

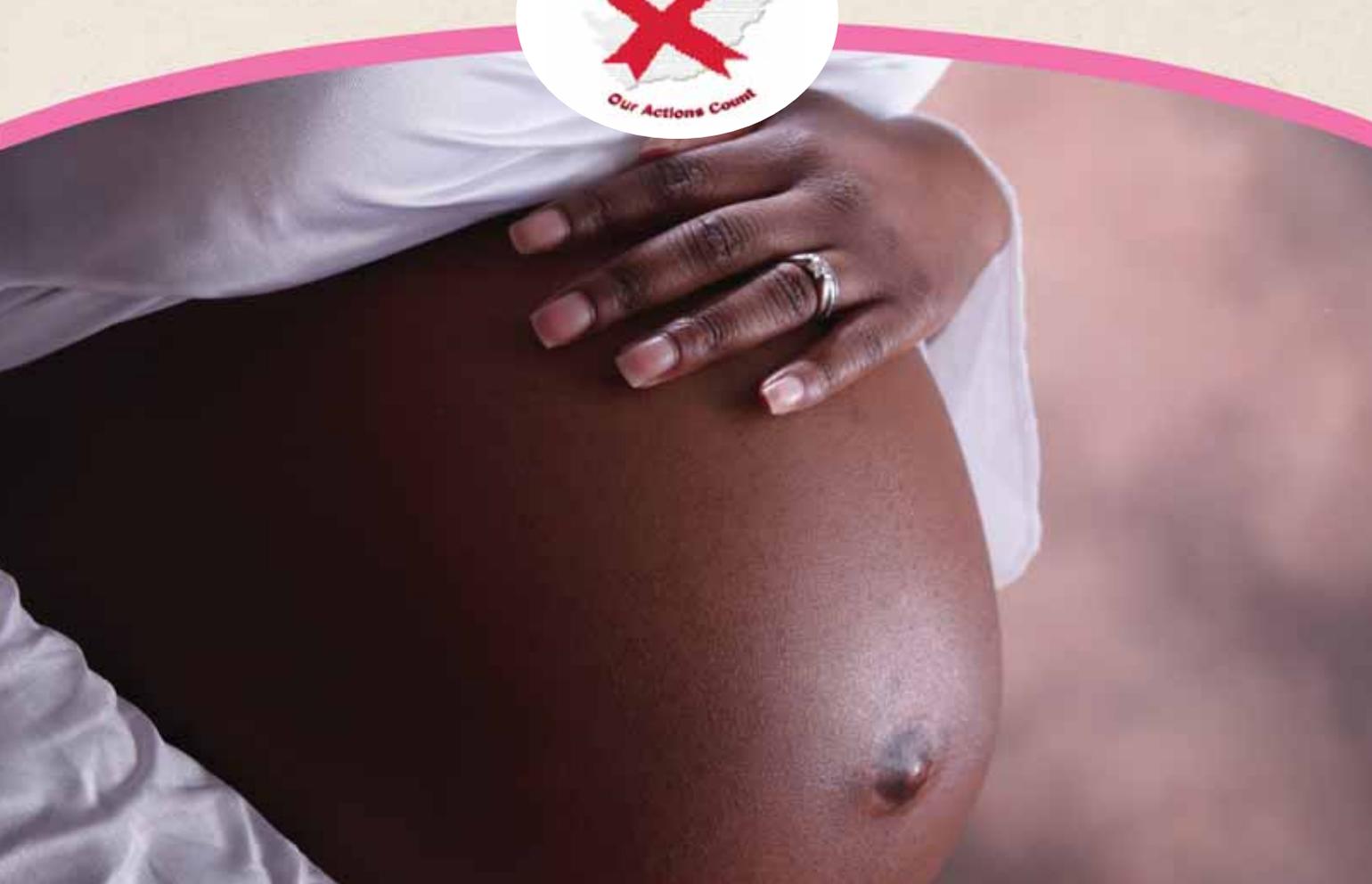


Health

Department:
Health
REPUBLIC OF SOUTH AFRICA

CLINICAL GUIDELINES: Prevention of Mother-to-Child Transmission (PMTCT) 2nd Edition 2010

National Department of Health, South Africa
South African National AIDS Council



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Department of Health
Private Bag X828, Pretoria, 0001

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FOREWORD

It is with pleasure that I present the revised prevention of mother-to-child transmission of HIV (PMTCT) Guidelines.

Government has adopted a new outcomes based approach to accelerate attainment of the objectives outlined in the Medium Term Strategic Framework (MTSF) 2009-2014. One of the objectives is to improve the health profile of all South Africans.

The 10 point plan of the Health Sector is aimed at creating a well functioning health system capable of producing improved health outcomes. Priority seven of the 10 point plan is to accelerate implementation of the HIV&AIDS plan and the reduction of mortality due to TB and associated diseases.

On World AIDS Day, 2009, the Honourable President Jacob Zuma announced new interventions to improve antiretroviral therapy (ART) access for priority groups in order to decrease the disease burden, to address maternal and child mortality, and to improve life expectancy.

Based on the presidential announcements, all HIV-infected pregnant women with a CD4 count $350/\text{mm}^3$ will commence lifelong ART earlier. Furthermore, prophylaxis ART treatment will be started earlier, at 14 weeks pregnancy, for women who are not eligible for lifelong ART. For the first time, HIV-positive-infected women can safely breastfeed their children provided the child is taking ARV's during the breastfeeding period.

This document serves as a new guide to health practitioners with regard to the comprehensive management of pregnant women who are HIV-positive.

It is of paramount importance to note that prevention of mother-to-child transmission of HIV (PMTCT) has the potential to be the engine for strengthening delivery of comprehensive, integrated health care. The guideline therefore, promotes the integration of PMTCT with maternal, newborn and child health provision of sexually transmitted diseases and tuberculosis services.

The many comments from and the involvement of internal and external stakeholders is appreciated and has contributed significantly to the finalisation of these guidelines. I would like to thank all who contributed to the development of these guidelines despite their busy schedules.



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ABBREVIATIONS AND ACRONYMS

3TC	Lamivudine
ANC	Antenatal Care
AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Aminotransferase
ART	Antiretroviral Therapy
ARV	Antiretroviral
ART	Antiretroviral Therapy
AZT	Zidovudine
BANC	Basic Antenatal Care
BF	Breast Feeding
BFHI	Baby Friendly Hospital Initiative
BBA	Born Before Arrival (to delivery unit)
CCMT	Comprehensive Care Management and Treatment for HIV and AIDS
CHW's	Community Health Workers
CTX	Cotrimoxazole
DNA	Deoxyribonucleic Acid
d4T	Stavudine
ECD	Early Childhood Development
EBF	Exclusive Breastfeeding
EFF	Exclusive Formula Feeding
EFV	Efavirenz
EPI	Expanded Programme on Immunisation
FTC	Emitracitabine
HAART	Highly Active Antiretroviral Therapy
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
IMCI	Integrated Management of Childhood Illness
LPV/r	Lopinovir/ritonavir
MTCT	Mother-to-Child Transmission of HIV
NHA	National Health Act
NHC	National Health Council
NSP	National Strategic Plan
NVP	Nevirapine
PEP	Post-Exposure Prophylaxis
PCP	Pneumocystis jiroveci Pneumonia
PCR	Polymerase Chain Reaction

PICT	Provider-Initiated HIV Counselling and Testing
PMTCT	Prevention of Mother-to-Child Transmission of HIV
PNC	Postnatal Care
RF	Replacement Feeding
RTHC	Road-to-Health Chart
sdNVP	Single-Dose Nevirapine
SRH	Sexual and Reproductive Health
TC	Testing and Counselling
TDF	Tenofovir
UNAIDS	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

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

Refers to 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 in 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

Feeding practice in which an infant receives only breast milk and no other liquids or solids, including 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 practice in which infants receive no breast milk, but receive a diet that provides adequate nutrients until the age at which they can be exclusively fed family foods. During the first 6 months of life, formula feeding requires 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, 1978 (Act No. 53 of 1974)
- Pharmacy Act, 1974 (Act No. 53 of 1974)
- 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 is not a health care provider as defined above. This includes lay counsellors and community caregivers.

HIV-exposed infant

Infant born to an HIV-positive woman.

HIV-negative

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

HIV-positive

Refers to people who have taken an HIV test with a positive result and 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 (e.g., vitamins and minerals), as compared with macronutrients (e.g., protein, fats and carbohydrates), which are found in larger amounts.

Mixed feeding

Feeding breast milk as well as other milks (including commercial formula or home-prepared milk), foods, or liquids.

Mother-to-child transmission

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

Nutritional status

An individual's state 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.

Provider-initiated counselling and testing (PICT)

A routine, opt-out process in which health care personnel offer group information and HIV-testing, with the patient/client always retaining the option to decline. The patient/client also receives post-refusal or post-test counselling.

Replacement feeding

Feeding of infants who are receiving no breast milk with a diet that provides adequate nutrients until the age at which they can be exclusively fed on full 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.

Safe infant feeding

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

1. EXECUTIVE SUMMARY

This document is an update of the national *PMTCT Policy and Guidelines*. It aims to provide continued guidance towards a reduction in the vertical transmission of HIV, building on work done since the inception of the programme and the 2008 Policy and Guidelines document.

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. These include:

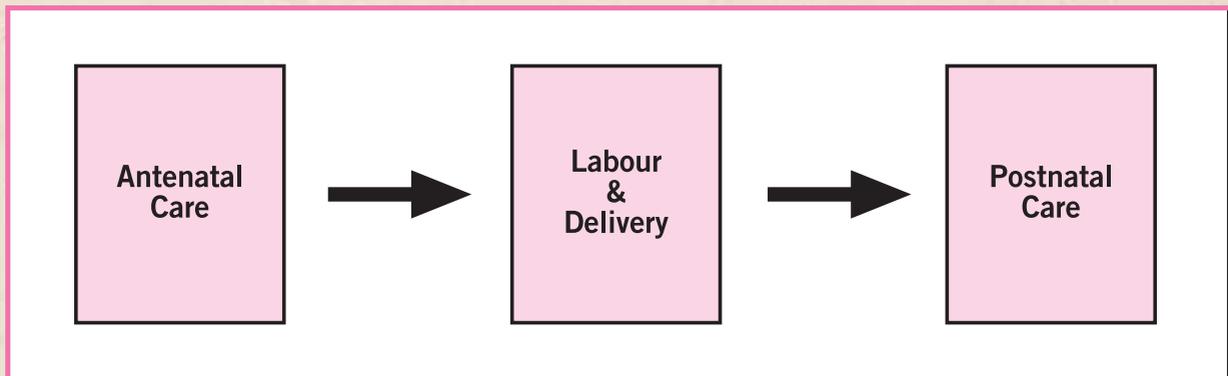
- Primary prevention of HIV, especially among women of childbearing age;
- Preventing unintended pregnancies among women living with HIV;
- Preventing HIV transmission from a woman living with HIV to her infant; and
- Providing appropriate treatment, care, and support to women living with HIV and their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

The National PMTCT programme aims to ensure:

- **Primary prevention** of HIV, especially among women of child-bearing age.
- **Integration of PMTCT interventions** with basic antenatal care (BANC), sexual and reproductive health (SRH), Child and Adolescent Health, comprehensive care, management and treatment for HIV (CCMT) and tuberculosis (TB) services.
- **Strengthen postnatal care** for the mother-baby pair.
- **Provision of an expanded package** of PMTCT services, including:
 - Routine offer of HIV counselling and testing for all pregnant women attending antenatal care;
 - Provision of provider-initiated counselling and testing services in the context of PMTCT, in facilities offering routine antenatal care;
 - Involvement of the partner and the family in order to ensure a comprehensive approach;
 - Provision of 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;
 - Provision of other appropriate treatments, such as those for opportunistic infections (OI) management and nutritional support;
 - Provision of psychosocial support to HIV-positive pregnant women;
 - Provision of quality, objective, and individualised counselling on safe infant feeding practices (as defined in this document) for HIV-positive women in health facilities offering routine ANC services, through trained lay counsellors and health care professionals;
 - Strengthened obstetric practices which reduce MTCT;
 - Provision of antiretroviral prophylaxis to infants;
 - Integrated follow-up of infants born to HIV-positive women through routine child health services and the Integrated Management of Childhood Illness (IMCI) strategy;
 - Infant HIV testing using HIV DNA-PCR at 6 weeks of age for all infants born to HIV-positive women (integrated with the expanded programme on immunisation (EPI) 6-week visit), irrespective of feeding option;
 - Strengthened of community-based household and door-to-door activities to educate and enhance the utilisation rates and effectiveness of health programs;

2. PMTCT PROCESSES AND GOALS OF INTERVENTION

Figure 1: Summary of PMTCT processes

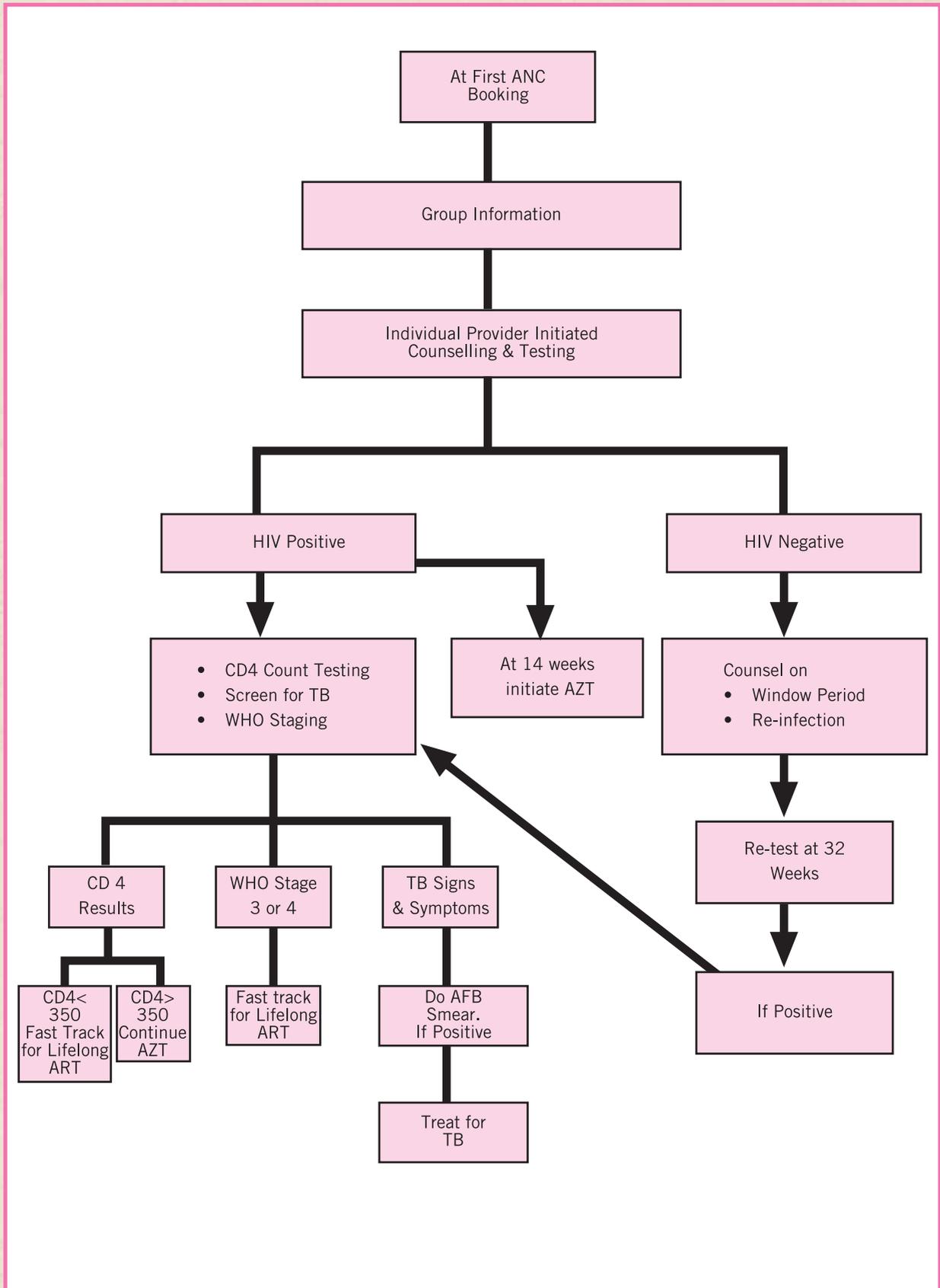


2.1 ANTENATAL CARE

Goals of interventions:

- Improve the quality of the mother's health and prevent mortality;
- Identify women who are HIV-positive;
- Ensure HIV-positive women enter the PMTCT programme;
- Prevent mother-to-child transmission; and
- Provide zidovudine (AZT) from 14 weeks of pregnancy or lifelong ART as soon as possible, depending on a mother's clinical indications

Figure 1.1: Activities at the Antenatal Clinic

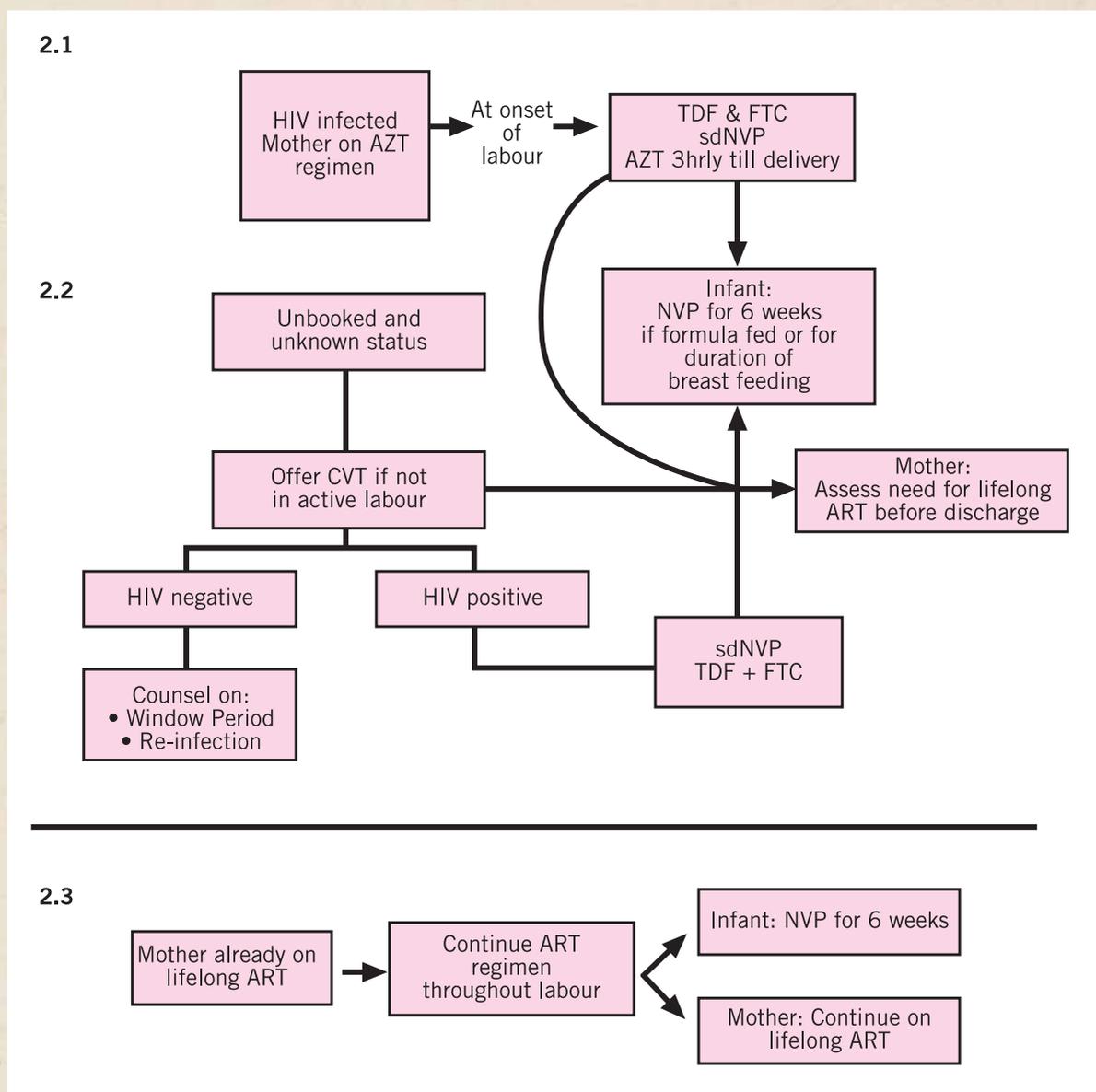


2.2 LABOUR AND DELIVERY

Goals of interventions:

- Identify HIV-positive women;
- Provide adequate PMTCT coverage;
- Provide continuity of care of prophylactic and treatment antiretroviral regimens;
- Reduce maternal nevirapine (NVP) resistance; and
- Initiate neonates born to HIV-positive mothers with antiretroviral prophylaxis immediately at birth.

Figure 2: PMTCT algorithm



All women of unknown HIV status should be offered HIV testing and counselling before discharge, preferably prior to, or immediately after, delivery to ensure that the baby gets antiretroviral prophylaxis if the test is HIV positive.

- All abandoned infants judged to be in their first 72 hours of life should be given NVP as soon as possible and then daily for 6 weeks, or until rapid testing of the mother or infant confirms the absence of HIV exposure.
- Breastfed infants whose mothers are not on lifelong ART should continue NVP beyond 6 weeks of age until all cessation of breastfeeding.

2.3 POSTNATAL FOLLOW-UP OF MOTHER AND INFANT

Goals of interventions:

- Provide follow-up post-partum care including a postnatal visit within 3 days;
- Improve the quality of the mother's health and reduce mortality by including family planning counselling and cervical cancer screening where applicable;
- Provide post-exposure prophylaxis for infants;
- Reduce postnatal HIV transmission through breastfeeding;
- Identify all HIV-exposed infants;
- Reduce mortality in HIV-exposed infants; and
- Identify all HIV-positive infants and start ART early.

Figure 3: Infants who are formula fed

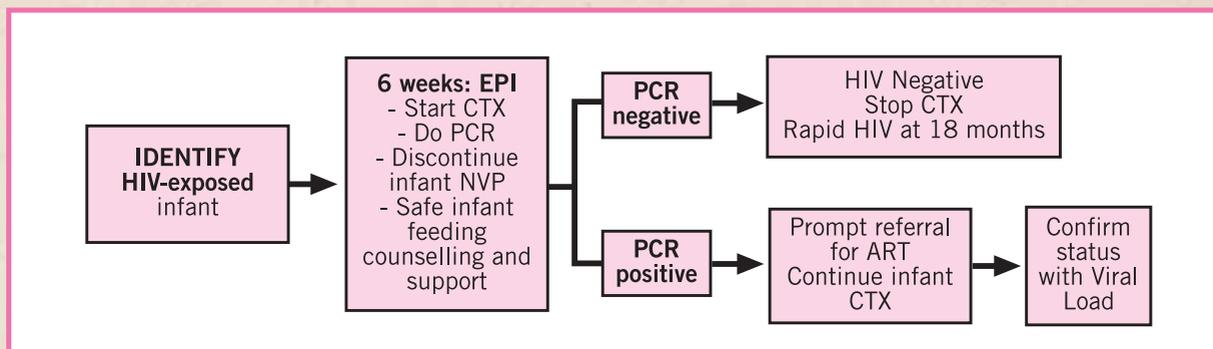


Figure 4: Infants who are breastfed whose mothers are on lifelong ART

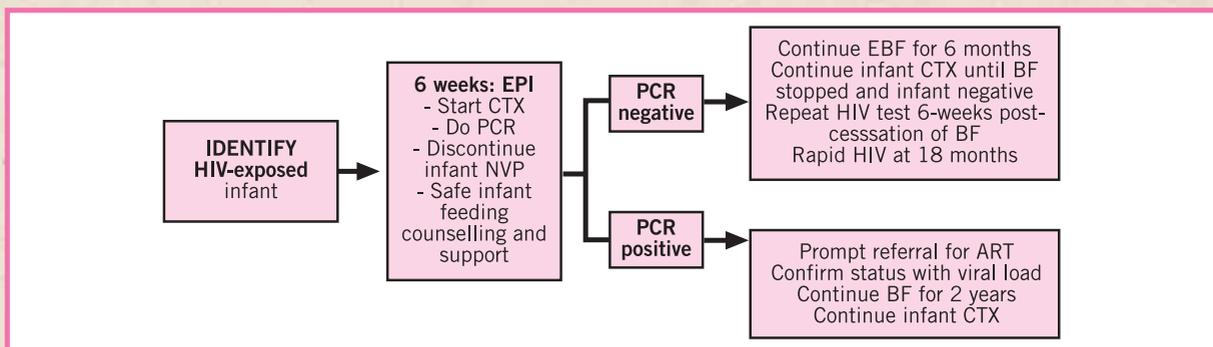
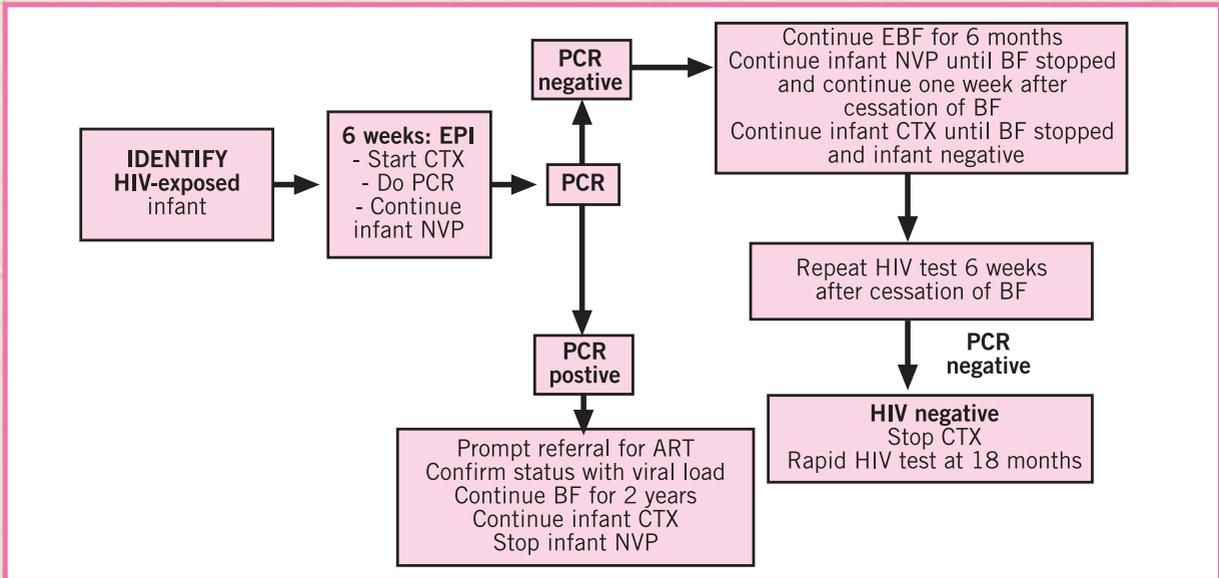
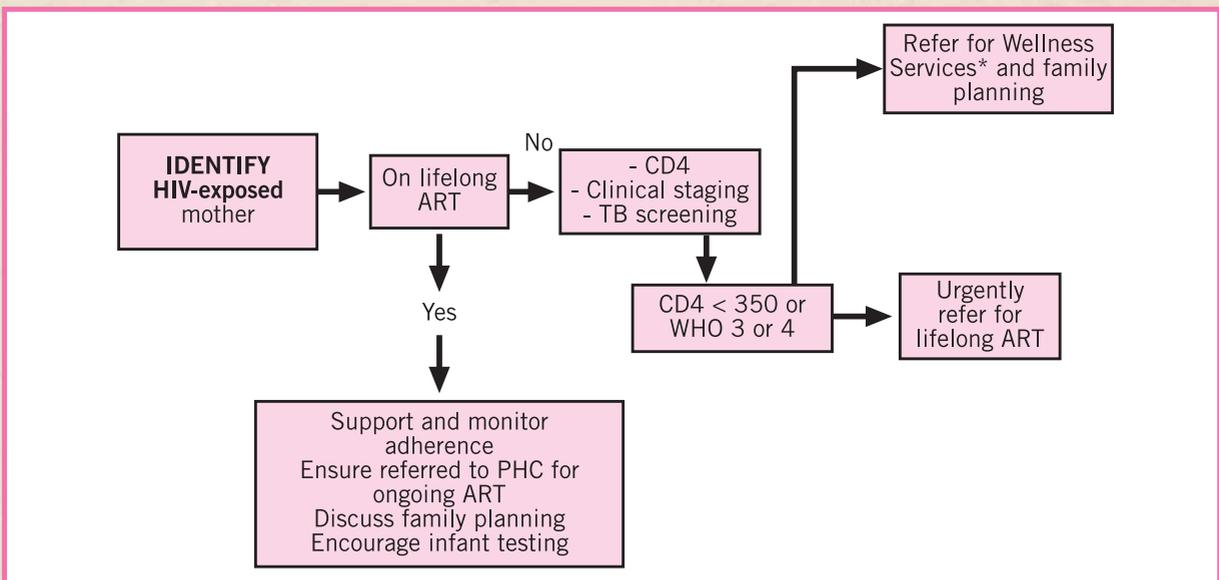


Figure 5: Infants who are breastfed whose mothers are NOT on lifelong ART



NB: All HIV-exposed infants not on ART should have a rapid test at 18 months of age to confirm HIV status conferred by the 6-week PCR test.

Figure 6: All mothers at scheduled check-up, 6 weeks post-partum



* Wellness Services entails follow-up of HIV-infected individuals not yet on ART and includes: provision of TB screening, isoniazid (INH) prophylaxis, cotrimoxazole (CTX) prophylaxis, nutritional and psychosocial support, cervical cancer screening, monitoring of CD4 cell count, clinical staging and preparedness for ART.

Mothers of unknown HIV status or who are HIV negative should be offered an HIV test during postnatal care visits.

3. KEEPING WOMEN AND CHILDREN HEALTHY AND IMPROVING THEIR QUALITY OF LIFE AND REDUCING MORTALITY

All pregnant women should:

- Be encouraged to book early into antenatal care, as soon as they believe they are or are confirmed to be pregnant.
- Receive routine antenatal care, including micronutrient supplementation.
- Be offered information on the availability of PMTCT interventions during all health care consultations.
- Be routinely offered HIV counselling and testing and encourage partner or spouse testing.
- Be encouraged to involve partners or spouses in caring for the pregnancy.
- Be counselled on safer sex and provided with condoms.
- Be counselled on safe infant feeding options and assisted in making an appropriate feeding choice.
- Be supported on the choice of infant feeding at all times.

All pregnant women who are HIV-positive should:

- Receive routine antenatal care, including iron and folate supplementation.
- Be offered information on the availability of PMTCT interventions at all health care consultations, and not only when visiting the antenatal clinic.
- Be clinically staged and have a CD4 cell count taken on the same day as the HIV test is done, and preferably at the first ANC visit (or at the earliest opportunity).
- Be screened for TB, in line with the BANC.
- Be screened and treated swiftly for syphilis and other sexually transmitted infections (STIs), in line with BANC.
- Receive regimens to prevent mother-to-child transmission of HIV (PMTCT regimen) OR lifelong ART if CD4 cell count ≤ 350 cells/mm³ (ART regimen).
- Be offered appropriate Pneumocystis jiroveci Pneumonia (PCP) and TB prevention prophylaxis.
- Be counselled on safer sex, family planning, postnatal contraception and partner testing.

Women who **start lifelong ART in their pregnancy** should be monitored and managed, where possible, by the same provider in the same facility. They should receive follow-up from an antenatal health care worker **until at least 6 weeks postpartum**, before being referred for ongoing care to an appropriate facility.

Women who test HIV-negative should receive post-test counselling and counselling on risk reduction interventions including involvement of partners or spouses, focusing mainly on how to maintain their HIV-negative status. They should continue to receive routine antenatal care, and should be encouraged to use condoms. They should be offered a repeat HIV test at or around 32 weeks gestation, to detect those who may have sero-converted during pregnancy.

Women who choose not to be tested should receive individual 'post-refusal' counselling and be offered HIV testing at every subsequent visit in a non-coercive manner during the antenatal period. They should also be offered an HIV test at the onset of labour; if this is not possible, they should be offered testing shortly after childbirth.

Women who initially test negative and subsequently test positive during pregnancy should be given a CD4 cell count test, clinically staged, and initiated onto AZT whilst awaiting the CD4 cell count result. If the result of CD4 is 350 or less the woman must commence lifelong ART within 2 weeks. If the CD4 is more than 350, then she continues on AZT.

Unbooked women reporting in labour should be counselled and tested for HIV during the first stage of labour and offered a PMTCT intervention as per guidelines. If this is not possible, counselling and testing should be offered after delivery. If the mother tests positive, the infant should be initiated onto NVP, the mother should be counselled on feeding options and counselled about infant testing. The mother must be staged and a CD4 cell count taken prior to discharge with a follow-up visit scheduled within one week. If eligible for ART (CD4 of 350 or less or WHO stage 3 or 4) she should commence lifelong ART within 2 weeks.

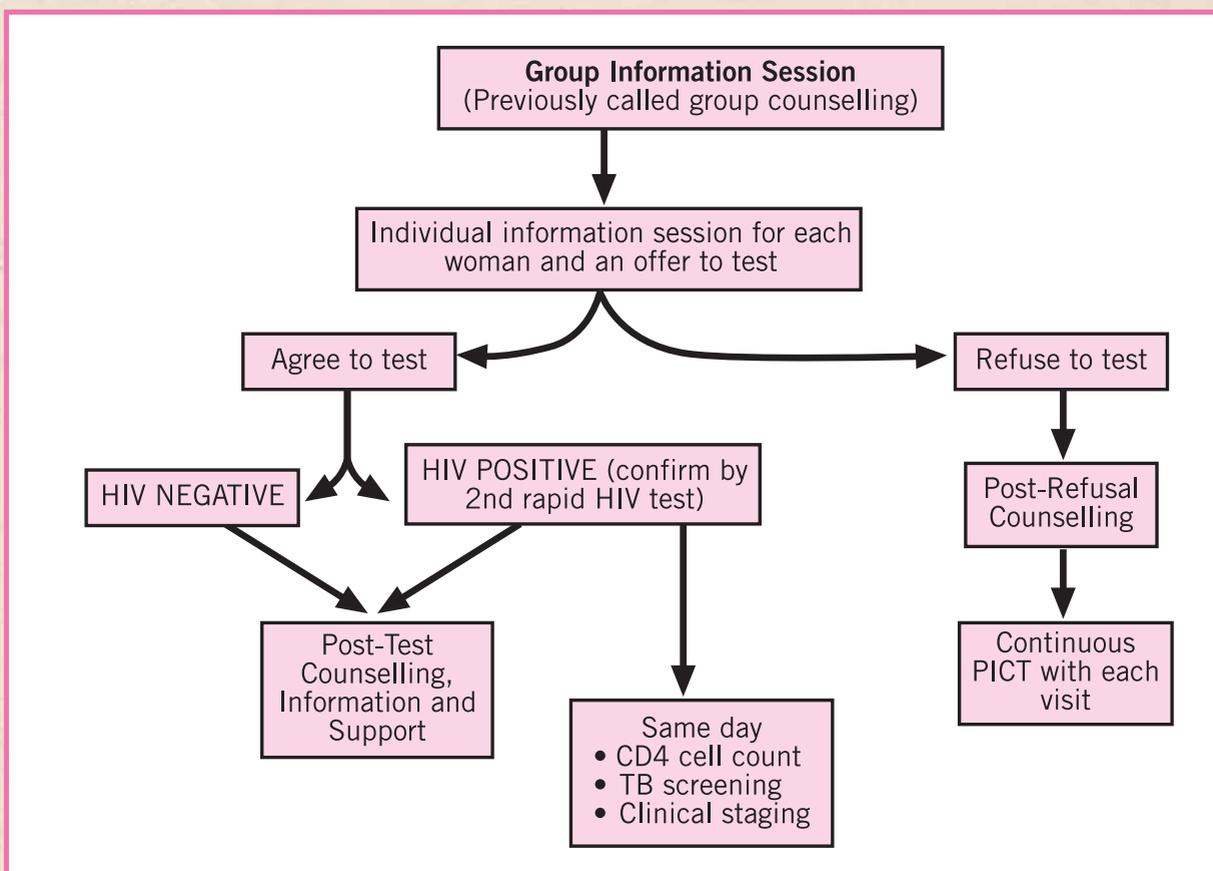
Information on a patient's HIV status, PMTCT or ART regimen, and CD4 cell count should be shared between health care personnel at all levels of the health service, while respecting the confidentiality of women and children. This is called **shared confidentiality** among health care workers, and is essential for maintaining continuity of care among women and infants. This entails thorough completion of the Road-to-Health Card, particularly as it relates to HIV.

4. PROVIDER-INITIATED COUNSELLING AND TESTING

4.1 OVERVIEW

- All women attending antenatal care (both first-time attendees and women attending follow-up visits) should be given routine information about 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 meet with a counsellor, nurse, or midwife for a one on one '**Individual Information Session**'.
- At the individual information session, each woman should be informed of the **routine HIV testing procedure** and should be given the opportunity to ask further questions. The woman should **then be offered** an HIV test and asked to provide verbal consent to the testing. A woman may refuse an HIV test ("opt-out").
- Women who opt-out of HIV testing should be offered post-refusal counselling to explore the reasons for this choice, address any misunderstandings, and encourage her to reconsider her decision not to test, but without applying undue pressure. These women should be offered routine HIV testing at each subsequent clinic visit.
- Information should be offered before the testing procedure and counselling should occur after the test results are provided.
- All women who test HIV positive should have their HIV status confirmed using a second rapid HIV test.
- Post-test counselling should be offered to both HIV-positive and HIV-negative women; HIV-positive women should only be counselled after a second rapid HIV test has been performed to confirm a positive HIV status.
- The flow chart on the next page summarises the processes involved in provider-initiated counselling and testing.

Figure 7: Provider-initiated counselling and testing



Details of what information should be provided during pre-test and individual information sessions are contained in the boxes 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 as an individual and as a couple.
 - Information about the HIV testing process.
 - Emphasis on the importance of early access to antiretroviral therapy, for the mother's own health.
 - Information about the high mortality due to HIV & AIDS.
 - Information that maternal deaths are preventable, and that PMTCT is one such effort.

- *Benefits to the foetus and infant:*
 - *Information about mother-to-child transmission of HIV and possible measures to reduce this occurrence.*
 - *Information on interventions that can keep HIV-exposed infants healthy, such as cotrimoxazole prophylaxis and antiretroviral therapy.*
 - *Assurance on confidentiality, a discussion of shared confidentiality, and couple counselling.*
 - *Emphasis on the need for PCR testing at 6 weeks post-partum and its benefits.*
 - *Emphasis on the importance of adherence to prophylaxis or treatment.*

The group information session should provide further information on the programme, and include the fact that HIV testing is a necessary step for enrolment into the PMTCT programme, unless a woman's status is already known to be positive. Furthermore, CD4 cell count and clinical staging are important for clinical decision making.

INDIVIDUAL INFORMATION SESSION

- *An individual information session should be available to all pregnant women following the group information session. This should instil a positive focus and acceptance on the client's side.*
- *The components of the individual information session include:*
 - *An assessment of whether the information provided in the group session has been understood;*
 - *Answers to any remaining questions, with an aim to clarify any misunderstanding;*
 - *A discussion of the way forward and the treatment options within the PMTCT intervention; and*
 - *Verbal consent for HIV testing.*

4.2 TESTING ALGORITHM FOR PREGNANT WOMEN

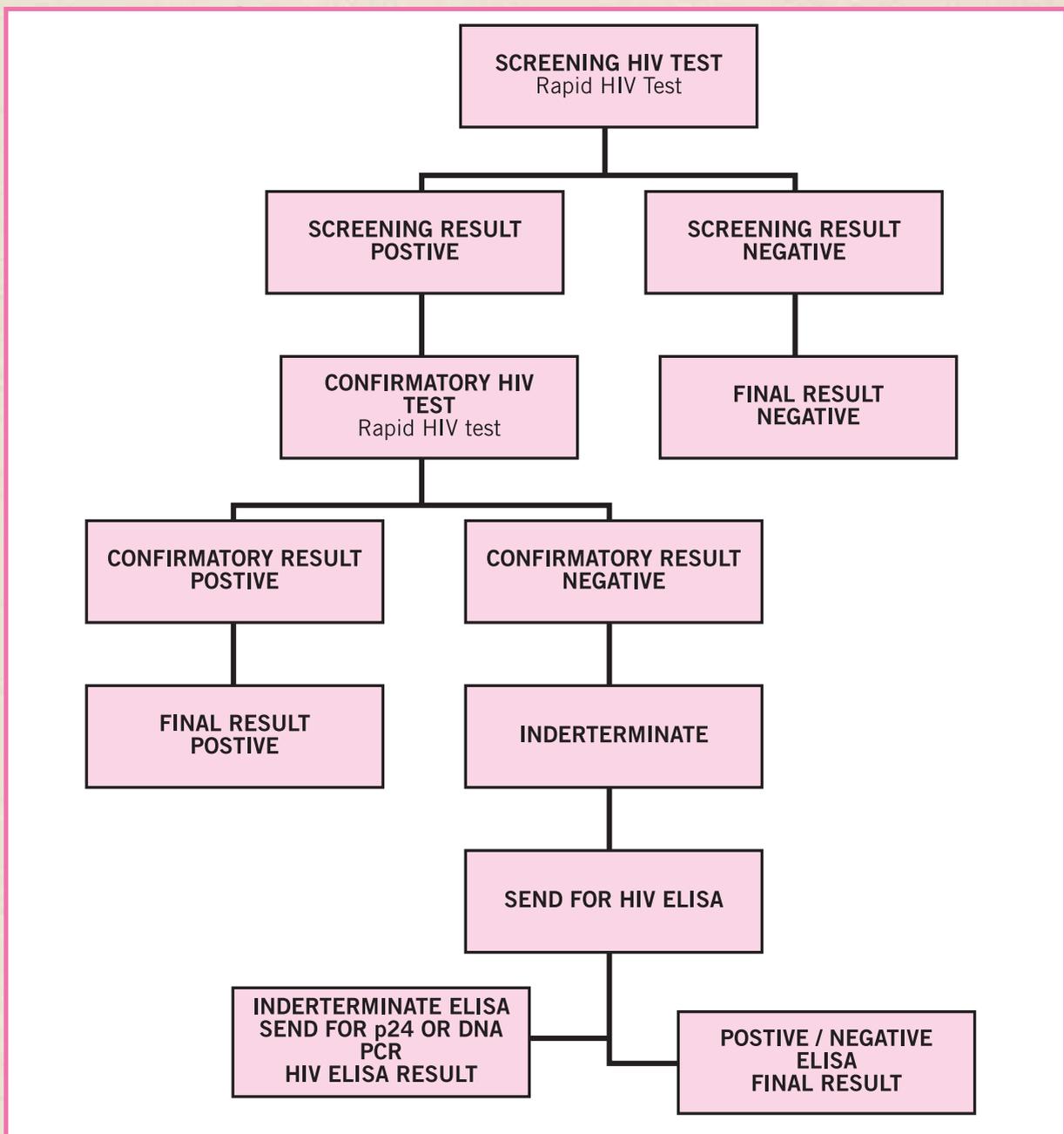
- Testing must be seen as a key entry point to accessing HIV care and PMTCT services.
- Ensure that the testing algorithm outlined in the HCT Policy is followed.
- HIV testing of women should occur as part of the first antenatal encounter. Enough blood should be collected for routine antenatal screenings – including haemoglobin, Rhesus factor, and syphilis tests – as well as a rapid HIV test and CD4 cell count, if required.
 - At the time this routine blood sample is drawn, **a rapid HIV test** should be done using either a drop of blood from the venepuncture site or a finger prick.
 - 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 from 32 weeks gestation to detect late sero-conversion or late infection.
 - **If the rapid HIV test is positive, a second confirmatory HIV test** should be done utilising blood from a second finger prick and another rapid HIV test kit (from a different supplier). The woman should be present when this confirmatory test is done. A client is HIV-positive only if the second confirmatory rapid test is also positive.
 - 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 conducted. The

woman must be asked to return for the HIV ELISA test results urgently (ideally within a week).

The health care provider should explain the reason for the laboratory test to the client.

- For women who missed the opportunity to be tested at the first antenatal visit, the testing algorithm should be followed whenever consent is given and testing occurs.
- The CD4 cell count and TB screening should follow the HIV test and should be done at the same visit.
- Professional nursing staff and lay counsellors or community health workers (CHWs) in the facility should be trained to perform the rapid HIV tests, following specific manufacturer's instructions and quality control protocols

Figure 8: Algorithm for HIV testing:



4.3 POST-TEST COUNSELLING

All HIV-positive and HIV-negative women should receive post-test counselling. The box below summarises the information that should be provided during post-test counselling.

POST-TEST COUNSELLING FOR ALL WOMEN REGARDLESS OF HIV STATUS

- *Post-test counselling sessions should include information on:*
 - *HIV transmission risks.*
 - *Safe sex and the availability and use of condoms.*
 - *Contraception and future fertility.*
 - *Treatment options.*
 - *MTCT and HIV and possible interventions (ART, revised obstetric practices).*
 - *Partner testing.*
 - *Safe infant feeding options for HIV positive women.*
 - *Infant prophylaxis.*
 - *Infant feeding counselling for HIV negative women.*
 - *Stigma.*
 - *Referral to support services.*

- *All women regardless of their HIV status must receive post-test counselling. The component of post-test counselling for all women should:*
 - *Include one-on-one interaction with clients;*
 - *Provide HIV test results as soon as possible after testing;*
 - *Give the results clearly in a manner that does not instil fear or anxiety;*
 - *Deal with the feelings arising from positive and negative results;*
 - *Discuss prevention of infections and the “window period”;*
 - *Identify and help with the woman’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;*
 - *Discuss the benefits of disclosure;*
 - *Identify what difficulties the client foresees and how to deal with them;*
 - *Educate and encourage safer sexual practices; provide condoms;*
 - *Encourage the woman to ask questions;*
 - *Provide information on a healthy lifestyle, medical follow-up, and local support systems; and*
 - *Provide ongoing follow up and counselling.*

Details of what information to discuss during post-test counselling for all women, and topics specific to HIV-positive and HIV-negative women, are listed in the boxes below.

- *Identify what difficulties the client foresees and how to deal with them;*
- *Educate and encourage safer sexual practices; provide condoms;*
- *Encourage the woman to ask questions;*
- *Provide information on a healthy lifestyle, medical follow-up, and local support systems;*
- *Encourage disclosure; and*
- *Provide ongoing follow up and counselling.*

POST-TEST COUNSELLING ISSUES FOR HIV-POSITIVE WOMEN

- *All HIV-positive women should be clinically staged and have their CD4 cell count checked and be screened for TB preferably on the same day as the confirmation of their HIV-positive status.*
- *Women who have WHO clinical stage 3 or 4 disease should be initiated on lifelong ART as soon as possible.*
- *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 about antiretroviral therapy, the side effects of the medication, and where to report these side-effects;*
 - *Counselling on safe infant feeding options;*
 - *Counselling on exposure to stigma;*
 - *Information and counselling on contraception and future family planning;*
 - *Information about safer sexual practices during pregnancy and in the long-term;*
 - *Information on and referral to support services and positive living; and*
 - *Information on disclosure.*
- *HIV-positive women should be offered counselling at every subsequent antenatal care visit, or earlier if the woman or counsellor deems this necessary to assist her with coping and thinking through the consequences of her diagnosis. Women should be encouraged to join a support group. Women requiring additional support should be referred to a social worker or psychologist. If counsellors identify complex issues that they are unable to handle, they should refer the client to a social worker or psychologist.*

POST-TEST COUNSELLING ISSUES FOR HIV-NEGATIVE WOMEN

- HIV-negative women should be offered routine antenatal services, as stipulated in the National Department of Health's *Guidelines for Maternity Care in South Africa*. A repeat HIV test is done from 32 weeks gestation.
- HIV-negative women should be counselled on:
 - Prevention and risk reduction behaviour (the risk of transmission from mother-to-child is particularly high for women infected with HIV during pregnancy);
 - Safe sexual practices;
 - The high risk of transmission of HIV to her infant, if newly infected during pregnancy or breastfeeding; and
 - The benefits of exclusive breastfeeding for the first 6 months and continued breastfeeding thereafter and introduction of complementary foods.

5. ROUTINE CLINICAL CARE FOR HIV-POSITIVE PREGNANT WOMEN

HIV-positive pregnant women require all components of routine antenatal care. These include: iron and folate supplementation; the provision of antiretroviral drugs for prophylaxis and treatment; the prevention and management of opportunistic infections; the modification of obstetric practices, especially during labour and delivery; integrating HIV management, especially 3-hourly AZT into the partogram as part of labour management; counselling on infant feeding options; and counselling on safer sex, family planning, and contraception.

5.1 ANTENATAL MANAGEMENT

INITIAL ASSESSMENT

At their first antenatal clinic visit all HIV-positive women should have the following, in addition to routine antenatal procedures:

- CD4 cell count;
- HIV clinical staging;
- Clinical screening for TB and STIs;
- Alamine Aminotransferase; and
- Initiation of antiretroviral prophylaxis or treatment.

CD4 CELL COUNT

- The follow-up date must be one week after the CD4 cell count has been taken to ensure prompt initiation of lifelong ART if eligible.
- Laboratory turnaround times for CD4 cell counts should be under one week.
- Women who do not return for CD4 cell count results should be actively traced and advised to return for their results.

HIV CLINICAL STAGING

Clinical assessment and staging of all HIV-positive women should be conducted at their first antenatal visit, and subsequent visits.

CLINICAL SCREENING FOR TUBERCULOSIS

Co-infection with TB and HIV is common. If an HIV-positive patient has symptoms suggestive of TB, two sputum specimens should be collected for smear microscopy and a TB culture. It is very important to

investigate patients for tuberculosis before starting ART.

The health care provider should suspect TB if two or more of the following are present:

- Cough >2 weeks.
- Sputum production, which may occasionally be blood stained.
- Fever >2 weeks.
- Drenching night sweats >2 weeks.
- Unexplained weight loss (≥ 1.5 kg over the past 4 weeks or poor weight gain during pregnancy).
- Loss of appetite, malaise, or tiredness.
- Shortness of breath or chest pains.

ALAMINE AMINOTRANSFERASE

A baseline ALT to measure liver function should be done before administering NVP.

INITIATION OF ANTIRETROVIRAL THERAPY

It is important to avoid unnecessary delays in initiating lifelong ART. Pregnant women should be staged to determine indication for ARV treatment or prophylaxis, according to WHO clinical staging and CD4 cell count. The following eligibility criteria apply for pregnant mothers:

Women with a CD4 cell count of more than 350 cells/ mm³ and WHO stage 1 and 2 disease should receive antiretroviral prophylaxis with AZT to reduce mother-to-child transmission.

Women with a CD4 cell count of 350 cells/ mm³ or less WHO clinical stage 3 or 4 should receive lifelong antiretroviral treatment, both for their own health and to reduce the likelihood of mother-to-child transmission.

ANTIRETROVIRAL PROPHYLAXIS

HIV-positive pregnant women who are not eligible for lifelong ART are given a PMTCT regimen for prophylaxis to reduce mother-to-child transmission. The regimen includes antenatal, intrapartum, and postnatal components. The maternal PMTCT regimen is:

- **Antenatal** AZT from 14 weeks;
- **Intrapartum** single-dose of TDF and FTC nevirapine (sdNVP), 3 hourly AZT.

Antenatal AZT should be initiated from 14 weeks gestation or as soon as possible thereafter, unless laboratory findings indicate that the mother is severely anaemic (i.e., Hb<8g/dl) or if the woman is clinically pale. Iron and folate supplementation should be provided to all antenatal women routinely. Women should return monthly for AZT.

LIFELONG ANTIRETROVIRAL TREATMENT

HIV-positive pregnant women eligible for lifelong ART should start lifelong ART as early as possible and continue throughout pregnancy, delivery, and for the rest of their lives. Lifelong ART benefits maternal health and contributes to maternal survival and reduces mother-to-child transmission.

Initiation of ART is recommended for all HIV-positive pregnant women with CD4 cell count of 350 or less,

irrespective of WHO clinical staging, and for all HIV-positive pregnant women in WHO clinical stage 3 or 4, regardless of CD4 cell count and women co-infected with TB/HIV.

Pregnant women initiated on lifelong ART should be seen two weeks after ART initiation and then monthly. Monitoring for treatment failure and toxicity should follow the recommendations in the adult ART guidelines.

Women on lifelong ART who become pregnant continue with treatment as per adult ARV guidelines (including those on second line regimens). In cases in which a woman is taking an efavirenz (EFV) containing regimen, EFV should be substituted with NVP only if she is still in the first trimester.

Women who initially test negative and subsequently test positive during pregnancy should be initiated onto AZT immediately. A CD4 cell count should be taken, clinical staging and TB screening done, and lifelong ART commenced if eligible. If CD4 is more than 350 then the mother should continue with AZT.

SPECIAL CIRCUMSTANCES:

TUBERCULOSIS INFECTION (see 12.11 in National TB Management Guidelines)

Tuberculosis is a WHO stage 3 disease and as such, TB-infected pregnant women, regardless of CD4 cell count, qualify for ART. TB treatment should be prioritised prior to initiating lifelong ART.

- **If CD4 > 350 cells/mm³:** Start ART only after patient has completed on TB treatment and initiate ART from 12 weeks gestation onwards.
- **If CD4 < 350 cells/mm³:** Start ART only after patient has stabilised on TB treatment (2-8 weeks after starting treatment).
- **If severe morbidity or very low CD4 count (< 50 cells/mm³):** Start ART after 2 weeks of TB treatment.
- **Pregnant women who develop TB while on lifelong ART** should continue their existing ART regimen, unless they are taking lopinavir/ritonavir (LPV/r). In this case, the LPV/r dose should be doubled.

HEPATITIS B INFECTION

Two antiretroviral agents with activity against hepatitis B should be used to control both HIV and hepatitis B. TDF and lamivudine (3TC)/FTC have activity against hepatitis B, and it is recommended that TDF should substitute for stavudine (d4T) in these co-infected patients.

5.2 INTRAPARTUM MANAGEMENT

The woman's serostatus should be recorded in the maternity register. Health care workers should check the woman's documented HIV status and details of the antiretroviral drugs received during pregnancy. If her HIV status is unknown and she is in the first stage of labour, HIV testing and counselling should be provided. If this is not possible prior to delivery, then HIV testing and counselling should be provided as soon as possible after delivery.

ANTIRETROVIRAL PROPHYLAXIS

HIV-positive women who are not on lifelong ART should receive AZT 3-hourly and sdNVP, and a single dose of TDF+FTC.

ANTIRETROVIRAL TREATMENT

Women who are on lifelong ART should continue their regimen throughout labour and delivery. They **do not** require **additional** intrapartum sdNVP, 3-hourly AZT or TDF + FTC.

INTRAPARTUM SPECIAL CIRCUMSTANCES

Caesarean sections should be performed for obstetric indications and are not recommended to reduce mother-to-child transmission. For planned (elective) caesarean sections, antiretroviral prophylaxis (sdNVP + TDF + FTC) should ideally be given four hours prior to the procedure. Women who are on lifelong ART should continue their standard ART regimen. In the case of an emergency caesarean section, ensure that the woman receives sdNVP + TDF + FTC prophylaxis prior to the procedure.

All HIV-positive women who undergo caesarean sections should receive prophylactic antibiotics.

5.3 SAFE DELIVERY TECHNIQUES

MTCT risk is increased by prolonged rupture of membranes, assisted instrumental delivery, invasive monitoring procedures, episiotomy, and prematurity. Only suction the baby's nose and airway when there is meconium-stained liquor.

5.4 POSTNATAL CARE

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

- Within an hour of delivery:
 - Infants born to HIV-positive women should receive skin-to-skin contact with their mothers, regardless of the mother's infant feeding choice.
 - All infants should start feeding (exclusive breastfeeding on demand or exclusive formula feeding). Initiate HIV-exposed infants on NVP prophylaxis immediately after birth.
 - If the mother has not made a decision about feeding yet, she should be counselled on infant feeding.
- All women, whether on ART or not, and their infants should receive follow-up at the health facility within the first 3 days postpartum, and should be seen again at the health facility prior 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). Contraception should be discussed and offered to all women after delivery and at subsequent visits.

- Ongoing psychosocial support should address the following:
 - Infant feeding choice and practice.
 - Social security issues.
 - Child health.
 - Positive prevention for HIV and AIDS

ANTIRETROVIRAL PROPHYLAXIS

There is high morbidity and mortality of HIV-positive women in the postpartum period. Therefore, women who are not on ART should be assessed for lifelong ART eligibility by doing a CD4 count test. If the woman is found to be eligible she should commence lifelong ART within 2 weeks. Support for women initiated on lifelong ART during pregnancy is particularly important in the postnatal period. Appropriate referral for ongoing care must be ensured.

OTHER CONSIDERATIONS

TB co-infected women:

- PMTCT guidelines. CD 4 </> 350 scenarios. Page 17 follow Adult guidelines Page 22
- Cotrimoxazole prophylaxis. See Adult Guidelines Page 29
- Pap smear screening. See Adult guidelines page 30.
- INH Prophylaxis. See guidelines for TB preventative therapy in Adult guideline from page 43 -49
- OI management according to guidelines.
- PNC HIV positive women - antibiotic prophylaxis as in maternity care guidelines.

INFANT PROPHYLAXIS

Antiretroviral prophylaxis given soon after birth to all HIV-exposed infants is effective in reducing mother-to-child transmission whether maternal ARVs are received or not, and forms the basis of a post-exposure prophylaxis strategy. Infant antiretroviral prophylaxis is also highly effective in reducing transmission through breast milk.

Ideally, all infants born to HIV-positive women should receive skin-to-skin contact with their mothers, regardless of the mother's feeding choice.

Infants born to HIV-positive women should receive daily nevirapine for 6 weeks, with dosing determined as follows:

If birth weight \geq 2.5 kg: 15 mg

If birth weight < 2.5 kg: 10 mg

Infant prophylaxis should be initiated as soon as possible after delivery.

ABANDONED INFANTS The HIV status of abandoned infants less than 72 hours old should be established as soon as possible. An HIV rapid test should be used to establish whether the child is HIV-exposed, and if the test is positive, the child should be given nevirapine (stat dose plus daily until six weeks of age). If a rapid test result cannot be obtained within 1-2 hours, treatment with nevirapine should be commenced. HIV

antibody testing should be performed as soon as possible. If the infant tests negative, nevirapine should be discontinued.

IF MATERNAL STATUS IS UNKNOWN, including cases in which the mother is indisposed (due to severe illness, coma, mental illness, or death), the infants should receive NVP and have an HIV test (ELISA or e rapid test) to inform further management of the infant.

WHERE THE MOTHER IS KNOWN TO BE HIV-POSITIVE, BUT REFUSES ARV PROPHYLAXIS FOR THE INFANT, a counsellor must intervene to explain the risks of mother-to-child transmission and the benefits of antiretroviral therapy. Should this counselling fail to convince the mother to adopt infant prophylaxis, the mother should then be informed of the infant's right to receive protection from acquiring HIV. The health care worker should consult the head of the facility and, with his or her permission, provide the necessary treatment in the best interest of the infant. In all actions concerning children, the best interests of the child shall be a primary consideration (Children's Act, No 38 of 2005).

6. REGIMENS

Table 1: Standardised national ART and ARV regimens for women who are HIV-positive and pregnant and their infants

Woman	Maternal regimens Regimen	Comment
Eligible for lifelong ART (i.e. CD4 \leq 350 or WHO clinical stage 3 or 4)	TDF + 3TC/FTC + NVP	Start lifelong ART within 2 weeks
Currently on lifelong ART	Continue ART	Substitute EFV with NVP if in first 12 weeks of pregnancy
Contraindication to TDF (renal disease)	AZT+ 3TC + NVP	
Not eligible for ART i.e. CD4 > 350 and WHO stage 1 or 2	AZT from 14 weeks sdNVP + AZT 3-hourly in labour TDF + FTC single dose (stat) intrapartum	
Unbooked and presents in labour	sdNVP and TDF + FTC single dose in labour	Assess maternal ART eligibility before discharge

Table 2: Infant Regimens

Infant	Infant regimens Regimen	Comment
Mother on lifelong ART	NVP at birth and then daily for 6 weeks irrespective of infant feeding choice	
Mother on PMTCT regimen	NVP at birth and then daily for 6 weeks continued as long as any breastfeeding	If formula fed baby can stop NVP at 6 weeks
Mother did not get any ARV before or during delivery	NVP as soon as possible and daily for at least 6 weeks continued as long as any breastfeeding	Assess ART eligibility for the mother within 2 weeks
Unknown maternal status because orphaned or abandoned	- Give NVP immediately* - Test infant with rapid HIV test. If positive continue NVP for 6 weeks. If negative discontinue NVP	Follow up 6 week HIV DNA PCR

* If rapid HIV test can be done within 2 hours, then wait for HIV result before commencing NVP

Table 3: ARV Adult Dosing Guide

Drug	Dosage	Notes
TDF (Tenofovir)	300 mg daily	Tenofovir is contraindicated in creatinine clearance of <50ml/min (only diagnosed renal patients)
d4T (Stavudine)	30 mg 12-hourly po	All adult patients now receive 30 mg regardless of weight
3TC (Lamivudine)	150 mg 12-hourly po OR 300 mg daily	
FTC (Emtricitabine)	200 mg daily	
NVP (Nevirapine)	200 mg dly po X 2 weeks then 200 mg 12-hourly po For PMTCT purposes single dose (sdNVP) is used as a 200 mg tablet given once.	Should be used with caution with TB treatment
EFV (Efavirenz)	600 mg nocte	Avoid in first trimester of pregnancy and psychiatric conditions
Kaletra® (lopinavir 133.3 mg /ritonavir 33.3 mg)	3 tabs 12-hourly (Lop400 mg/Rit100 mg)	Preferably taken with food. Boosting required with TB treatment Store in a cool place
Aluvia® (lopinavir 200 mg /ritonavir 50 mg)	2 tabs 12-hourly (Lop400 mg/Rit100 mg)	Preferably taken with food. Boosting required with TB treatment
AZT (Zidovudine)	300mg 12-hourly po	Avoid if severe anaemia (Hb <8g/dl)

**Doses and frequency will remain the same when used intrapartum*

Table 4: NVP Infant Dosing Guide

Drug	Birth Weight	Dose	Quantity
NVP syrup (10 mg/ml)	Birth to 6 weeks < 2.5 kg birth weight	10 mg/d	1 ml
	Birth to 6 weeks ≥ 2.5 kg birth weight For all:	15 mg/d	1.5 ml
	6 weeks to 6 months	20 mg/d	2 ml
If mother continues to breastfeed	6 months to 9 months	30 mg/d	3 ml
	9 months to end BF	40 mg/d	4 ml

Note: All mothers opting to continue with exclusive breastfeeding beyond 6 months should be counselled on NVP resistance and liver toxicity.

7. ESTABLISHING SAFE INFANT FEEDING PRACTICES

7.1 BACKGROUND

- The South African national PMTCT programme adopts an approach to infant feeding that maximises child survival, not only the avoidance of HIV transmission.
- The *South African Infant and Young Child Feeding Policy*, its implementation guidelines, and the *Baby Friendly Hospital Initiative (BFHI)* – in particular, the ten steps to safe infant feeding outlined in the BFHI – should be followed to facilitate feeding support for HIV-positive and HIV-negative women.
- All mothers who are known to be HIV-infected either on lifelong ART or not, who exclusively breastfeed their infants should do so for 6 months, introduce appropriate complementary foods thereafter.
- Mothers who are willing to, can continue breastfeeding for the first 12 months of life.
- Mothers who are known to be HIV-infected, and not on lifelong ART, who decide to stop breastfeeding at any time should do so gradually during one month whilst the baby continues to receive daily NVP and should continue for one week after all breastfeeding has stopped.
- It is very much necessary for the mother or the baby to be covered with ART for the duration of the breastfeeding.

7.2 PRINCIPLES OF SAFE INFANT FEEDING

- Health care personnel, lay counsellors, and community caregivers should receive standardised training on infant feeding, counselling, and HIV.
- Trained health care personnel should provide high quality, unambiguous, and unbiased information about risks of HIV transmission through breastfeeding, ART prophylaxis to reduce this risk, and risks of replacement feeding.
- Counselling on infant feeding must commence after the first post-test counselling session in pregnancy.
- Infant feeding should be discussed with women at every antenatal visit.
- Mixed feeding during the first 6 months of life should be strongly discouraged as it increases the risk of childhood infections.
- Mass mobilisation and communication on infant feeding and HIV should be done through mass media, including distribution of information education communication (IEC) materials and community-based activities.
- In an attempt to optimise child survival, HIV-positive pregnant women should be fast-tracked for lifelong ART or PMTCT regimens in order to keep them healthy and reduce MTCT.

HIV-negative women

At every antenatal visit, HIV-negative women or women of unknown HIV status should be advised to exclusively breastfeed their babies during the first 6 months of life and continue breastfeeding for at least 2 years. Every effort should be made to have all pregnant women HIV tested and retested as outlined in the testing section of this document.

HIV-positive women

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

Postnatal support for infant feeding

- During the postnatal period, mother-infant pairs should have a follow-up visit within 3 days after delivery to review feeding practices, check breast health, maternal health and child health, and provide general support.
- All HIV-positive infants should continue breastfeeding for at least 2 years.

Formula feeding HIV-positive women

- Free commercial infant formula will be provided to infants for at least 6 months.
- Women should receive practical support, including demonstrations on how to safely prepare formula and feed the infant.
- At 6 months of age, infants with or 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 <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.
- 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 they are promulgated. These regulations have been adapted to allow for infant feeding in the context of HIV.
- In cases in which commercial formula is provided free of charge at health facilities, managers, supervisors, and health care personnel should ensure an uninterrupted supply at clinic level. A reliable procurement and distribution system should be put in place.

For mothers who have chosen to avoid all breastfeeding:

- *Formula feeding mothers require support at every well-child/routine visits, every immunisation 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.*
- *Health care personnel should:*
 - *Provide clear guidance regarding the volume 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 breastfeeding – ensure that the woman has a supporter outside the health facility to help her avoid all breastfeeding.*

8. INFANT FOLLOW-UP

Prior to discharge, notes should be written on the Road-to-Health Chart to indicate whether the infant has received ARVs and what feeding choice the mother has made. This will optimise infant prophylaxis, improve the infant's access to appropriate care, and reduce morbidity and mortality.

Infants should receive follow-up visits according to the IMCI clinical case management guidelines, including:

- Weekly visits during the first month of life;
- Monthly visits thereafter, until the age of twelve months; and
- Three-monthly visits between the age of 12 months and two years of age unless the child is ill; in this case they should be seen more often.

During the first post-delivery visit:

- All HIV-exposed infants should receive NVP daily for 6 weeks. If the infant is formula fed, the health care worker should check the method of cleaning utensils and preparing formula. Formula preparation should be demonstrated after counselling when women have chosen not to breastfeed. Demonstration (to ensure safe and correct preparation) is essential for HIV-positive women.
- If the infant is breastfed, the pattern of feeding, attachment, and positioning and the mother's breast health must be checked.

HIV-exposed infants should be tested for HIV at 6 weeks of age, or before 6 weeks of age if they are sick (see section on HIV testing).

NVP to be stopped at 6 weeks in infants:

- Who are formula fed,
- Whose mothers are on lifelong ART,
- Who are diagnosed as HIV infected.

ALL HIV-exposed infants commence CTX prophylaxis at 6 weeks of age.

All infants identified as being HIV-positive should have a confirmatory viral load and be referred for urgent ART initiation.

Early ART should be initiated in all HIV-positive infants.

HIV-exposed infants should be followed up AT LEAST monthly in the first year of life and every three months thereafter, regardless of their method of feeding. Infants clinically suspected of having HIV should be tested for HIV, regardless of their age.

At 6, 10, and 14 weeks, and at 9 and 18 months, all children should be immunised according to the South African EPI schedule.

All HIV-exposed infants not on ART should have a rapid HIV test at 18 months of age.

ROUTINE FOLLOW-UP OF HIV-EXPOSED INFANTS

At each visit, perform the following:

- *Monitor growth.*
- *Monitor developmental milestones.*
- *Check history of current illnesses.*
- *Check immunization status.*
- *Conduct a clinical examination where indicated, and refer to a higher level of care if needed.*
- *Assess feeding difficulties and discuss ways of overcoming the problems.*
- *Assess feeding pattern.*
- *Provide free commercial formula milk to formula-fed infants on a monthly basis until six months postpartum.*
- *Provide nutritional support for ALL breastfeeding HIV-positive mothers and for formula feeding mothers with food insecurity.*
- *Provide NVP for breastfed infants whose mothers are not on lifelong ART, until one month after breastfeeding cessation.*
- *Continue CTX in breastfed infants until cessation of breast feeding and confirmed HIV negative.*

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