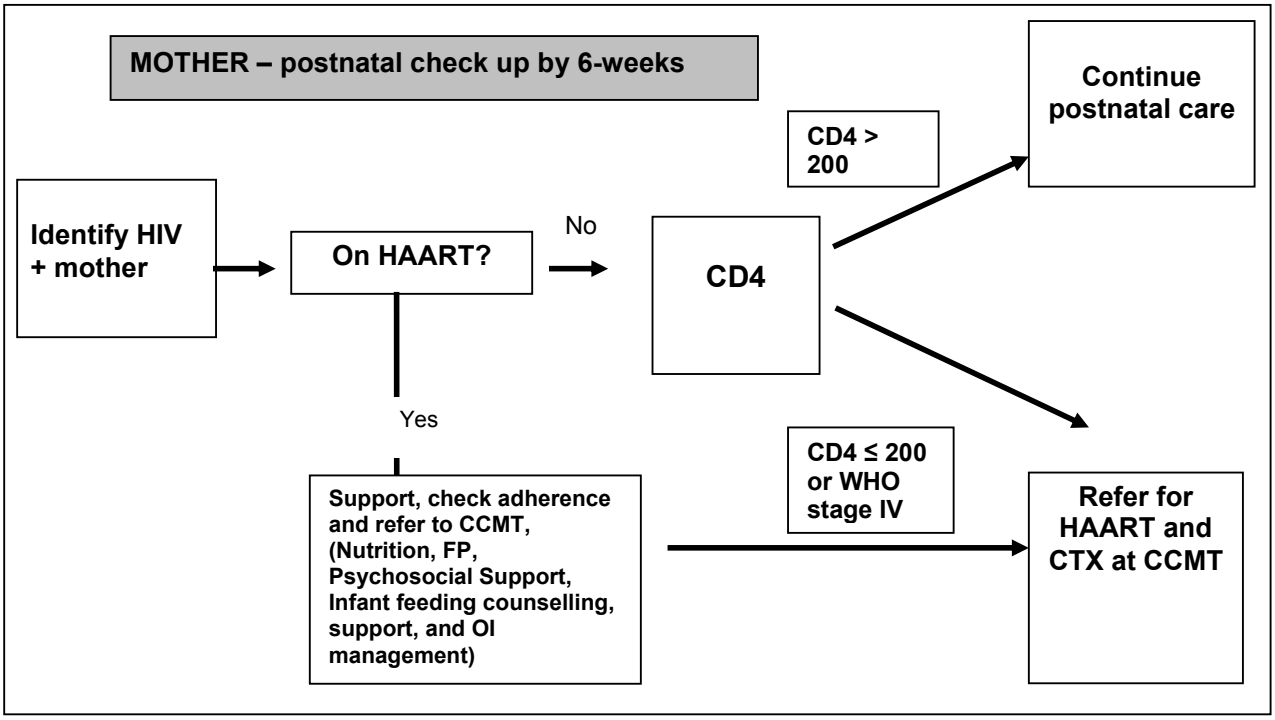


Figure 6: Postnatal care for mothers



SECTION A: INTRODUCTION and BACKGROUND

HIV is one of the major challenges facing South Africa today. The annual antenatal **National HIV and Syphilis Prevalence Survey** is currently the most reliable form of HIV surveillance in South Africa. This survey has been conducted since 1990. Trends show that during the period 1992 -1999 there was an exponential growth in prevalence. In the past few years it has been encouraging to note some decline in HIV prevalence amongst women aged below 20 years as well as a tendency towards global stabilization of prevalence in the past three years. The national HIV sero-prevalence rate in 2005 among pregnant women attendees in public health facilities was estimated to be 30.2%, and had gone down to 29.1% in 2006.

The commonest route of HIV infection for HIV positive children under 5 is through mother to child transmission. Preventing mother-to-child transmission of HIV would be the main intervention to reduce HIV infection amongst children. Transmission of HIV from a mother to her infant can take place during pregnancy, labour, and delivery and after birth via breastfeeding, especially mixed feeding. It is thought that the risk of transmission varies at the different stages with the risk during pregnancy ranging from 5-10%, 10-20% during labour and delivery and 10-20% through mixed feeding. In the absence of any interventions to prevent MTCT, it is estimated that in about thirty percent of cases the virus will pass from the mother to the infant.

A comprehensive package for a Prevention-of-Mother-to-Child-Transmission (PMTCT) programme was introduced in 2001, initially as a pilot programme and later, in response to a Constitutional Court ruling, as a full-scale national programme. Policy guidelines for the standards of care were developed.

The national PMTCT programme is available in about 3000 primary health care facilities countrywide. The package includes; primary HIV prevention programmes for women of child-bearing age, routine offer of voluntary HIV counselling and testing to pregnant women, safe infant feeding counselling and support, safe obstetric practices, single-dose nevirapine (sdNVP) to the mother and to the infant, as well as the provision of infant formula to women who choose this route and who will be able to do it safely, in an acceptable, feasible, affordable and sustainable manner.

This programme was expected to reduce HIV transmission by 50%.

HIV and AIDS policy and guidelines are constantly under review to consider new scientific evidence and adapt to the availability and affordability of interventions.

When the sdNVP was recommended by the World Health Organisation (WHO) on the basis of a randomized controlled clinical trial (HIVNET 012) that was done in Uganda, the South African government raised the question of the risk of resistance development with the use of single ARV. NVP was however registered by the Medicines Control Council (MCC) in April 2001 for use as monotherapy in PMTCT with the condition that Boehringer Ingelheim Pharmaceutical Company would conduct and support resistance-monitoring research. This company offered to donate NVP in South Africa and other African countries for use in PMTCT. The South African government contributed 50% towards resistance monitoring.

The original Departmental Plan for PMTCT was to implement 18 pilot sites in all provinces; one in a rural setting and another in an urban setting, both to establish the operational requirements of a nationwide programme but also to assess the effectiveness of the intervention in a real life situation. Systems were being developed to implement the pilot phase when in July 2002, lobby groups won a case against the Department of Health. The Constitutional Court ordered the Department of Health to, with immediate effect make Nevirapine and the provision thereof, available to all HIV positive pregnant women who wish to receive it in public health facilities.

The Department of Health implemented the court rulings to the letter and the PMTCT programme is now widely available.

The National Health Council and the Department of Health on various occasions interrogated reports on scientific developments and recommendations relating to;

- Nevirapine resistance development and its implications
- Postnatal HIV transmission related to infant feeding practices
- WHO guideline recommendations, and
- The performance of the National PMTCT programme.

Further changes to PMTCT regimens are now recommended on the basis of the balance in emerging evidence, broad consultation with key opinion leaders and, informed by national experience, situation and context. The reviewed South African policy and guidelines for the implementation of the PMTCT programme is presented in this document.

SECTION B: GUIDING PRINCIPLES

The Principles guiding the national PMTCT policy include the imperatives of the Constitution, Batho Pele, those outlined in the Comprehensive Care Management and Treatment Plan (CCMT) and those guiding the implementation of the NSP 2007-2011. These Principles are:

- **Supportive Leadership:** South Africa's political leadership with support from leaders from other sectors of civil society should ensure the implementation of this policy.
- **Effective Communication:** Clear and ongoing communication is an essential tool for the attainment of the aims of the PMTCT policy.
- **Effective Partnerships:** All sectors of government and all stakeholders of civil society shall be involved in the PMTCT and AIDS response.
- **Tackling Inequality and Poverty:** The NSP affirms government's programmes and measures to ensure progressive realisation of rights to education, health care services and social security for all people of South Africa. HIV and AIDS interventions including PMTCT will be implemented in a way that complements and strengthens other developmental programmes.
- **Using Scientific Evidence:** The interventions outlined in the PMTCT policy shall, wherever possible, be evidence-informed.
- **Strengthening Service Delivery and Integrating Services:** Strengthening of health and social systems, including the organizational capacity of NGOs, FBOs and CBOs, and ensuring integration between services, is central to effective implementation.
- **A Human Rights Paradigm and Life-course Approach:** All interventions for pregnant women and their infants should be framed within a human rights paradigm and should take a life-course approach; interventions that optimise physical, mental and psychosocial health and development through pregnancy, infancy, childhood, adolescence and adulthood are needed. The family unit should be prioritized all the time.

- **Rights of women, pregnant women and mothers to information, treatment, management and care:** Women of childbearing age have the right to receive information that helps to prevent HIV infection. Pregnant women and mothers have a right to HIV-related information, and to access treatment, management and care that will optimize their health and survival and prevent mother-to-child transmission of HIV. In particular:
    - Pregnant women have a right and responsibility to know their HIV status so they can receive maternal and child care
    - PMTCT services should be regarded as a key entry point for pregnant women and their families into accessing the CCMT programme
- **Protecting and Respecting Children:** The impact of HIV on the rights of children is enormous. Respect for the best interests of the child dictates that children's rights and needs must be at the forefront of all interventions for HIV prevention, treatment and support. In particular:
    - The child's best interest is of paramount importance
    - The right to be protected from acquiring a preventable infection
    - ALL children have the right to a standard of living adequate for the child's spiritual, mental, physical, moral and social development, and to the highest attainable standard of health care
    - ALL children have the right to be fed in the safest possible way that optimizes child health and reduces mother-to-child transmission of HIV
    - The right to access care through early identification of disease and prompt referral to a treatment site.
- **Duty and responsibility of ALL health care personnel:** It is the duty and responsibility of ALL health care workers to identify HIV-positive women and their partners, HIV-exposed infants and HIV-positive infants so that they can access HIV-care. Practiced within a human rights framework, this critical intervention should prolong life and optimize maternal and child survival.

SECTION C: AIMS and OBJECTIVES

The aim of this policy and guidelines document is to provide an update on the approach to the implementation of the National PMTCT programme.

OBJECTIVES

To optimize maternal and child health and survival by preventing HIV infection in infants and managing HIV positive women through effective and comprehensive evidence-based set of interventions provided at all levels, premised on the integration of relevant components and services in the health care and social development system, as part of a continuum of care.

SECTION D: THE PMTCT POLICY and GUIDELINES

1. ENROLMENT OF PREGNANT WOMEN INTO THE PMTCT PROGRAMME

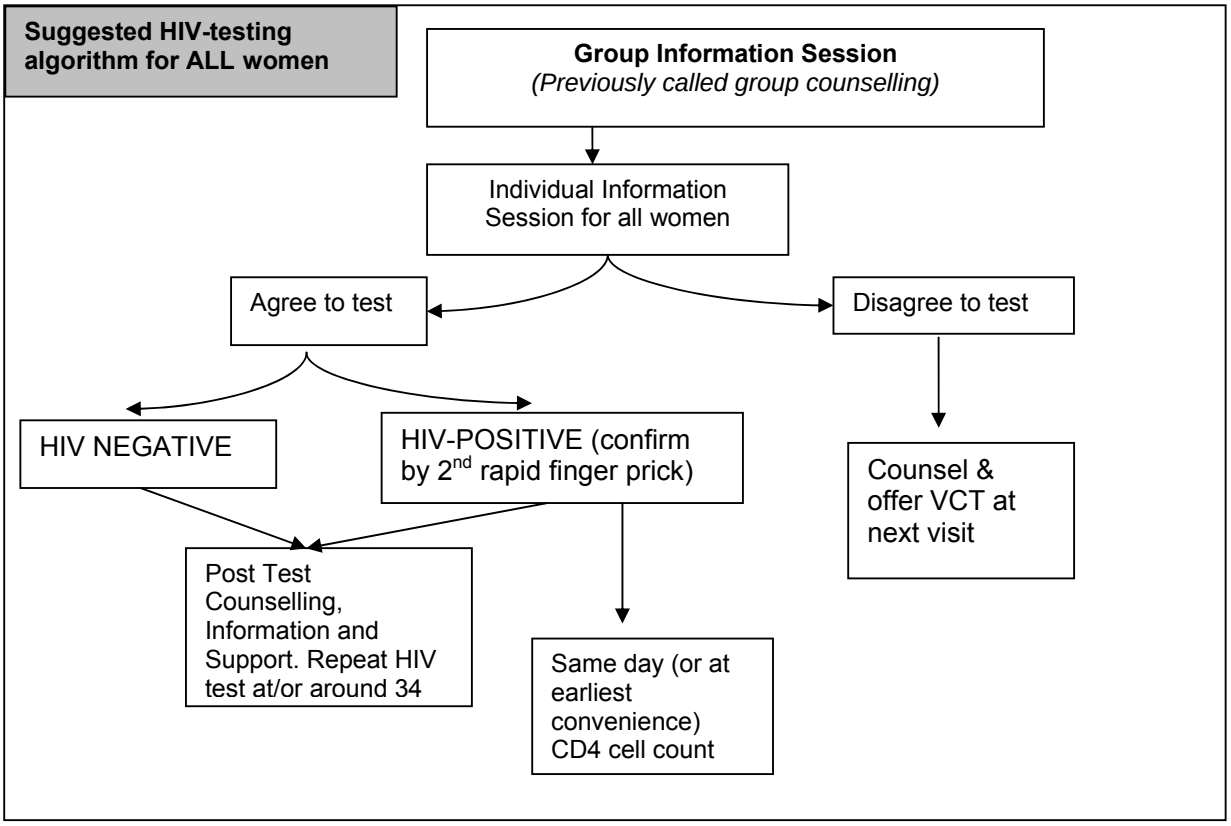
- Receive routine antenatal care, including micronutrient supplementation.
- Be offered information on the availability of PMTCT interventions during any health care consultation.
- Be counselled on safer sex and provided with condoms
- Be counselled on safe infant feeding options and assisted in making an appropriate feeding choice
- All pregnant women who are HIV-positive should:
    - Have a **CD4 cell count taken on the same day that the HIV positive status is established, and preferably at the first ANC visit** (or at the earliest opportunity) and assessed for clinical stage according to WHO staging
    - Be screened for **TB,** in line with the Basic Antenatal Care (BANC)
    - Receive ARV regimens prescribed by a registered health professional (in line with the relevant legislation and regulations) for PMTCT short course or HAART
- Women who **start HAART in their pregnancy** should be monitored and managed, where possible, by the same provider and in the same setting, and should be followed-up by the antenatal healthcare worker **until at least 6 weeks postpartum** before being referred onto a CCMT service point
- Women who test HIV-negative should receive post-test counselling and counselling on risk reduction interventions, focusing mainly on how to maintain their HIV-negative status and will continue to receive routine antenatal care.
- Women who test HIV-negative should be offered a repeat HIV test at or around 34 weeks to detect late seroconversion
- **Women who choose not to be tested** should be offered voluntary HIV testing at **every subsequent visit** during the antenatal period or shortly after childbirth if testing at onset of labour was not possible
- **Unbooked women reporting in labour:** should be offered voluntary counselling and testing for HIV during the first stage of labour and offered a PMTCT intervention if positive.

- For continuity of care and management, information on HIV status, infant feeding choice, PMTCT/HAART regimen and CD4 cell count should (with patient consent) when necessary be shared between health care personnel at all levels of the health service.

2. VOLUNTARY COUNSELLING and TESTING

- All women attending antenatal care (first attendees and women attending follow-up visits) should be given routine information about voluntary HIV testing and the PMTCT programme
- The initial information on HIV and its transmission should be given in a '**Group Information Session'**
- Thereafter all women who have not previously been tested or those who require repeat testing should go to a counsellor for a one on one '**Individual Information session'**
- At the individual information session, each woman should be informed of the **routine voluntary HIV testing procedure and** the option of not accepting for whatever reason. She should be given the opportunity to ask further questions. The woman should then be offered an HIV test and asked to provide verbal and written consent to the testing. A woman may refuse an HIV test
- Women who refuse to have an HIV test should be offered routine voluntary HIV testing on every subsequent clinic visit
- All women who test HIV-positive on the screening rapid test should have their HIV status confirmed using a second rapid finger prick with a different kit.
- Post-test counselling should be offered to both HIV positive and negative women; HIV-positive women should only be counselled after the second rapid HIV test has been performed and confirmed a positive HIV status

The flow chart below summarises the processes involved in routine voluntary counselling and testing



Details of what information to provide during pre-test information and post-test counselling sessions are contained in the box below:

PRE-TEST GROUP INFORMATION SESSION

- Staff should conduct a general group information session on HIV and PMTCT-related issues for all women coming for first or repeat antenatal visits
- A group information session should include the following key components:
    - **Benefits to the woman**
        - Information about HIV transmission and how to prevent it
        - Information about the HIV testing process
        - Importance of early access to treatment
        - Information about choices for infant feeding
    - **Benefits to the foetus and infant:**
        - Information about mother-to-child transmission of HIV and possible measures to reduce this
        - Interventions that can keep HIV-exposed infants healthy such as cotrimoxazole prophylaxis and antiretroviral therapy
    - Assurance on confidentiality and discussion of shared confidentiality and couple counselling
    - Option not to take test
- The group information session should provide further information on the programme and include the fact that an HIV test is a necessary step for enrolment onto the PMTCT programme, unless a woman's HIV status is already known to be positive. Furthermore, CD4 cell count and clinical staging are important for clinical decision-making.

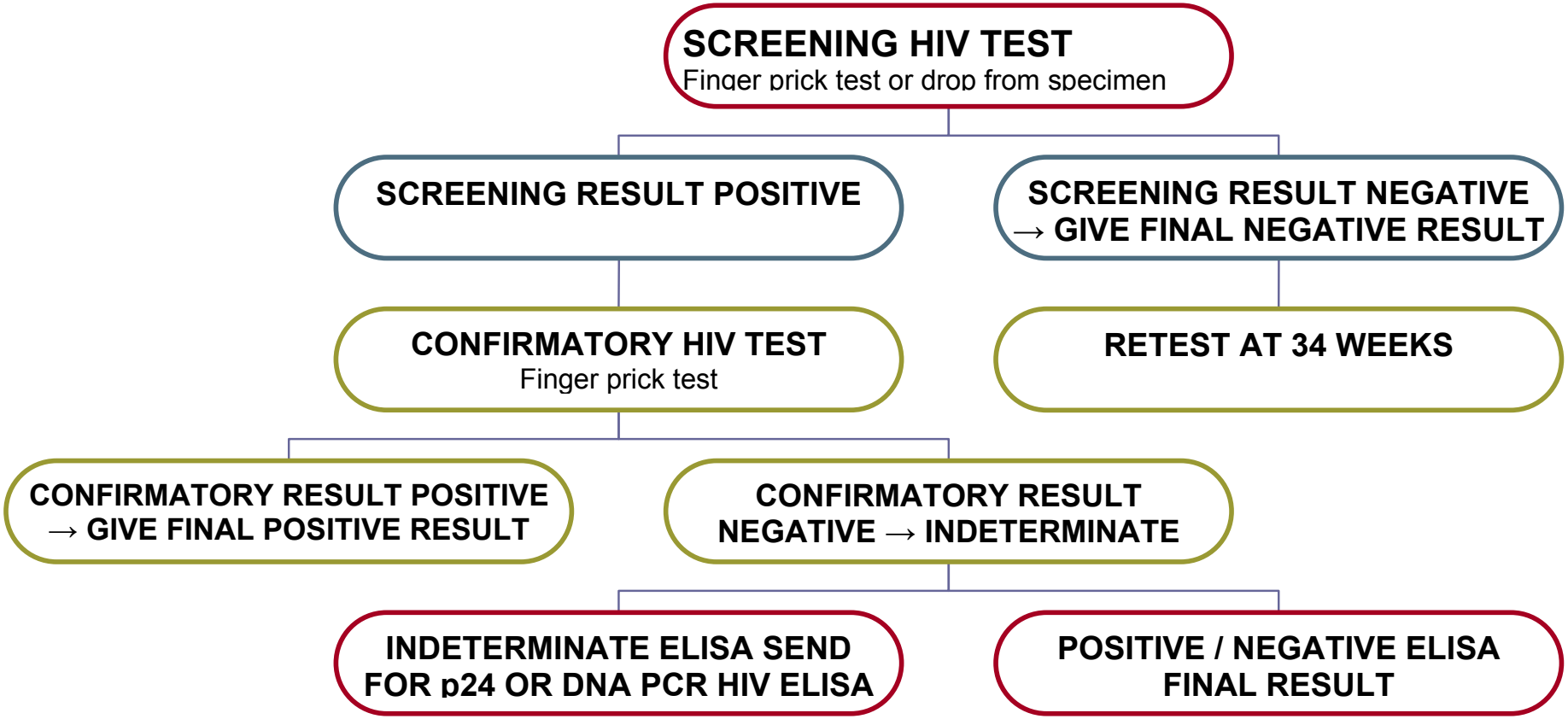
INDIVIDUAL INFORMATION SESSION

- Individual information should be available to all pregnant women following the group information session.
- The components of the individual information session include:
    - Assess if the information provided in the group session has been absorbed.
    - Answer any remaining questions, and seek to clarify any misunderstanding.
    - Discuss the way forward and the treatment options for enrolment in the PMTCT intervention.
    - Obtain consent (written and verbal) for HIV-testing.
    - Option to refuse test

2.1 TESTING ALGORITHM FOR PREGNANT WOMEN

- Testing must be seen as a key entry point to re-enforce HIV primary prevention and accessing HIV-care and PMTCT services.
- HIV testing of women should occur as part of the first antenatal encounter. Blood collected for routine antenatal screening, including haemoglobin, HepBs Ag, Rhesus factor, syphilis screening should include a sufficient sample to perform a rapid HIV test, and CD4 cell count, if required ('tube specimen'). The sample taken for HIV-testing will not be processed if the pregnant woman objects to being tested for HIV.
    - At the time this routine blood is drawn and where there is written and verbal consent, **a rapid HIV test** should be done, with either a drop of blood from the venepuncture site or a finger prick.
    - **If the rapid HIV test is positive**, a **confirmatory HIV test** should be done utilizing blood from a finger prick and utilising another rapid HIV test kit (different test kit). The woman should be present when this confirmatory test is done. A woman should be considered to be HIV-positive if the second rapid test is also positive. She should then be given her results and post-test counselled.
    - If the test is negative and the woman is asymptomatic, she is considered to be HIV-negative. Women who test HIV-negative should be offered a repeat HIV test at or around 34 weeks to detect late sero-converters.
    - If the results are discordant, i.e. the first rapid HIV test is positive and the second rapid HIV test is negative, a specimen of blood should be collected and a laboratory ELISA test should be conducted. In this case the woman should be asked to return for the HIV test results following the completion of the ELISA test or at a subsequent antenatal visit. Explain to the woman the implications and need for the laboratory test.
- For women who have missed the opportunity of being tested during the first antenatal visit, the testing algorithm should follow the above protocol whenever they are tested.
- Following testing, all HIV-positive women should have a CD4 cell count done and should be screened for TB and assessed according to the WHO clinical staging guideline.

- Professional nursing staff in the facility should be trained in performing the rapid HIV tests and on the importance of confidentiality.
- The following algorithm should be applied for HIV- testing



Testing Algorithm for pregnant women:

2.2 POST-TEST COUNSELLING

- HIV-positive and HIV-negative women should receive post-test counselling.
- HIV-positive women should only be given their HIV test results and post-test counselled as being positive if the second test (confirmatory test) is also positive.

2.2.1 POST TEST COUNSELLING FOR ALL WOMEN WHO TOOK THE HIV TEST

All women regardless of their HIV status should receive post-test counselling which should include:

- Give the results clearly
- Deal with the feelings arising from positive and negative results
- Explain the meaning of an HIV test and the "window period"
- Discuss prevention of infection
- Identify and help with the women's immediate concerns
- Discuss what support the woman has and needs
- Discuss with whom the client may want to share the results
- Discuss the importance of partner testing
- Encourage the woman to ask questions
- Provide information on a healthy lifestyle, medical follow up highlighting benefits of early PMTCT intervention especially during pregnancy and at delivery
- Educate and encourage safer sexual practices and provide condoms
- Discuss infant follow-up and testing
- Discuss infant feeding options
- Discuss the dangers of mixed feeding
- Provide ongoing follow up and counselling
- Provide information on future fertility

2.2.2 POST-TEST COUNSELLING FOR HIV POSITIVE PREGNANT WOMEN

- All HIV-positive women should be assessed according to the WHO clinical staging guideline, and have their CD4 count checked, preferably on the same day as the confirmation of their HIV-positive status.
- The post-test counselling session for women who are HIV positive should have the following key components covered over a number of counselling sessions, which may not occur all on the same day:
    - Information on and referral to support services and positive living.
    - Information about therapy, the side effects of the medication and where to report these
    - The transmission risks associated with STI infection
    - Dealing with stigma, and
    - Information about safer sexual practices during pregnancy and in the long term.
- Women who are in WHO clinical stage 4 should be considered for commencement of HAART as soon as possible.

HIV positive women should be offered counselling at every subsequent antenatal care visit or earlier if the woman or counselor deems this necessary to assist her with coping and thinking through the consequences of her diagnosis.

Women requiring additional psychosocial support should be referred to a Social Worker or psychologist. Counsellors identifying complex issues, which they are not comfortable handling should similarly make a referral to a Social Worker or Psychologist.

2.2.3 POST-TEST COUNSELLING FOR HIV NEGATIVE PREGNANT WOMEN

- HIV negative women should be offered routine antenatal services as stipulated in the DOH Guidelines for Maternity Care in South Africa as well as testing a minimum of 6 weeks later or before 34 weeks (if not tested in last 6 weeks) if her first test was done early in pregnancy.
- HIV-negative women should be counselled on:
    - Safe sexual practices during pregnancy
    - The high risk of transmission of HIV to her infant associated with new infection
    - Invited for a repeat test at/or around 34 weeks gestation

3. CLINICAL CARE FOR HIV-POSITIVE PREGNANT WOMEN

The key elements of care for the HIV positive pregnant woman include routine antenatal care, the prevention and management of opportunistic infections especially TB, the prevention and management of STIs, infant feeding counselling, psychosocial support, positive prevention, use of micronutrient supplementation and where necessary nutritional support, the use of antiretroviral drugs, safe obstetric practices with emphasis on early detection and treatment of postnatal infections and anaemia.

3.1 ANTENATAL CARE

- Women enrolled in the PMTCT and/or HAART programmes need more frequent follow up:
  - A two-week follow up date must be given to women after their CD4 cell count has been taken.
  - Each health facility should have a mechanism in place to follow up on CD4 cell count, results from the lab, discuss results with clients and trace women who do not return for results

3.2 MANAGING OPPORTUNISTIC INFECTIONS

Women with CD4 ≤200 cell count are particularly vulnerable to opportunistic infections. Some **Opportunistic Infections** that HIV-positive pregnant women experience, particularly with CD4 ≤200 cell count, include tuberculosis, urinary tract infections, *pneumocystis jiroveci* pneumonia (PCP), cervicitis and other STIs, vaginal candidiasis, human papilloma virus, vulvovaginal candidiasis and diarrhoea. Cotrimoxazole prophylaxis should be provided to women with either WHO stage IV disease or those who have a CD4 cell count below ≤200 cells/ml. This should be done in accordance with the Adult ARV Guidelines.

All opportunistic infections should be managed according to the DOH National Guidelines on the Management of Opportunistic infections in HIV positive adults. Care must be taken with drug choices in the first trimester of pregnancy. Combination of cotrimoxazole, AZT and anaemia of pregnancy requires careful monitoring with the support of a doctor. AZT for PMTCT regimen must be prescribed according to existing regulatory frameworks.

Management of Opportunistic Infections

Opportunistic infection	Treatment	Prophylaxis
Urinary Tract Infection	Uncomplicated cystitis: Amoxicillin/clavulanic acid, oral, 375 mg 8 hourly for 7 days.	
Pneumocystic jiroveci Pneumonia (PCP)	Trimethoprim/sulfamethoxazole 80/400, oral, 6 hourly for 21 days: < 60kg three tablets; > 60kg four tablets	***SECONDARY PROPHYLAXIS*** Continue for at least 6 months and until CD4 count increases to >200 on HAART or life long if patient is not on HAART. • Trimethoprim/sulfamethoxazole 80/400, oral, 1 tablet daily
Cervicitis	Ceftriaxone 250mg imi stat and Erythromycin 500mg 4 times a day and Metronodazole 400mg BD. 500 mg Ampicillin four times a day and 400mg Metronidazole three times a day over 5 days. This will be managed as part of the syndromic management of STI (vaginal discharge syndrome) with: • **Cefixime,** oral, 400 mg single dose **AND** • **Amoxicillin**, oral 500 mg 8 hourly for 7 days **AND** • **Metronidazole** 2 g immediately as a single dose	
Vaginal or vulva candidIasis	**Clotrimazole** vaginal pessary 500 mg inserted immediately as a single dose **AND If vulval irritation**: **Clotrimazole** vaginal creams applied thinly to vulva twice daily and continue for 3 days after symptoms resolve. (Maximum 2 weeks).	
Systemic Candidiasis	Ketoconazole 200 -400 mg orally daily for 5-7 days, and Clotrimazole 100mg pessaries every night for 7-10 days (or longer for severely immune-compromised women) • Fluconazole, IV/oral, 200 mg daily for 14 days The usual route is oral, but give IV if patient unable to swallow. An early relapse should be treated with a 4-week course of fluconazole as above. **Note:** Fluconazole prophylaxis is discouraged.	
Diarrhoea	If infective, give cotrimoxazole orally twice a day for 5 days. For **cryptosporidiosis** Rehydration Antimotility agents are partially effective, e.g. • Loperamide, oral, 4 mg initially, followed by 2 mg as required up to four times daily There is no specific antimicrobial therapy for **cryptosporidiosis.** As with other opportunistic diseases it responds well to HAART. For **Isosporiasis**: • Trimethoprim/sulfamethoxazole 80/400, 4 tablets 12 hourly for 10 days	**For Isosporiasis**: **Secondary prophylaxis** **Continue for at least 6 months and until CD4 count increases to >200 on HAART or life long if patient is not on HAART:** • Trimethoprim/sulfamethoxazole 80/400, 2 tablets daily

3.3 NUTRITIONAL SUPPORT

Micronutrient supplementation for HIV-positive women is the same as that routinely provided during pregnancy for all women. Supplementation includes multivitamins, iron and folate. However in the case of advanced HIV disease where malnutrition, or wasting or poor weight gain is evident, nutritional support in the form of vitamin and mineral fortified porridge should be provided. These women should also have an opportunistic infection such as tuberculosis excluded and be followed up closely.

3.4 ANTIRETROVIRAL (ARV) INTERVENTIONS

Antiretroviral therapy provides the opportunity to significantly reduce maternal HIV viral load and MTCT to the infant. A reduction in HIV transmission rate is achievable using regimens containing single, dual- or triple-drug combinations. Decisions around supporting women's choices of infant feeding to avoid mixed feeding and reducing MTCT need to be made during pregnancy.

Indications for ARVs during pregnancy are as follows:

a. To treat women with advanced HIV that meet criteria to start treatment with Highly Active Antiretroviral Therapy (HAART) in order to delay progression of disease. Whilst being used for maternal health, it is expected that this regimen will also reduce the risk of mother-to-child transmission of HIV. This regimen will be referred to as ***HAART***. HAART describes the use of a triple combination of antiretroviral therapy to treat advanced HIV disease.

a. To reduce the viral load in a pregnant woman so as to decrease the risk of HIV transmission to her child. This regimen will be referred to as the ***PMTCT regimen***. Here PMTCT regimen refers to the combination of ARVs used at various stages of the antenatal, intrapartum and/or postnatal period that aim to reduce transmission as well as any resistance to these drugs.

Women with a CD4 cell ≤200 cells/mm^3 and/or women who are at WHO stage IV disease should be prioritized to initiate HAART at any stage of pregnancy.

For pregnant women not requiring HAART, a PMTCT regimen is the main strategy to reduce MTCT. The use of dual therapy in the PMTCT Treatment Strategy is outlined below and summarised in Table 1. Women presenting at 28 weeks or later, should be started on AZT prescribed by a registered health professional (in line with the relevant legislation and regulations) at that visit, unless clinically anaemic (pale) or laboratory findings indicate that they are severely anaemic (i.e. Hb<7g/dl). HIV positive women with anaemia should be managed by a doctor prior to initiation of any antiretrovirals, including AZT. Toxicity monitoring for pregnant women on AZT is essential *(refer to table 4 on toxicity monitoring below)*

ARVs given soon after birth to infants born to women who are HIV-positive have been found to be an effective strategy for reducing MTCT whether maternal ARVs are received or not and forms the basis of a post-exposure prophylaxis strategy. The administration of sdNVP and a 7-day course of AZT prescribed by a registered health professional (in line with the relevant legislation and regulations) to the infant have been shown to be effective in reducing MTCT. In instances where there has been only sdNVP given to the mother or she has had less than 4 weeks of AZT or HAART regimen, the infant will require sdNVP and 28 days of AZT.

3.4.1 The ART approach

In summary, to maximally reduce risk of MTCT and to ensure women who could benefit from HAART receive it, specific categories of women can be defined, as shown below. The use of ARVs in infants is also detailed. The following treatment protocol is therefore recommended (see also Table 1. below).

A. **Pregnant women not eligible for HAART** i.e. CD4 cell count >200 cells/ mm^3 (WHO stage I-III) or CD4 cell count unknown should, at a minimum receive a *dual therapy* PMTCT regimen initiated at 28 weeks of pregnancy or as soon as possible thereafter (listed as '**PMTCT regimen'** in the table below)
    - Where the CD4 cell count is unknown, AZT should be prescribed and commenced if the woman is ≥28 weeks of pregnancy and blood

should be sent for a CD4 cell count.

- If the CD4 cell count indicates the need for HAART, AZT should be continued up to the point that HAART is initiated when PMTCT regimen will be substituted by HAART.
- The same recommendation applies for women with WHO stage IV disease. Women started during pregnancy with the PMTCT regimen should be counselled on early presentation for delivery.

B. **Pregnant women with a CD4 cell count ≤ 200 cells/mm^3 or WHO stage IV** should be initiated onto HAART. (see table 2 below)
   - The regimens recommended in the Comprehensive Plan should be used. The choice of HAART in this group of women would be **regimen 1b** of the National Adult ARV treatment guidelines i.e. d4T, 3TC, NVP. All doses to be consistent with Adult ARV guidelines and are the same as for non-pregnant women.
   - Prophylaxis with CTX should also be commenced in accordance with the National Adult ARV treatment guidelines.

This HAART regimen should ideally be provided to women at the PMTCT service point by trained medical and support staff. This means that doctors, midwives and nurses working within these service points will be able to assess, stage as well as monitor HAART treatment.

C. **Women already on HAART before pregnancy**. Women on ART who become pregnant continue with treatment as per Adult ARV guidelines. A woman who becomes pregnant whilst on HAART should have EFV switched to NVP in the first trimester. After the first trimester there is no need for the switch. Adverse event monitoring is critical in all cases and should be ongoing, including foetal anomaly scans where available if there has been first trimester EFV exposure.

D. **Pregnant women presenting in labour** that are not on any antiretroviral drugs (either unbooked, or HIV status unknown) should be offered VCT in the 1st stage of labour; If found to be HIV-positive they should be given antiretroviral drugs in the form of sdNVP during labour. Decisions around

supporting women's choices of infant feeding after delivery need to be made at the time of initiation of HAART.

E. **Infants born to women who received optimal PMTCT or HAART** (groups A-C above that have had ≥ 4 weeks of treatment) should receive **sdNVP** as soon after birth as possible within a 72-hour period. AZT prescribed according to regulatory requirements should be commenced soon after birth and be administered for **7 days**.

F. **Infants born to women who received suboptimal PMTCT or HAART** (see also table 3 below)

Where no maternal ARVs were taken

- Where maternal ARVs (PMTCT or HAART regimen) were taken for less than 4 weeks
- Where women received only sdNVP

These infants should receive **sdNVP** as soon after birth as possible, preferably within 6 hours of birth but not later than after 72 hours after birth. **AZT** should be commenced soon after birth and be administered for **28 days**.

Table 1 - Antiretroviral Protocols for Pregnant Women and Infants

CLINICAL DECISION	REGIMEN FOR WOMAN	REGIMEN FOR INFANT
PMTCT regimen for ALL groups of women from 28 weeks of pregnancy unless already on HAART		
CD4 cell count >200, continue with this PMTCT regimen CD4 cell count ≤200 continue AZT up to point HAART initiated.	▪ AZT started from 28 weeks onwards AND ▪ sd NVP + AZT at onset of labour on a 3 hourly basis ▪ If in false labour continue with AZT	**Sd-NVP + AZT for 7 days*** **AZT for 28 days if** • Mother received < 4 weeks AZT during pregnancy • Mother received < 4 weeks HAART or • Mother only received sdNVP
HAART regimens (1a and 1b). If on AZT as above need to switch to regimens below		
CD4 cell count ≤200 or WHO stage IV HAART group	▪ d4T + 3TC + NVP **(Regimen 1b)** ▪ **Preferred regimen for pregnant women** ▪ Begin at any gestation ▪ d4T + 3TC + EFV **(Regimen 1a),** ▪ For pregnant women on regimen 1a, switch EFV to NVP in the first trimester ▪ If presenting after first trimester, continue regimen 1a ▪ Continue through labour, delivery and postnatal periods ▪ After the first trimester, if women develop NVP-associated toxicity, then NVP should be substituted with EFV	**Sd-NVP + AZT for 7 days*** **AZT for 28 days if** • Maternal HAART < 4 weeks
Unbooked woman presents in labour	Also includes women of known status who have had no ARVs during pregnancy. Do not require testing.	
Consent and test for HIV only in stage 1 labour. If in advanced stage of labour, defer maternal testing until after delivery.	**If HIV positive** • sd NVP + AZT at onset of labour and on AZT at 3 hourly basis If she is in false labour continue with AZT.	**Sd-NVP + AZT for 28 days**

Postnatal follow up of women initiated onto a HAART regimen

Decisions around the postnatal follow up of women commencing HAART during pregnancy need to be made at the time of initiation. This is in order to have a *patient management plan* that seeks to ensure a continuum of care between different service points. This at the very minimum requires an established line of communication and referral system from the PMTCT to the CCMT service point. Six weeks after delivery, women on HAART should be referred back to the CCMT service point for continuity of care.

Table 2 - HAART Adult Dosing Guide

Drug	Dosage	Notes
d4T (Stavudine)	30mg 12hrly po	All adult patients must receive 30mg regardless of weight
3TC (Lamivudine)	150mg 12 hourly po	
NVP (Nevirapine)	200mg dly po X 2 weeks then 200mg 12 hourly po For PMTCT purposes single dose (sdNVP) is used as a 200mg tablet given once.	Should not be prescribed with TB treatment or if CD4>200
EFV (Efavirenz)	600mg nocte	Avoid in pregnancy (first trimester) and psychiatric conditions
AZT (Zidovudine)	300mg 12 hourly po	Avoid if severe anaemia (Hb <7g/dl)

Doses and frequency will remain the same when used intrapartum.

Table 3 - PMTCT Infant Dosing Guide

Drug	Weight	Dose	Notes
NVP syrup (10mg/ml)	>2kg	0.6ml (6mg) Stat	To be administered as soon as possible after birth as a single dose (sdNVP)
	< 2kg	0.2ml/kg stat (2mg/kg)	
AZT syrup (10mg/ml)	>2kg	1.2ml 12 hrly (12mg 12 hrly)	For 1 week if mother received 28 days of AZT or HAART, otherwise for 4 weeks. Administered with a 2ml syringe

Table 4: Contraindications for AZT / Toxicity monitoring when using AZT

- Women who are on AZT and who appear pale should have blood taken to measure haemoglobin. The results should be discussed with a doctor trained in HIV & AIDS management.
- If a woman is clinically pale, follow the guidelines below:
  - If the Hb is **<7g/dl**, do NOT START AZT – Investigate causes of severe anaemia
  - If the Hb is **between 7g/dl and 10g/dl**, continue AZT and give Ferrous Sulphate 1 tds. Repeat Hb in 2 – 4 weeks. If there is no response, or the Hb is dropping, continue AZT BUT urgently refer the woman to a doctor for investigation of the anaemia.
  - If the Hb is **10g/dl,** continue AZT AND give Ferrous Sulphate 1 bd. Re-check Hb after 4 weeks on AZT.
- All women commencing AZT (not clinically pale or Hb>**7g/dl**) should have baseline haemoglobin taken.
- During subsequent visits the baseline haemoglobin results of women on AZT should be reviewed by a doctor, and used to determine the next set of actions, if any, to be taken. These actions are listed in the bullets above.

3.5 CARE OF HIV POSITIVE WOMEN AND THEIR INFANTS IN THE IMMEDIATE POST-DELIVERY PERIOD

- Within an hour of delivery:
  - All infants born to HIV-positive women should ideally receive skin-to-skin contact with their mothers, regardless of the mother's feeding choice
  - All infants should start feeding (exclusive breastfeeding on demand or exclusive formula feeding)
  - If the mother has not made a decision about feeding yet, she should be counselled on infant feeding and AFASS determined.
- Women with CD4 counts ≤200 who have not yet initiated HAART, for whatever reason should be prioritized for such therapy

- Women on HAART, and their infants should be followed up at the health facility within the first two weeks, and should be seen at the health facility up to 6 weeks postpartum. Thereafter follow-up should occur at the well-infant clinics, as per the IMCI guidelines.
- Infant testing should be done at 6 weeks (see section on infant testing).
- The mother should be referred to CCMT.
- Fever related to opportunistic infections, fever of unknown origin all HIV positive women postpartum should be managed according to existing guidelines.
- Ongoing psychosocial support to address the following
    - Infant feeding choice and practice
    - Social security issues
    - Child health
    - Positive prevention for HIV & AIDS

4. ESTABLISHING SAFE INFANT FEEDING PRACTICES

4.1 BACKGROUND

- The South African national PMCT programme adopts an approach to infant feeding that seeks to maximise child survival.
- Infant feeding counselling should take cognisance of the specific circumstances of the pregnant woman / mother, including her individual ability to meet the AFASS criteria, so that appropriate infant feeding choices are made. Thus detailed, comprehensive and individualised feeding counselling is critical to enable women to make the feeding choice that will maximize HIV-free survival.
- The South African Infant and Young Child feeding policy and implementation guidelines and the Baby Friendly Hospital Initiative (BFHI) - including the ten steps to safe infant feeding, as outlined in the BFHI – provide a framework to facilitate feeding support for HIV-positive and HIV-negative women.
- Data from international and South African studies (mainly the Good Start study and Vertical Transmission Study) (Miotti, Taha et al. 1999; Breastfeeding and HIV International Transmission Study Group, Coutsoudis et al. 2004) (Coutsoudis, Pillay et al. 2001; Iliff, Piwoz et al. 2005; Rollins 2006; Coovadia,

Rollins et al. 2007) have been used to guide the approach to infant feeding outlined in these policy guidelines.

4.2 PRINCIPLES OF SAFE INFANT FEEDING

- Health care personnel, lay counsellors and community caregivers should receive standardized training on infant feeding counselling and HIV.
- Trained health care personnel should provide high quality, unambiguous, unbiased information about risks of HIV transmission through breastfeeding and risks of replacement feeding.
- Counselling on infant feeding must commence after the first post-test counselling session.
- Infant feeding should be discussed with women during every antenatal visit,
- Mixed feeding should be strongly discouraged as it predisposes to childhood infections and increases the risk of HIV transmission in HIV-positive women.
- Mass mobilization and communication on infant feeding and HIV should be done through mass media, distribution of IEC materials and community-based activities including door-to-door campaigns.
- In an attempt to optimize child survival HIV positive pregnant women should be prioritized for HAART or PMTCT regimens in order to keep them healthy and reduce their viral load.

4.2.1 HIV-negative women

- At every antenatal visit HIV negative women or women of unknown HIV status (every effort should be made to get all pregnant women tested or re-tested as stated in the testing section of this document) should be counselled to exclusively breastfeed their babies during the first 6 months of life and continue breastfeeding for at least 2 years.

4.2.2 HIV-positive women

- At every antenatal visit HIV-positive women should be counselled on infant feeding options
- Each pregnant HIV-positive woman should receive at least four antenatal counselling sessions on infant feeding.

- The feeding options for the first 6-months of life are exclusive breastfeeding or exclusive formula feeding. All HIV-positive infants should continue breastfeeding for at least 2 years, regardless of whether the mother meets the AFASS criteria
- For each woman, the Acceptability, Feasibility, Affordability, Safety and Sustainability criteria **(AFASS)** should be assessed and discussed, and the woman should be assisted to make the feeding choice that would be most appropriate for her individual situation. The summary table 6 below table 5 contains more details on what questions to ask to determine if the AFASS criteria are met.

Table 5 – Operationalising the AFASS criteria

AFASS criteria to assist with infant feeding choice in HIV-positive women
Acceptable: The mother perceives no barrier to choosing and executing the option for cultural or social reasons, or for fear of stigma and discrimination.
Feasible: The mother (or family) has adequate time, knowledge, skills and other resources to prepare and feed the infant, and the support to cope with family, community and social pressures.
Affordable: The mother and family, with available community and/or health system support, can pay for the purchase/production, preparation and use of the feeding option, including all ingredients, fuel and clean water and equipment, without compromising the health and nutrition spending of the family.
Sustainable: Availability of a continuous and uninterrupted supply and dependable system of distribution for all ingredients and commodities needed to safely implement the feeding option, for as long as the infant needs it.
Safe: Formula milk would be correctly and hygienically prepared by clean hands, using clean, safe water and clean utensils. Nutritionally adequate quantities of formula milk would regularly be available. Clean water and fuel would be regularly available. Formula milk would be fed using clean hands and utensils, and preferably with cups rather than bottles.

Use the questions in the table below to check the AFASS criteria

Table 6 - AFASS criteria to assist with infant feeding choices in HIV positive women

CRITERION	Questions to ask to see if mother is able to follow through with Exclusive Formula Feeding (avoiding all breastfeeding)
Acceptability *Is EFF acceptable for the mother?*	Are there cultural or social reasons that could create a problem if the mother were to choose formula feeding? Does the mother have fear of stigma or discrimination if she were to choose replacement feeding?
Feasibility *Is the mother able to begin EFF correctly for the required six-month period of time?*	Does the mother or caregiver have enough time, knowledge, skills, resources and support to correctly prepare breast-milk substitutes? Is she able to feed the infant 8-12 times in 24 hours?
Affordability *Is the mother able to afford the costs of EFF?*	Can the mother pay for the costs of buying, preparing, storing, the ERF without compromising the health and nutrition of the family? NOTE: Costs include those for ingredients/supplies, fuel, clean water, and medical expenses that may result from unsafe preparation and feeding practices.
Sustainability *Will the mother be able to continue with EFF for the recommended 6 month period, once she has begun?*	Will the mother be able to have a continuous, uninterrupted supply of replacement food (e.g. formula)? Will the mother have the products (e.g. ability to boil water) needed to safely practice ERF?
Safety *Will the mother be able to practice EFF safely?*	Will the mother be able to prepare and feed the EFF with clean water, clean hands, clean cups and other utensils, but not bottles or teats? Will the mother be able to store the replacement food correctly and in a place that is hygienic?

- For HIV-positive women who do not meet ALL the AFASS criteria or the SAFETY criterion for HIV-negative women; the health and child survival benefits of exclusive breastfeeding should be emphasised

4.3 Family support for infant feeding

- Family members influence how infants are fed. Where possible and acceptable, feeding counselling should include a family member / home supporter to help women implement their feeding choice.

4.4 Ongoing support and counselling for feeding at delivery

- HIV-positive women who enrol in the PMTCT programme during labour or within 72 hours of delivery should be counselled on infant feeding options, as outlined above.
- Before the infant attaches to the breast, health care personnel should confirm the mother's infant feeding choice and assist the mother according to her choice.
- The method used to heat-treat breast milk, the methods used to prepare commercial infant formula, and the technique that would facilitate exclusive breastfeeding (correct attachment and positioning) needs to be demonstrated to each individual woman, depending on her feeding choice (undecided / meets the AFASS criteria / does not meet the AFASS criteria).
- After demonstration, every woman should practice/demonstrate proper feeding in front of a health worker before discharge.
- Formula feeding women should receive at least a two-week supply of free commercial formula upon discharge. Thereafter formula should be dispensed at the local clinic monthly, for a period of six months and amounts will be calculated per age category.
- Nutritional support should be provided for ALL HIV-positive women who have chosen to breastfeed
- Furthermore, all HIV-positive women with food insecurity should receive nutritional support, regardless of their feeding choice.

4.5 Postnatal support for infant feeding

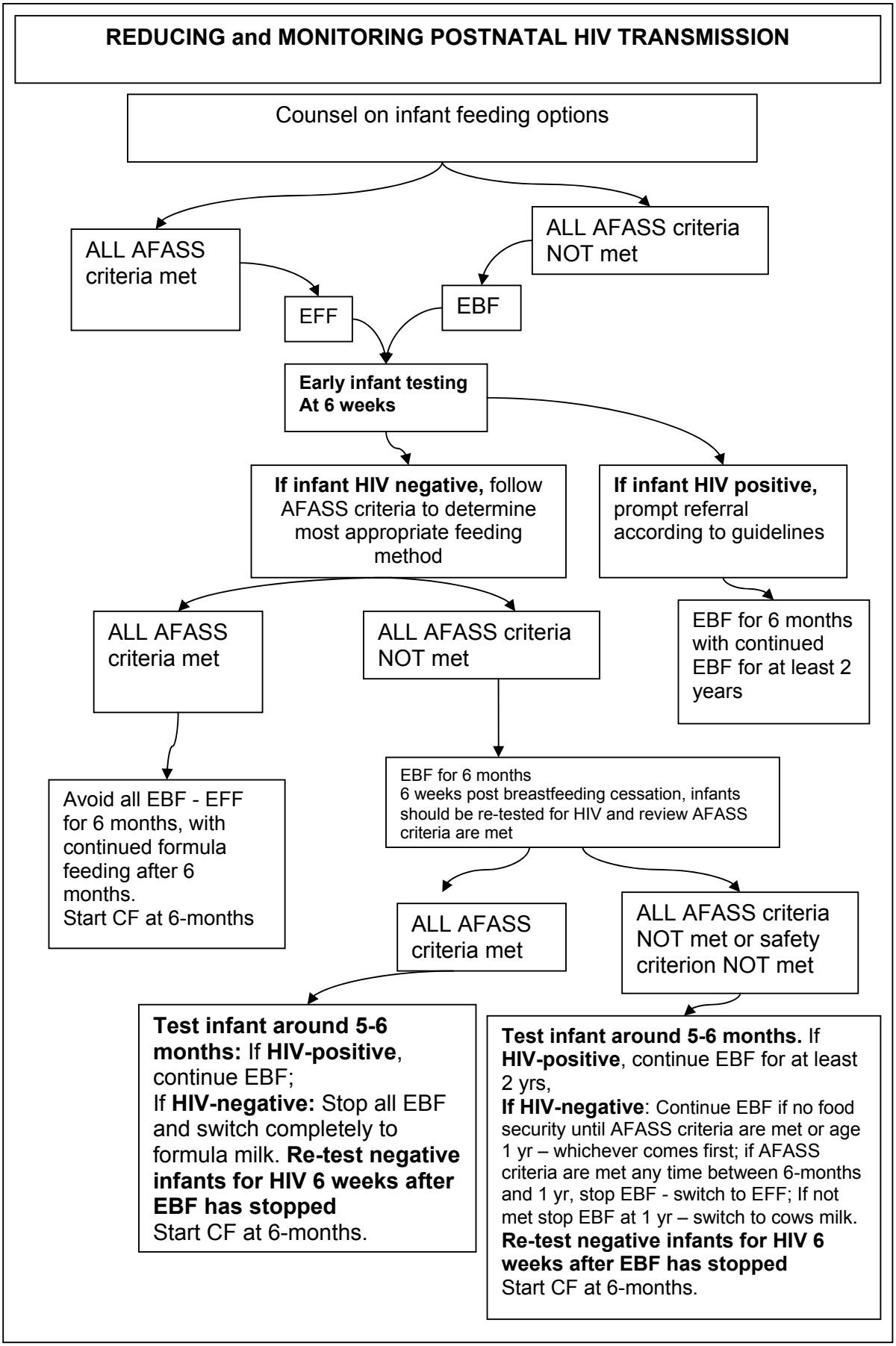
- During the postnatal period mother-infant pairs should be followed-up 3-10 days after delivery to review of feeding practice and check breast health, maternal health and child health and to provide support
- All HIV-positive infants should continue breastfeeding for at least 2 years, regardless of whether the mother meets the AFASS criteria

4.5.1 For breastfeeding HIV-positive women:

- Early cessation of breastfeeding (before 6 months) is not recommended
- For these mothers who will meet the AFASS criteria by 6-months. Cessation of breastfeeding needs to be planned and prepared for during the breastfeeding period as follows:
    - **Step 1:** Understand stopping BF around 6 months as part of the overall strategy to avoid HIV transmission while still gaining the maximum benefit of breastfeeding.
    - **Step 2:** Prepare the baby for stopping breastfeeding. From an early stage use expressed breast milk in a cup so that the infant becomes familiar with the cup. Heat-treating expressed breast milk may be used during this transition period to minimize breast milk viral load. From an early stage, regularly comfort the infant with methods other than breastfeeding e.g. massage. Plan how to comfort the infant in public places e.g. on the bus, once breastfeeding stops
    - **Step 3**: Discuss the importance of involving the family and prepare the family for stopping breastfeeding. Explain to a close family member, or even better the whole family, why breastfeeding will be stopped at around 6 months and how they can help with comforting the child at the actual time of stopping breastfeeding e.g. holding and comforting infant so that mother does not have to be the only one trying to comfort infant if upset.
    - **Step 4:** Manage any breast health difficulties. Stopping breastfeeding may result in engorgement of the breasts, or even mastitis. Teach mother how to deal with these and not to feed the infant as a way of relieving discomfort
    - **Step 5:** Look after the infant's nutritional needs. Make a plan regarding the food for the child and make sure that it is adequate both in energy and also vitamins and iron.
- All infants, whether breastfeeding or replacement feeding, should be given complementary foods starting at 6 months.
- Note that infants who are HIV-positive at 6-months should continue breastfeeding even if their mothers meet the AFASS criteria.

4.5.2 For formula feeding HIV-positive women:

- Free commercial infant formula will be provided to these infants for at least 6 months.
- Women should receive practical support, including demonstrations on how to safely prepare the formula and feed the infant.
- At 6-months infants at risk of poor growth should be referred for continued nutritional monitoring and dietary assistance.
- An appropriate formula milk product for the infant's age and circumstances should be chosen.
- Infants weighing less than 2 kg should receive a special low birth weight formula until the infant weighs at least 2 kg; thereafter infant formula for a term infant can be given. A soy protein based formula should not be given to an infant <2kg.
- Code of Marketing of Breast milk Substitutes: All health care workers caring for mothers, infants and young children should fully adhere with all the provisions of the International Code of Marketing of Breast milk Substitutes and its subsequent resolutions, which will be superseded by the South African Regulations relating to Foodstuffs for Infants, Young Children and Children once these are promulgated. These have been adapted to allow for infant feeding in the context of HIV.
- In situations where commercial formula is being provided free of charge through health facilities, managers, supervisors and health care personnel should ensure an uninterrupted supply at clinic level. This procurement and distribution system should be put in place and should abide by the Code of Marketing of Breast milk substitutes, its subsequent resolutions and the South Africa regulations.


REDUCING and MONITORING POSTNATAL HIV TRANSMISSION
Counsel on infant feeding options
ALL AFASS criteria met
ALL AFASS criteria NOT met
EFF
EBF
Early infant testing At 6 weeks
If infant HIV negative, follow AFASS criteria to determine most appropriate feeding method
If infant HIV positive, prompt referral according to guidelines
ALL AFASS criteria met
ALL AFASS criteria NOT met
EBF for 6 months with continued EBF for at least 2 years
Avoid all EBF - EFF for 6 months, with continued formula feeding after 6 months.
Start CF at 6-months
EBF for 6 months
6 weeks post breastfeeding cessation, infants should be re-tested for HIV and review AFASS criteria are met
ALL AFASS criteria met
ALL AFASS criteria NOT met or safety criterion NOT met
Test infant around 5-6 months: If HIV-positive, continue EBF;
If HIV-negative: Stop all EBF and switch completely to formula milk. Re-test negative infants for HIV 6 weeks after EBF has stopped
Start CF at 6-months.
Test infant around 5-6 months. If HIV-positive, continue EBF for at least 2 yrs,
If HIV-negative: Continue EBF if no food security until AFASS criteria are met or age 1 yr – whichever comes first; if AFASS criteria are met any time between 6-months and 1 yr, stop EBF - switch to EFF; If not met stop EBF at 1 yr – switch to cows milk.
Re-test negative infants for HIV 6 weeks after EBF has stopped
Start CF at 6-months.

POSTNATAL COUNSELLING ON SAFE INFANT FEEDING PRACTICES

- HIV-positive women who are enrolled in the programme during labour or within 72 hours of delivery should be counselled on infant feeding options, as outlined above.

Within an hour of delivery:

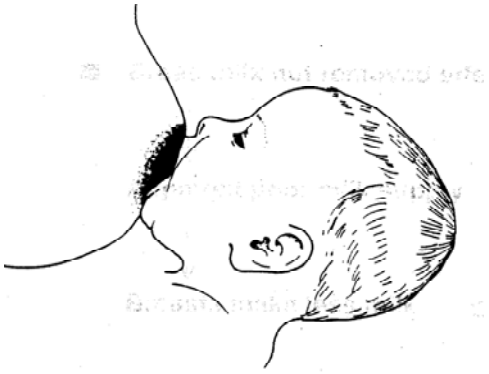
- All infants born to HIV-infected women should receive skin-to-skin contact with their mothers, regardless of the mother's feeding choice
- All infants should start feeding (exclusive breastfeeding on demand or exclusive formula feeding)
- If the mother has not made a decision about feeding yet, she should be counselled on infant feeding. Her infant should still receive skin-to-skin contact and should be fed heat-treated expressed breast milk until she has decided the best and safest way to feed her child.

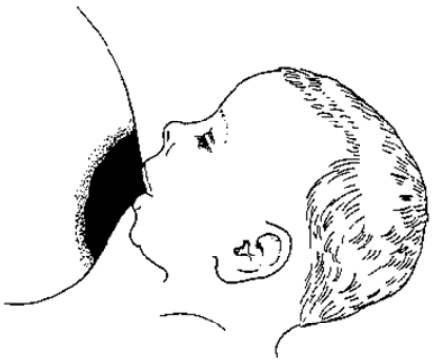
Support the mother's feeding choice, which should be guided by the AFASS criteria:

Breastfeeding HIV-positive women should be counselled and shown: **GOOD POSITIONING**

- Mother relaxed and comfortable
- Baby's body close, facing the breast, with nose opposite the nipple
- Baby's head and body straight
- If the baby is newborn, baby's bottom supported

And **GOOD ATTACHMENT**





GOOD ATTACHMENT:

Four points of good attachment:

- More areola above baby's mouth
- Mouth wide open
- Lower lip turned outwards
- Chin touching breast

Also:

- Slow deep sucks, sometimes pausing
- No smacking or clicking noises

POOR ATTACHMENT:

Formula feeding women should be shown how to safely prepare adequate quantities of formula milk.

Mothers who have chosen to exclusively breastfeed:

- Mothers need support at EVERY well child / routine visit, EVERY immunization visit and EVERY sick child visit to facilitate and support exclusive breastfeeding. Exclusive breastfeeding does not come naturally but needs support for it to be practised.
- Prevent and pre-empt breastfeeding problems such as sore / cracked nipples, engorgement and mastitis by counselling mothers on attachment and positioning.
- Check mother's breast health at every clinic visit – check for sore nipples, cracked nipples, bleeding nipples, engorgement and mastitis. Women who have bleeding nipples should avoid breastfeeding from the affected breast until it has healed – they should feed from the unaffected breast and express and discard breast milk from the affected breast.
- Counsel the mother that breast milk production depends on the suckling of the infant: the more the infant suckles the more milk will be produced
- Recommend exclusive breastfeeding on demand, day and night for six months.
- Discuss home support for EBF – ensure that the woman has a carer / supported out of the health facility who would help her to avoid mixed feeding. Facilitate these linkages.
- Continue EBF until 6-months. After 6-months, review the AFASS criteria, and where PCR is feasible and results are available within 2 weeks, it is strongly recommended that a HIV PCR test should be performed on infant's whose mothers meet the AFASS criteria prior to stopping breastfeeding to inform that decision. The infants HIV status at 5 to 6-months, and the AFASS criteria should be used to guide feeding after 6 months:
    - If the infant is confirmed HIV positive, breastfeeding should continue.

Mothers who have chosen to avoid all breastfeeding:

- Mothers need support at EVERY well child / routine visit, EVERY immunization visit and EVERY sick child visit to facilitate and support exclusive formula feeding.
- Formula milk preparation should be demonstrated at the first postnatal visit, and as needed thereafter, and discussed at every visit. These demonstrations should take place in an environment / setting that abides by the Code of Marketing of Breast milk substitutes, the subsequent resolutions and the South African regulation once these are promulgated
- Health care personnel should:
    - Provide clear guidance regarding the volumes and frequency of feeding needed at each age
    - Discuss the dangers associated with bottle-feeding and how bottles should be cared for, if used. Discuss and demonstrate cup feeding as a recommended alternative to bottle-feeding.
    - Discuss home support for avoiding all breastfeeding – ensure that the woman has a carer / supporter outside the health facility to help her avoid all breastfeeding.

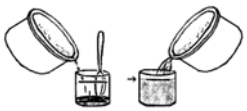
➢ **Safe Preparation of Formula Milk**

Always use a marked cup or glass and spoon to measure water and a scoop to measure formula powder.

Wash your hands before preparing a feed.

Bring the water to the boil and then let it cool. Keep it covered while it cools.

Measure the formula pow-der into the marked cup or glass.
Make the scoops level.
Put in one scoop for every 25 ml of water.



Add a small amount of cooled boiled water and stir. Fill the cup or glass to the mark with the water. Stir well.

Feed the baby using a cup.

Wash the utensils.

Age	Weight in kilograms	Approximate amount of formula needed in 24 hours	Previously boiled water per feed	No. of scoops per feed	Approximate no. of feeds
Birth	3	400ml	50 ml	2	8 X 50ml
2 weeks	3	400ml	50 ml	2	8 X 50ml
6 weeks	4	600ml	75 ml	3	7 X 75ml
10 weeks	5	750ml	125 ml	5	6 X 125ml
14 weeks	6.5	900ml	150 ml	6	6 X 150ml
4 months	7	1050ml	175 ml	7	6 X 175 ml
5 months	8	1000ml	200 ml	8	6 X 200ml

5. INFANT FOLLOW-UP

- Prior to discharge, follow up activities should be discussed with the mother in order to facilitate the infant's access to appropriate care.
- Infants should be followed up according to the South African IMCI clinical case management guidelines:
  - Weekly during the first month of life at the nearest clinic, and
  - Monthly thereafter until the age of twelve months.
  - Three monthly between the age of 12 months and two years of age unless the child is ill in which case they should be seen more often.

- During the first post-delivery visit:
  - If the infant is being formula fed, the health care worker should check the method of cleaning utensils and mixing formula. Formula preparation should be demonstrated **only** to HIV-positive women who after counselling have chosen not to breastfeed.
  - If the infant is being breast-fed, the pattern of feeding, attachment, positioning and mother's breast health must be checked.

- HIV-exposed infants should be tested for HIV at six weeks of age (see section on HIV testing).
- ALL HIV-exposed infants who are awaiting confirmation of their HIV status at 6-weeks should start CTX prophylaxis whilst awaiting their HIV test results
- All infants identified as being HIV positive by early testing should be investigated further as soon as possible by checking RNA PCR (viral load), CD4 cell count, CD4 cell percent, and undertaking a baseline clinical staging as part of their baseline assessment.
- HAART should be initiated in HIV infected infants as per the revised paediatric guidelines (2007)
- HIV exposed infants should be followed up AT LEAST monthly in the first year of life and 3-months thereafter, regardless of their mode of feeding.
- At six, ten and fourteen weeks and at nine months and eighteen months all children should be immunized according to the South African EPI schedule.

ROUTINE FOLLOW-UP OF HIV EXPOSED INFANTS

At each visit, perform the following:

- Growth monitoring
- Check history of current illnesses
- Conduct a clinical examination where indicated and refer to a higher level of care if needed
- Assess feeding difficulties and discuss ways of overcoming these
- Assess feeding pattern
- Provision of free commercial formula milk on a monthly basis for six months to infants who are fed on formula
- Nutritional support for ALL breastfeeding HIV-positive mothers, and for formula feeding mothers with food insecurity

5.1 Infant HIV testing

- Early infant HIV diagnosis is essential for child survival.

5.1.1 Testing infants younger than 18-months:

- Virological testing using PCR is the test of choice
- Either liquid blood or dried blood spot samples can be used depending on site-specific circumstances e.g. the skill of healthcare personnel in venesecting young babies.
- Consumables should be available in all facilities for collecting liquid blood and/or dried blood spots for PCR testing in infants younger than 18 months
- Test ALL HIV-exposed infants **at six weeks** of age using PCR.
- Do not use a positive HIV antibody tests to diagnose or confirm HIV infection in asymptomatic infants younger than 18 months (positive antibody tests in these infants could reflect maternal antibodies and therefore HIV exposure); however a negative antibody test in an infant younger than 18 months means that the infant is not HIV infected, providing that breastfeeding has stopped 6 weeks or more prior to the test date

5.1.2 Testing infants older than 18-months:

- At 18-months ALL exposed children (negative and positive) should be tested to confirm their HIV status
- HIV ELISA testing can be used to confirm HIV status in infants older than 18 months
- The use of Rapid HIV testing in children may be done provided the type of test used has been validated for use in children
- All HIV-exposed children who have never had a viral load done (including children identified as being HIV-negative during early testing) should be re-tested at 18 months or older with a Rapid or ELISA test to confirm their HIV status

5.1.3 Breastfeeding and Infant HIV testing:

- At 5 to 6 months where PCR is feasible and results are available within 2 weeks, it is strongly recommended that a HIV PCR test should be performed on infant's whose mother meet the AFASS criteria to inform the decision to stop EBF at 6-months:
  - If the infant is confirmed HIV positive, breastfeeding should continue.
  - If the infant is HIV-negative, breastfeeding can be stopped and the infant should be re-tested 6 weeks after breastfeeding has stopped, using PCR if <18 months or HIV ELISA if >18 months

5.1.4 Children not identified by PMTCT programme (active case finding):

- Immunization visits up to 14 weeks of age should be used to identify babies whose mothers are of unknown HIV status.
- All opportunities should be used to diagnose HIV in infants who display relevant signs and symptoms.
- Mothers should always be encouraged to take up an HIV test.

Clinical features and HIV test results

No laboratory test is 100% accurate and where clinical symptoms and signs do not match the HIV test results; repeat age-appropriate HIV testing should be done.

SECTION E: MONITORING and EVALUATION

Monitoring and evaluation of the PMTCT programme is essential. The following principles guide this process:

- Information must flow in both directions, in order to measure quality and ensure that service improvement occurs. This implies regular assessment meetings at all levels as well as the provision of individual attention to sites that report problems and unsatisfactory statistics.
- The minimum national set of indicators for the PMTCT programme, should be collected at the following stages of the intervention:
    - Antenatal care including routine offer of voluntary HIV counselling, testing and retesting
    - Administration of PMTCT prophylaxis to mother;
    - Deliveries, administration of PMTCT prophylaxis to infant and feeding choice;
    - Follow-up for mother and child, infant testing and feeding.
- The three key service points at which the above interventions in the health system are:
    1. Antenatal Clinic (ANC)
    2. Labour Ward and Postnatal Ward (LW)
    3. Infant Follow-up (Postnatal / EPI) services
- Other service points where either women or infants are accessing the health care system should also be included for data collection (falling under the three categories above, such as antenatal and paediatric wards, and high care areas as well as CCMT service points.
- Monitoring and Evaluation must act as a tool to improve the quality of service as well as address access limitations of the PMTCT programme.
- Part of the broader Monitoring and Evaluation framework includes aspects like the extent of service provision and proficiency. The National Health Information System of South Africa (NHISSA) framework should inform the development of all relevant indicators.

A system is required that will allow staff in the service to:

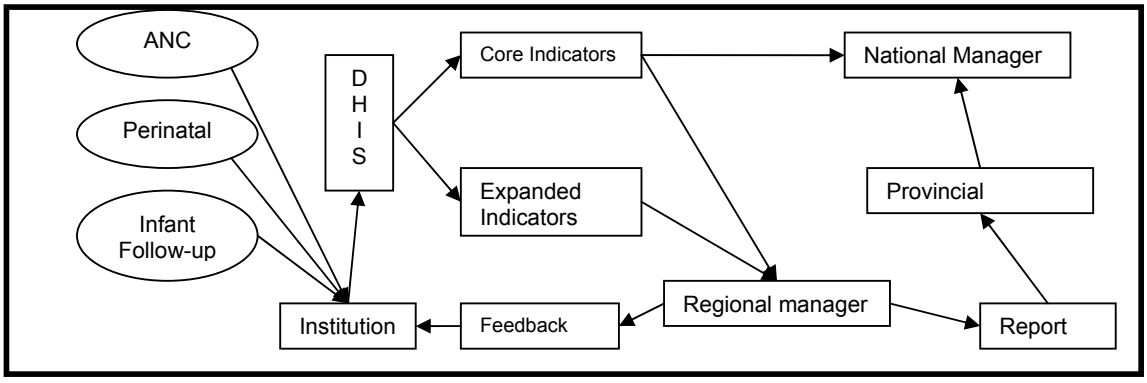
a. Identify HIV positive women who have enrolled in the PMTCT programme
b. Verify if PMTCT prophylaxis has been adequately received
c. Ensure that the medication is dispensed to the infants born to these mothers and that the mothers are counselled clearly about feeding options.
d. Ensure that infants exposed to HIV are adequately enrolled into a care program

The identified minimum data set are a "**core"** set of data; provinces, districts and facilities should collect the "**expanded"** data set, as outlined below, which will support district and provincial programme planning and monitoring. Refer to Figure 5 for information flow and relative importance.

Monthly Indicators, Numbers and Formulas

Tables 1-3 are the suggested PMTCT Indicator Protocol Reference Sheets (IPRS). Each table reflects in turn the indicators and client numbers that are gathered from each of the three service points on a monthly basis. Suggested registers and Results Protocol Reference Sheets (RPRS) to be used at the different service and management points are included in the Annexes. Standardised tools and registers should be used to monitor the PMTCT programme. Figure 1 shows a basic overview of information flow.

Figure 5: Basic overview of information flow



No.	Core Indicator	Expanded Indicator	Definition	Numerator	Denominator	Level
1.1	Proportion of women Counselled and Tested for HIV		Proportion of women who enrolled in antenatal care for the first time for their current pregnancy, (referred to as a “first booking”) who complete VCT = VCT uptake.	No. women accepting a test	No. women attending ANC - "first visits"	Output
1.1.1		Proportion of women counselled	VCT coverage	No. women counselled for VCT	No. women attending ANC - "first visits"	Output
1.1.2		Proportion of counselled women tested	Proportion of women opting to be tested - this shows a combination of VCT refusal and reflects women who have recently had a test elsewhere	No. women tested	No. women counselled for VCT	Output
1.1.3		Proportion of women testing positive	HIV Prevalence in the antenatal population receiving VCT	No. of women testing positive	No. women tested	Output
1.1.4		Proportion of women retested	Retesting Coverage in the whole antenatal clinic population	No. women retested	No. women attending ANC - all attendees minus "first visits"	Output
1.1.5		Proportion of retested women testing positive	HIV Prevalence in the antenatal population being retested	No. women testing positive on retest	No. women retested	Output
1.2	Proportion of Women with a clear HIV status		HIV status coverage at antenatal clinic	No. women clear positive + No. women clear negative	No. women attending ANC	Output
1.3	Proportion of women with a positive HIV status		HIV prevalence at antenatal clinic	No. women established positive	No. women established positive + No. women established negative	Impact
1.4	Proportion of HIV positive women receiving PMTCT prophylaxis		This indicator shows the coverage of PMTCT prophylaxis in the HIV positive population (one "course" is one client's supply for one month)	No. AZT courses dispensed to pregnant women at ANC	No. women established positive	Output
1.4.1		Proportion of positive women receiving Nevirapine at ANC	This reflects the proportion of clients receiving NVP at ANC as opposed to delivery setting	No. of NVP tablets dispensed to pregnant women at ANC	No. women established positive	Output
1.5	Proportion of HIV positive women referred for and receiving CD4 cell count testing		This indicator shows how many of the HIV positive women receive CD4 cell count testing	No. of HIV positive women with CD4 result	No. women established positive	Output
1.5.1		Proportion of positive women who received CD4 result after having blood taken	This indicator shows how many women received a CD4 result after having blood taken	No. of HIV positive women who had blood taken for CD4 test	No. women established positive	Output

No.	Core Indicator	Expanded Indicator	Definition	Numerator	Denominator	Level
1.6	Proportion of HIV positive women with CD4 cell count below 200 placed on ART		Antenatal ART coverage. The antenatal clinics initiating ART themselves should report on the DORA indicators	No. of HIV positive women receiving ART	No. women with CD4 cell count below 350	Output
1.6.1		Proportion of HIV positive women referred to another site for CD4 testing	This reflects CD4 availability at sites	No. of HIV positive women referred for CD4 test elsewhere	No. women established positive	Output
1.6.2		Proportion of HIV positive women referred to another site for CD4 testing that receive result	CD4 referral success - specifically relevant for sites having to refer elsewhere for CD4 testing. Indicators 1.6.1 and 1.6.2 are not relevant for sites that do not refer clients elsewhere for CD4 testing	No. of HIV positive women referred to another site for CD4 testing with CD4 result available	No. of HIV positive women referred to another site for CD4 testing	Output
1.6.3		Proportion of HIV positive women that have a CD4 cell count below 200	Prevalence of low CD4 in positive women	No. HIV positive women with CD4 cell count under ≤200	No. women established positive	Outcome

No.	Core Indicator	Expanded Indicator	Definition	Numerator	Denominator	Level
2.1	Proportion of Women delivering having a established HIV status		This reflects the coverage at delivery of having had the HIV status determined	No. women established positive + No. women established negative	No. pregnant women delivering	Output
2.1.1		Proportion of delivering women with a positive HIV status	HIV prevalence at delivery. It is important to look at this and compare to the antenatal HIV prevalence because the delivery group contains unbooked patients	No. women established positive	No. pregnant women delivering	Outcome
2.2	Proportion of HIV positive pregnant women on ART at delivery		This reflects a sites ability to start ART and later will be a reflection of improving ART coverage in the areas whole population.	No. women on ART at delivery	No. pregnant women established positive	Output
2.2.1		Proportion of HIV positive delivering women who received AZT>4weeks	This reflects PMTCT prophylaxis coverage with clients booking earlier and tested early	No. women on AZT > 4weeks	No. pregnant women established positive	Output
2.2.2		Proportion of HIV positive delivering women who received AZT<4weeks	This reflects PMTCT prophylaxis coverage with clients booking later and tested later	No. women on AZT < 4weeks	No. pregnant women established positive	Output
2.2.3		Proportion of HIV positive delivering women who are dispensed sdNVP in labour ward	This shows the amount of sdNVP that is dispensed at labour ward as opposed to at ANC and is required for calculating the total amount of sdNVP dispensed at an institution	No. of sdNVP tablets issued in labour ward	No. pregnant women established positive	Output
2.3	Proportion of exposed Infants receiving PMTCT Prophylaxis	One could split this indicator into "NVP+1" and "NVP+4" but it would be a repetition of the above two indicators	Infant PMTCT prophylaxis coverage	No. of infants given NVP and AZT	No. pregnant women established positive	Output
2.4		Ratio of HIV positive mothers choosing to formula feed vs breast feed	This indicator reflects the **Feeding Choice** distribution at a site, rather than the **Feeding Practice** at a site, as would be reflected in the Infant Follow-up Indicators	No. HIV positive mothers choosing to formula feed	No. pregnant HIV positive mothers choosing to breast feed	Output

No.	Core Indicator	Expanded Indicator	Definition (Numbers refer to mothers and children seen at EPI clinic)	Numerator	Denominator	Level
3.1	Proportion of HIV exposed infants PCR tested for HIV at six weeks		This reflects HIV PCR Testing Coverage at the six week follow-up visit.	No. PCR tests done at EPI clinic at the six week visit or earlier	No. of HIV positive mothers presenting at EPI clinic at the six week visit	Output
3.2	Ratio of HIV exposed infants PCR tested for HIV at six weeks vs tested later		This reflects HIV PCR Testing Coverage at the six week visit compared to later and the ratio should tend towards one over time as the service improves and more babies are being tested earlier (i.e. at six weeks)	No. PCR tests done by the six week immunisation visit	No. PCR tests done later than six week immunisation visit	Output
3.3	Proportion of HIV exposed Infants testing PCR positive		This is the Positive Testing Rate at any given infant follow-up service. The term "vertical transmission rate" is not used as it requires a very high follow-up rate and covers all infants until breastfeeding has ceased. If children are tested later (possibly by antibody testing, e.g. at one year or two years of age) it can be brought in as a separate indicator.	No. PCR tests positive at EPI clinic	No. HIV exposed Infants tested (PCR) at EPI clinic	Impact
3.3.1		Proportion of PCR HIV Positive results given to Mothers	This indicator shows how many of the infants tested actually get their result back	No. PCR tests given to mothers at EPI clinic	No. HIV exposed Infants tested (PCR) at EPI clinic	Output
3.4		Proportion of Mothers who have a established HIV status	This reflects the extent to which mothers presenting with their infants have had their own HIV status established and is very important to consider when looking at indicator 3.3 to determine if "HIV-exposure" has been clearly established in the majority of mothers. One may want to bring in a time frame for when mothers tested "HIV negative" (e.g. more than three months ago, less than three months ago)	No. mothers established positive + No. mothers established negative	No. Attending mothers (at EPI clinic)	Output
3.4.1		Proportion of Mothers with a positive HIV status	HIV prevalence in mothers presenting with their infants at service point	No. of HIV positive mothers presenting at EPI clinic	No. mothers established positive + No. mothers established negative	Outcome
3.5	Proportion of HIV exposed infants exclusively fed		This shows the extent of **Exclusive** feeding practice at a site and reflects the quality of feeding support in the area but also needs to be seen in careful conjunction with indicator 3.4.	No. of HIV exposed Infants exclusively formula fed + No. of HIV exposed infants exclusively breast fed	No. of HIV exposed babies presenting at EPI clinic	Outcome
3.6		Ratio of HIV exposed infants exclusively formula fed vs breast fed	This reflects the **Feeding practice** distribution as opposed to the **Feeding Choice** mentioned in the delivery indicator list.	No. of HIV exposed Infants exclusively formula fed (recall period = last 24 hours)	No. of HIV exposed Infants exclusively breast fed (recall period = last 24 hours)	Outcome

Requirements & Recommendations on Monitoring and Evaluation

The addition of new PMTCT indicators and modification of existing elements are required to be incorporated into the DHIS. In addition, data management systems at the facility and district level are required to be strengthened viz. the training of facility and district information officers (FIO and DIO), capacity building and training of health care professionals, responsible for entry of facility based information into registers at the site level, on the use of PMTCT tools and the importance of patient flow analysis and patient tracking in a PMTCT setting; ongoing training of FIOs and DIOs on the use of the DHIS as a monitoring and evaluation tool and to ensure successful feedback of information to the facility level. Provincial and district PMTCT managers and information officers must be trained on the fundamental principles of monitoring and evaluation of the PMTCT programme and be able to create M&E logic frameworks that will incorporate indicator results frameworks and target setting and measurements of performance indicators within these frameworks.

National office should recommend inclusion of Provincial and District M&E officers into the PMTCT programme to ensure that this programme has a level of M&E accountability attached to it.

Other Resources

There is a critical and valuable role for the National Health Laboratory Service (NHLS) to feedback district laboratory information disaggregated at the site level for the validation of laboratory requisition tests from the facility level. Specifically this resource may be used to validate and verify output indicators related to access of PCR and CD4 tests, etc.

Hardware for the collection of agreed data points needs to be available at all facilities implementing PMTCT.

SECTION F: IMPLEMENTATION PLAN FOR THE REVISED PMTCT POLICY and GUIDELINES

1. BACKGROUND

Since its inception in 2001 a lot of progress has been made in the implementation of the PMTCT programme, with services now available at 100% of hospitals and more than 90% of primary health care centres countrywide in the public health sector. Close to 2, 2 million pregnant women have utilized the service for the past 4 years, with testing uptake rates averaging 70%. Almost 60% of identified HIV positive women have received nevirapine. Government had committed and expended about R221, 548 million on this programme in the past three years. Additional financial and technical resources from partners; e.g. nevirapine donation from Boerhinger Ingelheim, financial and technical support from Development Partners, and others have enhanced the implementation of the programme. Organizational arrangements with appointment of coordinators at national and provincial levels, establishment of the national PMTCT Steering Committee, as well as development of a monitoring and evaluation system ensured efficiency in the implementation of the programme.

The implementation of the reviewed national PMTCT policy guideline is one of the most important interventions during the NSP 2007-2011 period. This section outlines the national perspective regarding the implementation of this guideline.

2. ORGANISATIONAL ARRANGEMENTS and PERSONNEL

The National Department of Health through the HIV & AIDS, STIs and the MCWH Cluster is responsible for the development of policy guidelines, provision of resources, provision of technical support to provinces and other implementing agencies, as well as monitoring and evaluation of the programme. Social safety network aspects of the programme are the responsibility of the Social Development Department and both departments will report regularly to the government's social cluster and to SANAC.

Provincial health departments will be responsible for the implementation of these guidelines. The Heads of Department are fully responsible for the successful implementation of the reviewed PMTCT policy and guidelines in their provinces. Development of business plans to advocate for financial resources to meet provincial targets and reporting according to the requirements of the Division of Revenue Act are the responsibility of the provincial Heads of Health. HIV and AIDS programme managers and MCWH managers shall collaborate for programme planning, budgeting, implementation, monitoring and regular reporting. PMTCT coordinators in each province should work with District managers to identify service points with capacity to implement, facilitate that personnel have the necessary skills, ensure efficient utilization of all resources, facilitate that information management systems are in place and there is regular collection, collation, analysis, reporting and use of data, facilitate that the provision of good quality of care, facilitate an uninterrupted supply of all commodities, facilitate that there is meaningful community involvement, and that the referral systems are effective as part of district-based plans.

Primary prevention of HIV infection among women of childbearing age is the most important, effective and sustainable intervention for PMTCT. Most of the relevant activities relate to behaviour modification interventions that either occur outside of the health facility or are part of the general provision of health services in a primary health care facility. District-based HIV prevention programmes should target this population. The entry point to health facility based PMTCT activities is mainly through Antenatal Care (ANC) services. The guidelines outline all the relevant activities from

The counselling, the testing, infant feeding choice education, the assessment of safety for the prescription of AZT, prescription of AZT, dispensing of AZT, (AZT to be prescribed by a registered health professional (in line with relevant legislation and regulations) and Nevirapine, management of opportunistic infections, nutrition status assessment and support, psychosocial support and social safety assessments are some of the activities during the antenatal care period.

3. SELECTION OF SERVICE POINTS

The current PMTCT programme is widely available, being implemented in all hospitals and in the majority of the clinics in the public health sector. The effectiveness of the programme is a reflection of the strength of the district health system in general.

The recommended policy guideline requires adequate access to, doctors, pharmacy assistants and community health workers – amongst other members of the health team. Training of all service providers is a critical requirement. The **minimum facility requirements** for the integrated implementation of the guideline could include the following:

1. A facility manager
2. Trained team on site.
3. Adequate physical space for consultation and counselling
4. Other relevant services on site; BANC, FP, Basic HIV and AIDS services,

5. Reasonable access to laboratory services with electronic access to medical records
6. Efficient information management systems to maintain medical records and to transmit core data to a central collection point
7. Good record of adherence to drug dispensing Standard Operating Procedures for OI management and ARVs, as well as management of other commodities and supplies
8. Functional pharmacovigilance activities
9. Reasonable demand, utilization, and supply numbers on the current PMTCT programme and other related activities
10. A patient/treatment tracking system in place
11. Established links with district and provincial authorities responsible for the programme
12. Participation in social mobilization activities to educate patients, families, and communities about the new PMTCT programme and its implications.

In selecting service points (that meet most of the criteria listed above) for preparation to implement, it is recommended that provinces consider the following:

- CCMT service points
- Non-CCMT hospitals with O&G Units and ANC services
- CHCs with MOUs and established comprehensive HIV&AIDS and MCHW programmes
- Other primary health care facilities that satisfy the criteria listed above.

4. TRAINING

Training of health care workers on PMTCT has been ongoing. Most of this is in-service training by accredited training organizations. In provinces where quality assurance and health promotion centres are functional, the PMTCT module will be updated to include the dual therapy, infant feeding, and the data management aspects of the programme. Sections relevant to nutrition, laboratory services, counselling and testing, drug stock management, etc. will be covered in the curriculum. Provinces will identify and send staff for training.

5. DRUG PROCUREMENT and DISTRIBUTION

Systems that have been developed for the comprehensive plan should be used to ensure an uninterrupted supply of drugs for the implementation of this guideline. Drug storage, inventory management, prescription tracking, packaging, contingency stock plans; all require effective pharmaceutical management systems. Readiness to implement should cover all of these aspects. Forecasts and projections will be critical for the business plan process.

6. LABORATORY SERVICES

The NHLS was commissioned to implement the laboratory quality assurance system for rapid HIV test kits that are used in the VCT and the PMTCT programmes. Since the introduction of CCMT, access to laboratory services for CD4 tests and PCR testing had increased considerably. Associated with this is increased laboratory human resources capacity. The choice of service points for the implementation of this guideline has to consider access to this infrastructure. There is no substantial increase envisaged regarding the range of laboratory tests to be done. The turn-around times will need to be managed to minimize delays in clinical decision-making. The experience from the Comprehensive Plan is that laboratory tests have been second only to drugs as cost-driving items in that programme.

7. SOCIAL MOBILISATION and COMMUNICATION

The main objective for social mobilization and communication is to raise awareness and provide information on the new policy and guidelines for the implementation of the PMTCT programme and its intended goal.

The identified target groups include:

- Policy makers
- The public at large
- Programme implementers – government and partners
- Service users
- Community leaders
- Service providers
    - Health care professionals

- Community care givers
- Other stakeholders

7.1 KEY COMMUNICATION AREAS

1. The essential components of the document
    a. Primary prevention of HIV among women of child bearing age; including empowerment of women and addressing gender-based violence
    b. Prevention of unintended pregnancies among HIV positive women
    c. Routine offer of VCT
    d. Counselling on infant feeding
    e. Clinical and laboratory staging, including CD4 testing
    f. Appropriate package of treatment, care and support services for HIV positive pregnant women
    g. Nutrition support
    h. TB screening and management
    i. ARV regimens available
    j. Management during labour and delivery
    k. Importance of exclusive breast feeding
    l. Importance of exclusive formula feeding
    m. Family and community support for treatment adherence and feeding practices
    n. Infant testing at 6 weeks, integrated with other child health services
    o. Importance of cotrimoxazole prophylaxis
    p. Links with the comprehensive plan for further management of the mother and the child.
2. How and where to access services
3. Progress with implementation.
4. Channels for Communication
    a. Khomanani government campaign
    b. GCIS
    c. Regular reports
    d. Community-based activities;
    e. Conferences and journals.

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SECTION H: Annexure A: Some Cited Evidence

[Box 1: Evidence for policy recommendations for use of antiretroviral drugs for securing the health of HIV-positive pregnant women and for reducing HIV infection in infants

More than 10 randomized trails have demonstrated the efficacy of ARV prophylaxis in reducing MTCT(WHO 2006). Similarly, studies in Africa and elsewhere have shown that triple-combination ARVs for pregnant women who require HAART for their own health reduces MTCT risk to around 2% (Cooper, Charurat et al. 2002; 2005; van der Merwe, Chersich et al. 2006; Read, Cahn et al. 2007). For women who do not have indications for HAART, AZT started at 28 weeks of pregnancy (or as soon as possible thereafter), together with sd-NVP is also highly efficacious (Lallemant, Jourdain et al. 2004; Dabis, Bequent et al. 2005).

In six randomized trials in Africa, 12% of HIV-positive pregnant women had a CD4 cell count below 200cells/mm^3, while 21% had a count from 200-349 cells/mm^3 (Leroy, Sakarovitch et al. 2005). It is likely that the distribution of CD4 cell counts will be similar among South African pregnant women. Women with a CD4 cell count between 200-349 have a high risk for MTCT – trials in Africa showed that without ARV drugs, 27%-33% of infants born to these women had HIV infection at six weeks postpartum (Leroy, Sakarovitch et al. 2005). With sd-NVP, in the HIVNET 012 trial, still 18% of infants born to women in this group were infected(Nakabiito C, Guay LA et al. 2002). Also, two trials in West Africa showed relatively poor efficacy of AZT in populations who breastfeed, especially among women with more advanced immunosuppression(Leroy, Karon et al. 2002). As a large proportion of HIV infections in children are attributable to women in the CD4 category 200-349, they require optimal interventions to reduce their risk for MTCT. Initiating HAART for these women, will maximally reduce MTCT (Cooper, Charurat et al. 2002; 2005; Read, Cahn et al. 2007), avoid resistance following sd-NVP, and prevent further maternal disease progression or mortality. In addition, these regimens may reduce transmission of HIV during breastfeeding (Gaillard, Fowler et al. 2004). Findings of studies investigating this topic are expected shortly.

In many parts of the world initiation of ART is recommended for adults with a CD4 200-350. This recommendation is supported by evidence in several large cohort studies. Firstly, without HAART, this group has a 2-10% risk (depending on age and viral load) of having a WHO stage four disease in the next six months (Phillips 2004). Secondly if HAART is initiated, the risk of death or progression to AIDS is lower in this group compared with those with a lower baseline CD4 (Table 1)(Egger, May et al. 2002). A 2007 paper reported similar results, with adults who started HAART with a CD4 cell count 200-350 having a low risk of death or AIDS compared with more immunosuppressed groups (May, Sterne et al. 2007).

The CD4 cell count would drop to below 200 within about 6-18 months, and these women would then require HAART. Some evidence indicates that initiating HAART within six months of receiving sd-NVP adversely affects the response to NNRTI-containing regimens(Jourdain, Ngo-Giang-Huong et al. 2004). When women start HAART 6-18 months after exposure to sd-NVP, the treatment outcomes appear the same as in women without previous exposure (Bedikou, Viho et al. 2005; Lockman, Smeaton et al. 2005 ; Coovadia, Marais et al. 2006). Therefore, it maybe beneficial to avoid exposing those women to sd-NVP who are most likely to initiate HAART in the next months.

Evidence indicates that the incidence of resistance following sd-NVP may be decreased if AZT and 3TC are given intrapartum and for seven days after childbirth. A randomized trial in South Africa showed this strategy reduced the development of resistance to NVP from 60% to about 10%(McIntyre, Martinson et al. 2005). 3TC and AZT are thus recommended during labour and for seven days after childbirth.

Trials in Malawi and South Africa demonstrated that antiretroviral prophylaxis given to infants shortly after childbirth can reduce MTCT even if their mother had not received ARV drugs(Taha, Kumwenda et al. 2004; Gray, Urban et al. 2005). In the Malawi trial, among infants born to women who had not received ARV prophylaxis, sd-NVP and seven days of AZT was more efficacious than sd-NVP alone(Taha, Kumwenda et al. 2004). A trial in Thailand found that longer infant prophylaxis (28 days) was more effective than a shorter regimen if the mother had received ARV drugs for less than four weeks during pregnancy(Lallemant, Jourdain et al. 2000).

There are concerns about the effect of AZT on haematological parameters for women during pregnancy, many of whom have anaemia. Evidence thus far on these effects of AZT from 28 weeks of pregnancy are reassuring, suggesting a minimal transient negative impact, which is largely reversed by delivery(Briand, Lallemant et al. 2007).

Summary of the evidence for the policy statements on infant feeding

Breastmilk from an HIV-infected mother can transmit HIV. (Dunn, Newell et al. 1992)

This risk of transmission continues throughout the breastfeeding period; thus the longer the duration of breastfeeding, the higher the risk of HIV transmission through breastmilk.(Miotti, Taha et al. 1999; Breastfeeding and HIV International Transmission Study Group, Coutsoudis et al. 2004)

Exclusive breastfeeding (EBF) is better than mixed feeding: It has been shown to be associated with a reduced incidence of diarrhoea, respiratory infections and allergy.(Victora CG 1987; Victora, Smith et al. 1989; Popkin, Adair et al. 1990; WHO Collabourative Study Team on the Role of Breastfeeding on the Prevention of Infant Mortality 2000; Arifeen, Black et al. 2001) Furthermore, recent data show that exclusive breastfeeding carries a lower postnatal HIV transmission risk than mixed feeding. (Coutsoudis, Pillay et al. 2001; Iliff, Piwoz et al. 2005; Rollins 2006; Coovadia, Rollins et al. 2007). In South Africa, a recent study estimated the risk of postnatal transmission of HIV by 20-26 weeks of age in exclusively breastfed infants who were negative at 6 weeks of age at 4.04%. (Coovadia, Rollins et al. 2007) This study also showed that the early introduction of solid foods to infants who were breastfed were nearly 11 times more likely to acquire HIV infection than were those who received breastmilk only. Infants, who at 14 weeks of age received formula milk and breastmilk, were nearly twice as likely to be infected as exclusively breastfed infants.

The Interagency task team, led by WHO recommends that the most appropriate infant feeding option for an HIV-infected mother should continue to depend on her individual circumstances, including her health status and the local situation, but should take greater consideration of the health services available and the counselling and support she is likely to receive. (WHO. 2000; World Health Organisation 2003; World Health Organisation on behalf of the Inter-Agency Task Team 2006) Exclusive breastfeeding is recommended for HIV-infected women for the first 6 months of life unless replacement feeding is acceptable, feasible, affordable, sustainable and safe for them and their infants before that time. When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected women is recommended. At six months, if replacement feeding is still not acceptable, feasible, affordable, sustainable and safe, continuation of breastfeeding with additional complementary foods is recommended, while the mother and baby continue to be regularly assessed. All breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided. Whatever the feeding decision, health services should follow-up all HIV-exposed infants, and continue to offer infant feeding counselling and support, particularly at key points when feeding decisions may be reconsidered, such as the time of early infant diagnosis and at six months of age. Otherwise, exclusive breastfeeding (feeding only breastmilk and no other foods or fluids) is recommended during the first months of life.

Amongst HIV-positive women who do not meet the AFASS criteria EBF is recommended because it is a key child survival strategy with maternal and child-health benefits over mixed breastfeeding (Popkin, Adair et al. 1990; Arifeen, Black et al. 2001), or formula feeding (Victora CG 1987; Victora, Smith et al. 1989; World Health Organisation 2001).

Furthermore modelling also indicates that universal coverage with exclusive breastfeeding for six months and continued breastfeeding until 11 months may prevent 13% of under 5 mortality, after accounting for HIV. (Jones, Steketee et al. 2003)

Despite the fact that avoiding all breastfeeding eliminates breastmilk transmission of HIV, a global meta-analysis shows that in the pre-HIV era avoiding breastfeeding carried increased mortality risks for infants (WHO Collabourative Study Team on the Role of Breastfeeding on the Prevention of Infant Mortality 2000). In the context of HIV, clinical trial and routine surveillance data across Africa show that this mortality risk remains for non-breastfed infants born to HIV-positive women – i.e. there is no added benefit of not breastfeeding (Taha, Kumwenda et al. 2006; Thior, Lockman et al. 2006; Coovadia, Rollins et al. 2007).

Mortality in the first 3 months of life was roughly doubled in the group receiving replacement feeding compared with exclusive breastfeeding group (15% vs 6%). (Coovadia, Rollins et al. 2007) The mothers that chose to exclusively formula feed were more likely to have CD4 counts below 200 (higher risk group for transmission of virus through breastfeeding). It is possible that if a mother had clinical symptoms she was not able to care for her infant correctly.
Modelling exercises show that this is especially true where background infant mortality rates are higher than 25-40/1000 live births (Kuhn, Stein et al. 2004; Piwoz and Ross 2005). Dangers of avoiding all breastfeeding include increased morbidity and growth faltering in infants born to HIV-infected women.(Coutsoudis, Pillay et al. 2003; Kafulafula, Thigpen et al. 2004; Kourtis, Fitzgerald et al. 2004; Creek, Arvelo et al. 2007) These risks have been documented not only in the first 6-months of life, but also between 6 months and 1-year, following cessation of breastfeeding at 6-months.(Kafulafula, Thigpen et al. 2004; Kourtis, Fitzgerald et al. 2004)

Summary of the evidence – continued

Counselling on infant feeding has been one of the weakest components of the current SA PMTCT programme (Doherty, Besser et al. 2003; Chopra, Jackson et al. 2005) – in many instances health care personnel have interpreted the UN recommendations as “promoting replacement feeding” or “avoiding breastfeeding”. In some countries, this advice has spilled over into the population with unknown or negative HIV status.(Botswana PMTCT Advisory Group 2001) In South Africa programmatic data show that quality of infant feeding counselling is poor, and that women’s choices are not being guided by the AFASS criteria. (Doherty, Chopra et al. 2006. Doherty, Chopra et al. 2007; Doherty, Chopra et al. 2007.) South African data show that at least 3 conditions need to be met before avoiding breastfeeding may be beneficial i.e. piped water must be available in the house or yard, and fuel must be regularly available and the woman should have disclosed her HIV status. (Doherty, Chopra et al. 2007) Data from the Good Start study shows that 195 (33%) of women made an inappropriate choice to exclusively formula feed (intending to formula feed but not having these 3 criteria) and 95 (16%) made an inappropriate choice to exclusively breastfeed (intending to EBF and having these 3 criteria). Good Start data show that HIV-free survival improves if the mother has at least piped water in the house or yard, and fuel and has disclosed, compared with if she only has piped water in the house or yard. Adherence to exclusive formula feeding was also improved if the mother met these 3 criteria, compared with if she only has piped water in the house or yard. In an intention to treat analysis women who made inappropriate choices for formula feeding had a 3 times increased risk of HIV transmission or death and women who made an inappropriate choice to breastfeed had a 2.72 times increased risk of HIV transmission or death compared with women who made an appropriate choice to formula feed. Furthermore, South African data also show that adherence to feeding choice is less likely if women have less than four antenatal visits (Doherty, Chopra et al. 2007) : amongst women intending to EBF, the odds of non-adherence was 1.69 times higher for women who received one antenatal counselling visit compared with those who receive four visits (95% CI: 1.04–2.76).; amongst women intending to EFF, the odds of non-adherence was 4.08 times higher for women who received one versus four visits (95% CI: 1.45–14.56).

Early cessation of breastfeeding (before 6-months) amongst women with CD4 counts>350 is not recommended as early breastfeeding cessation (before 6-months) in these women has been shown to carry no additional benefits for HIV-free survival, and may in fact be detrimental to child health. (Sinkala, Kuhn et al. 2006) Furthermore continued breastfeeding in infants already infected with HIV has been shown to reduce morbidity and prolong the time taken to reach AIDS. (Sinkala, Kuhn et al. 2006)

Children infected with HIV typically have a more rapid disease progression within the first years of life due to their developing immune system and susceptibility to other serious infections. In many developed countries, most infants receive ARV therapy immediately after being diagnosed with HIV, which has shown to be safe and effective. Data from South Africa show that HIV-positive infants from resource-limited settings who were presumptively treated with antiretrovirals within the first 3-month of life had a significantly lower mortality compared with infants who were treated only when their CD4 count dropped to <25% (HR 0.24 [95% CI 0.11 – 0.52]; p = 0.0002) (Violari, Cotton et al. 2007); furthermore as many as 60% of HIV-positive infants not on antiretroviral therapy deteriorated and required antiretroviral therapy in the first year of life.
Data also shows that approximately 25% of HIV-positive infants die in the first year of life.(Newell,

Coovadia et al. 2004) These data provide a scientific basis for recommending early infant diagnosis, and re-checking HIV status at 6-months so that HIV-positive infants can be identified as early as possible and life-saving interventions can be implemented.

With regards to maternal health data from South Africa and Kenya indicate that BF HIV-infected mothers tend to lose more weight postnatally than HIV uninfected BF mothers (fat vs. lean body tissue but not associated with increased mortality). (Papathakis, Rollins et al. 2007) This is the scientific basis for material nutritional supplements for breastfeeding HIV-positive women.

SECTION I: Annexure B: List of guidelines cited in the document

Department of Health Guidelines for Maternity Care in South Africa

Department of Health Guidelines for Maternity Care in South Africa

IMCI Clinical Case Management Guidelines

South African National Guidelines on Nutrition for People Living with HIV, AIDS, TB and other Chronic Debilitating Conditions

South African Infant and Young Child feeding policy and implementation Guidelines

Vaccinator's Manual, Expanded Programme on Immunisation South Africa (EPI-SA), Second Edition; April 2005