

THE SOUTH AFRICAN ANTIRETROVIRAL TREATMENT GUIDELINES

2013

PMTCT GUIDELINES: REVISED MARCH 2013



health

Department:
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CHAPTER 1: EXECUTIVE SUMMARY

This document is an update of the national PMTCT Policy and Guidelines 2010. 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 2010 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, CCMT and TB services.
- **Strengthening 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
 - Routine TB symptom screening at each visit with TB investigation or referral for TB investigations if symptom screen positive.
 - 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 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 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 lay counsellors and health care professionals.
 - Strengthened obstetric practices which reduce MTCT.
 - Provision of antiretroviral prophylaxis to infants, initiated soon after birth and continued for 6 weeks.
 - Integrated follow-up of infants born to HIV-positive women through routine child health services and the Integrated Management of Childhood Illness (IMCI) Strategy.
 - Early infant HIV testing using HIV DNA-PCR at 6 weeks of age for all infants born to HIV-positive women (integrated with the EPI 6-week visit), irrespective of feeding option.

- Testing of all HIV-exposed infants **at any age** from birth if symptomatic of HIV including all premature and low birth weight infants who are expected to have a higher incidence of transmission.
- Strengthening of community-based household and door-to-door activities to educate and enhance the utilization rates and effectiveness of health programs.

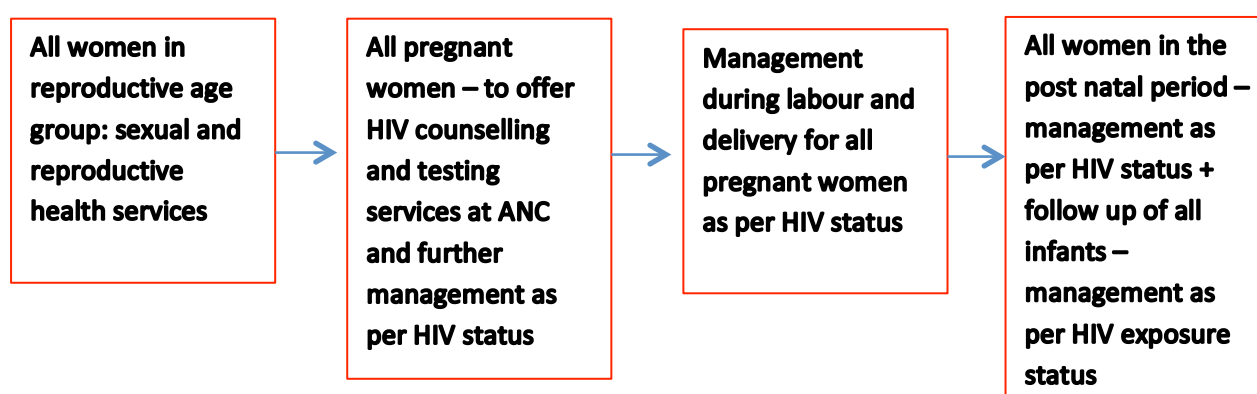
CHAPTER 2

PMTCT PROCESSES AND GOALS OF INTERVENTION

The PMTCT programme reaches out to all women before pregnancy, during pregnancy, through labour and delivery and through the post natal period up to a period of 18 months. The programme aims to result in healthy mothers and HIV-uninfected infants. The screening and referral for TB management in this population is also addressed.

Figure 1: Summary of PMTCT Processes

The below flow diagram highlights the various components in the PMTCT program with management as per HIV status of the woman and HIV exposure for infants



2.1 ALL WOMEN IN THE REPRODUCTIVE AGE GROUP

Goals of interventions:

- Improve the quality of sexual and reproductive health services
- Improve access to family planning services
- Improve access to safer sex options
- Prevent transmission of HIV infection
- Improve access to HCT services to know HIV status

2.2. ANTENATAL CARE

Goals of interventions:

- Improve the quality of the mother's health and prevent mortality
- Identify women who are HIV-positive including those who may sero-convert during pregnancy
- Ensure ALL women enter the PMTCT programme
 - If HIV-infected then require prompt provision of ARVs and further counselling
 - If HIV-uninfected require specific counselling and advice on repeat testing every 3 months after a negative test, and/or at 32 weeks, labour and through breastfeeding every 3 months
 - ALL women to have TB screening

- Prevent mother-to-child transmission of HIV
- Provide ART, as soon as HIV positive status known, in pregnancy for maternal health and to reduce HIV transmission to the baby

2.3 LABOUR AND DELIVERY

Goals of interventions:

- Provide HIV counselling and testing services to all women with unknown status
- Identify HIV-positive women
- Provide adequate PMTCT coverage
- Screen for TB in all women irrespective of HIV-status
- Continuity of care with prophylactic and treatment antiretroviral regimens
- Initiate neonates born to HIV-positive mothers with antiretroviral prophylaxis immediately at birth
- Establish safe infant feeding practices supporting exclusive breastfeeding and kangaroo mother care for all mothers and infants

2.4 POSTNATAL FOLLOW-UP OF MOTHER AND INFANT

Goals of interventions:

- Provide follow-up post-partum care including a postnatal visit within 3 – 6 days for mother and baby
- 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 of HIV for HIV-exposed infants
- Screen and where indicated exclude TB in mothers and infants
- Reduce postnatal HIV transmission through breastfeeding
- Identify all HIV-exposed infants as early. This means a PCR HIV test for all symptomatic infants* anytime after birth and at 6 weeks (for asymptomatic infants) at routine EPI 6 week visit. (* *Symptomatic Infants – any infants displaying the following failing to thrive (includes LBW), haematological abnormality like anaemia or thrombocytopaenia, congenital pneumonia, pneumonia, hepatosplenomegaly, extensive oral candidiasis, significant lymphadenopathy, any OIs*)
- Identify all HIV-infected infants *and* start ART promptly (within 7 days)

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 and 6 weeks post breast feeding test.

All HIV-infected individuals should have provision of TB screening, INH prophylaxis, CTX prophylaxis, nutritional and psychosocial support, cervical cancer screening, family planning options, monitoring of CD4 cell count and, clinical staging.

Mothers of unknown HIV status or who are HIV negative should be tested for HIV test

at 6 weeks, 3 months, 9 months and one year postpartum, particularly if they are breast feeding. Note at initial PICT in the ANC, mothers would be consenting once for the protocol of initial and repeated HIV testing throughout HIV exposure so as to ensure that this is efficiently done without any requirement for further counselling unless indicated.

Figure 2: **PMTCT Algorithm 1:** for all women who are newly diagnosed as HIV positive anytime during pregnancy AND women who enter ANC with known HIV positive status and not yet on ART.

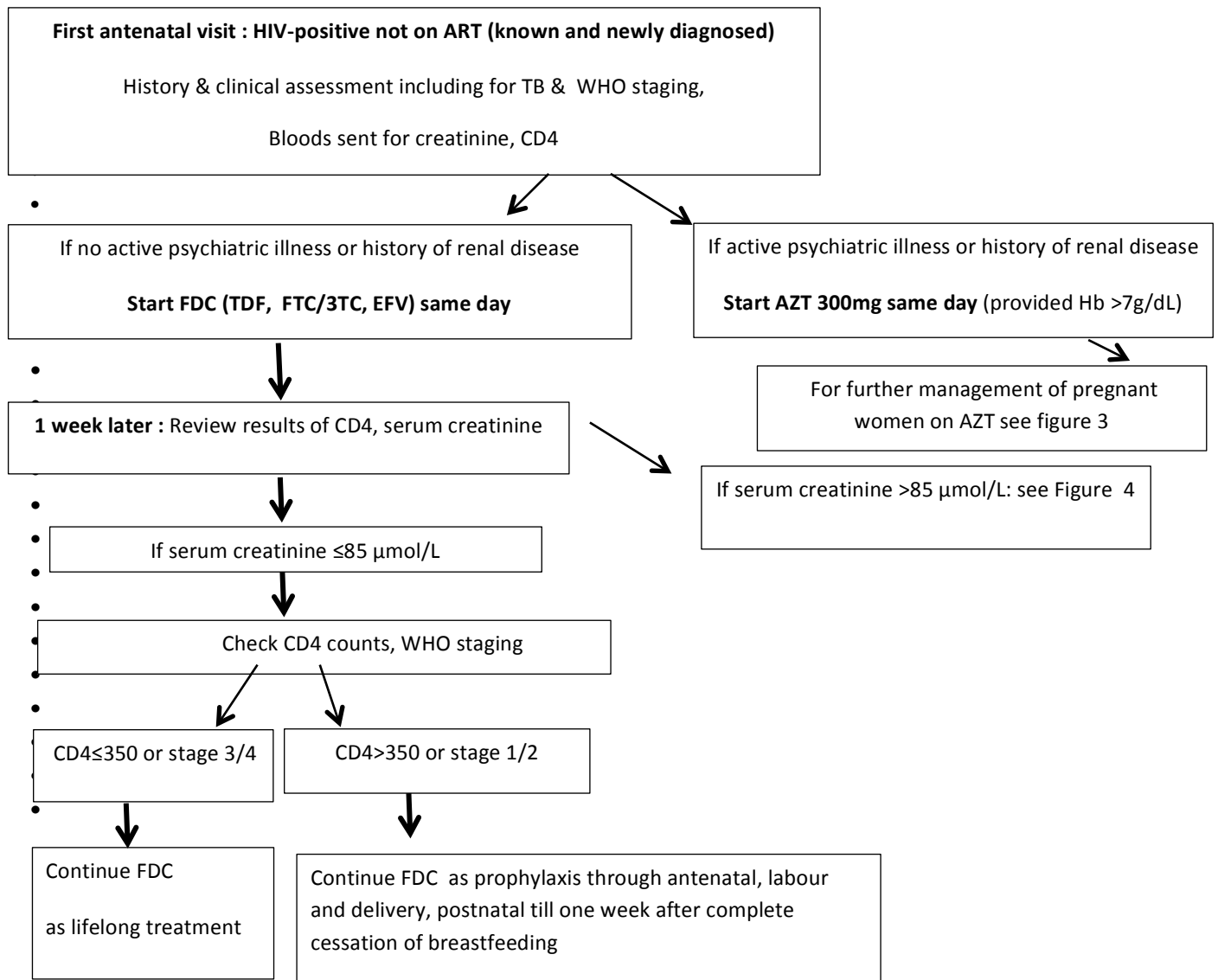


Figure 3 : PMTCT algorithm 2: Initiation of antiretrovirals during pregnancy in women with active psychiatric illness or history of renal disease

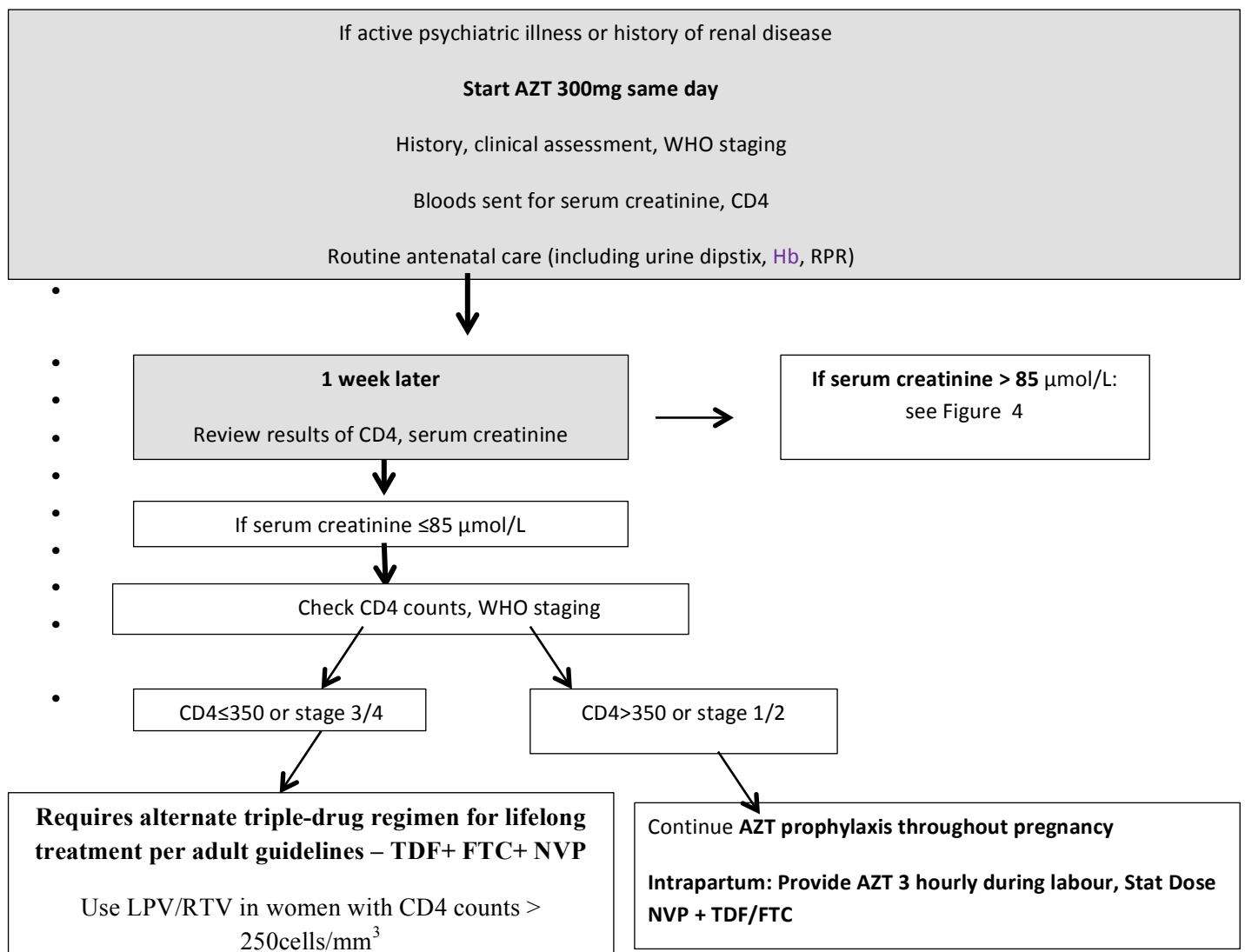
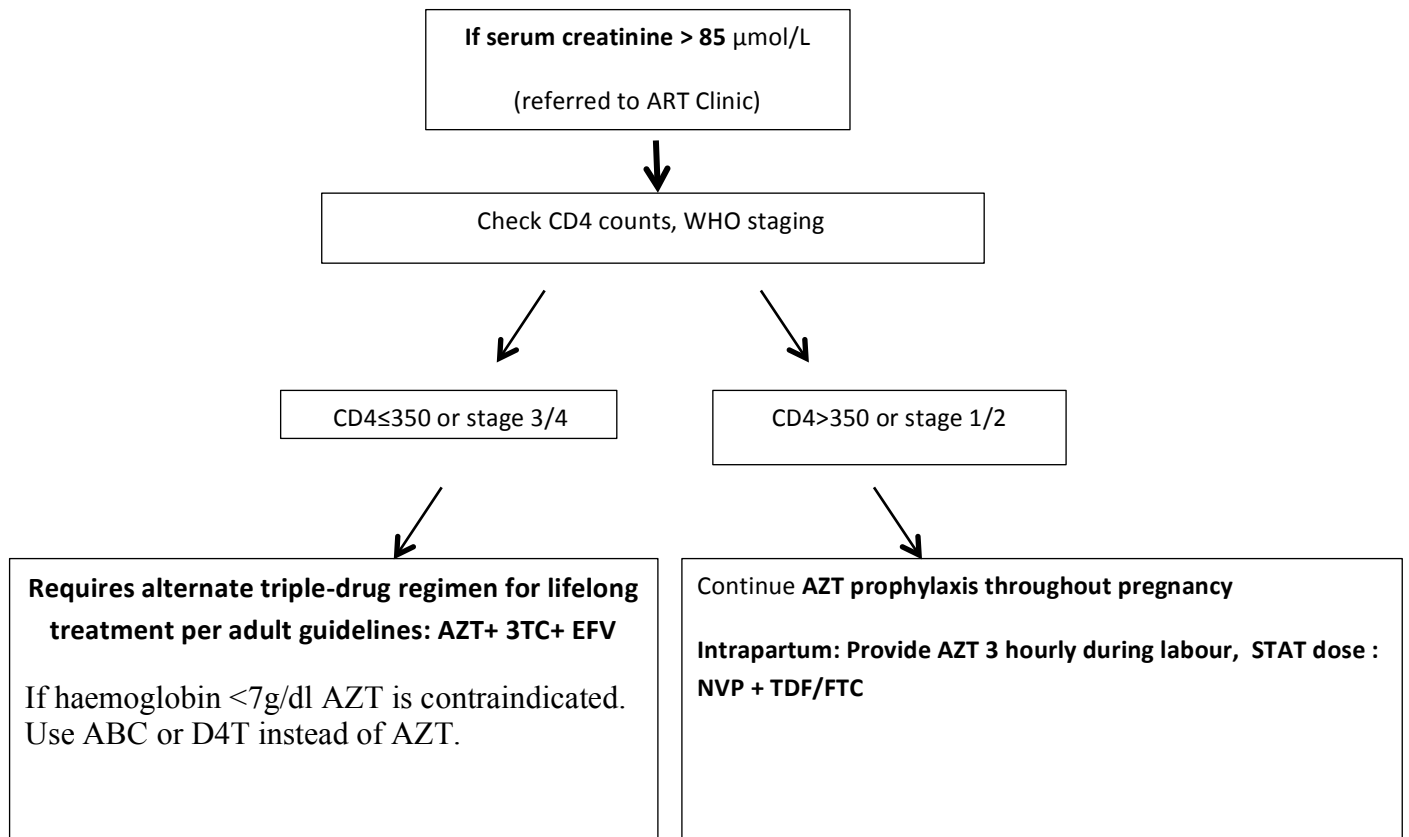
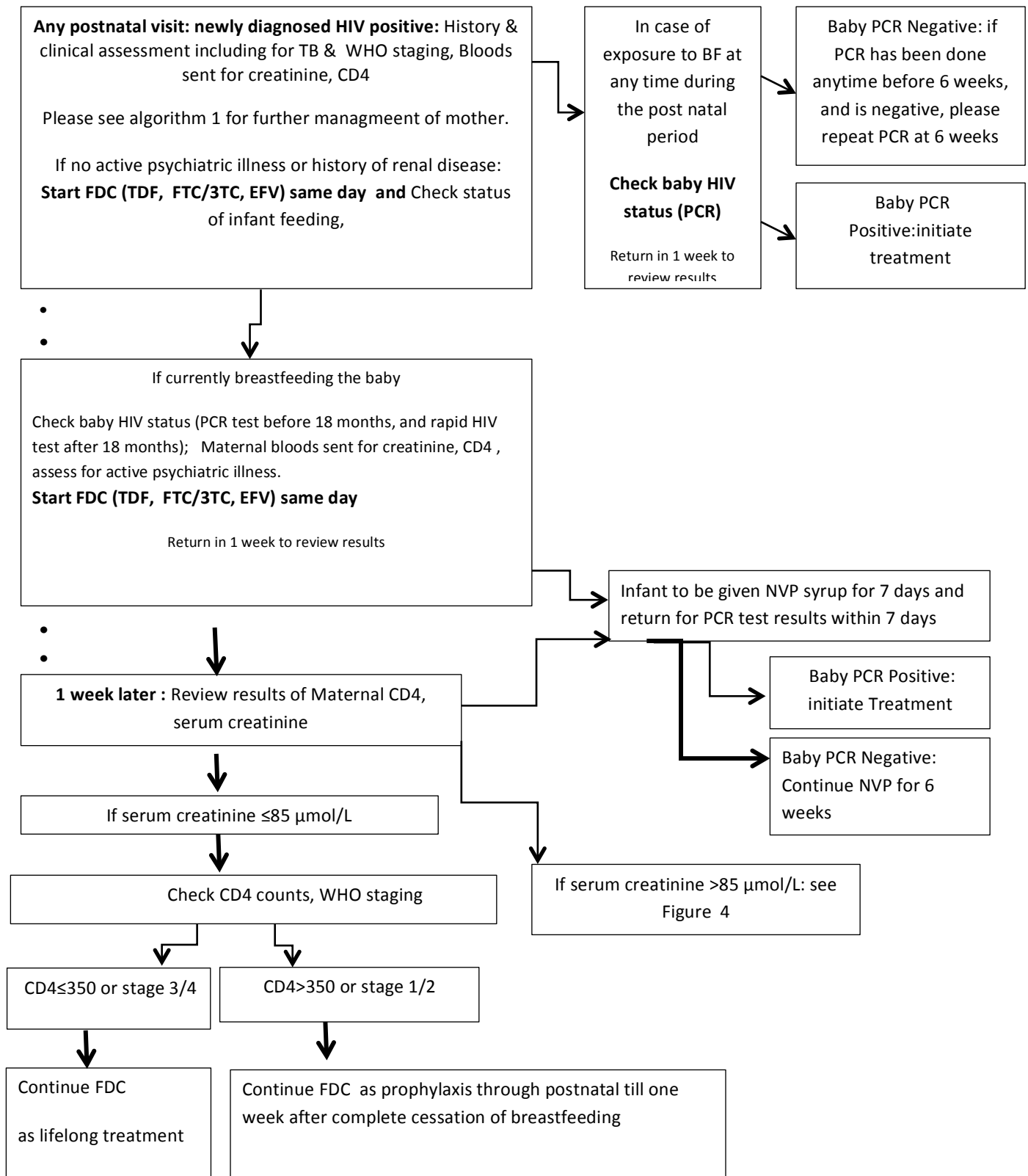


Figure 4: PMTCT algorithm 3: Initiation of antiretrovirals during pregnancy in women with serum creatinine > 85 $\mu\text{mol/L}$:



PMTCT Algorithm 4: for all women who are newly diagnosed any time during the **postnatal period**.



CHAPTER 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.
- Have a TB symptom screen at each visit with further TB investigations if any of the screening questions are positive.
- Be encouraged to involve partners or spouses in caring for the pregnancy.
- Be counselled on safer sex and provided with condoms and discuss future family planning options.
- Be counselled on safe infant feeding options and assisted in making an appropriate feeding choice.
- Be informed that breastfeeding is the preferred option.
- 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, folate and calcium 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 STIs, in line with BANC.
- Receive a triple-drug antiretroviral regimen as an FDC at the first antenatal visit, whether newly diagnosed or known to be living with HIV but not on ART. This is to prevent mother-to-child transmission of HIV and to reduce maternal morbidity and mortality. The duration of regimen is determined by CD4 counts, (> 350 cells/mm³ to receive FDC till 1 week after cessation of breast feeding cessation and < 350 cells/mm³ to continue lifelong treatment)
- Be offered appropriate PCP and assessed for eligibility for TB preventive therapy with isoniazid.
- Be counselled on safer sex, family planning, postnatal contraception and partner testing.

Women who are put on FDC in their pregnancy (either for her own health or for PMTCT) should be monitored and managed, where possible, by the same provider in the same facility through antenatal and post natal period until the end of breastfeeding.

Please note: these women will be managed by NIMART trained nurses and midwives and should be referred if required (in case of adverse events/complications) to an ART site with a doctor for further management.

Women who test HIV-negative anytime during antenatal, labour or postnatal periods are still considered part of the PMTCT programme and 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 12 weeks after the initial HIV test is negative and/or at 32 weeks or later gestation periods or in the labour ward, at the 6 week post natal visit , at 3, 6 and 12 months during breast feeding to detect those who may have sero-converted during pregnancy. They should have a symptom screen for TB at each visit.

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. They should have a symptom screen for TB at each visit.

Women who initially test negative and subsequently test positive during pregnancy should be initiated on FDC on same day of diagnosis.
Further management as per figure 2 on page 8.

Unbooked women reporting in labour should be counselled and tested for HIV during the first stage of labour , and if positive given a single dose of NVP and TDF and FTC and 3 hourly AZT until delivery.
Postdelivery, start FDC and do routine tests (creatinine and CD4) and manage as per figure 2 on page 8.

Please note: All infants born to HIV positive mothers: start NVP as soon after birth as possible (within 72 hours postdelivery) and continue for 6 weeks. Infants of HIV infected women not on ART (treatment or prophylaxis) who are breastfeeding should continue daily NVP until one week after cessation of breast feeding.

Please note: no woman should leave the delivery site with unknown HIV status.
All women who test positive during labour and delivery need to start FDC and return after 1 week for review of CD4 and creatinine results at the clinic (not at delivery site).

Further management of these women is based on creatinine and CD4 test results and is as per figure 2 on page 8.

Women tested postdelivery: counselling and testing should be offered to all women with unknown HIV status or those who tested negative 6 weeks prior to delivery as soon as possible. If the mother tests positive, the infant should be initiated onto NVP as soon as possible, the mother should be counselled on feeding options and counselled about infant testing. If the mother intends to breastfeed her baby, the FDC should be initiated for the mother, WHO staging done, and CD4 cell count and creatinine taken prior to discharge with a follow up visit scheduled within one week. Further management as per figure 2 on page 8.

NB: 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** amongst health care workers, and is essential for maintaining continuity of care among women and infants. This entails thorough completion of the **Road- to-Health Booklet** (RTHB Pages 7 & 8), particularly as it relates to HIV.

The **RTHB** is a health record of essential information relating to and influencing the health outcomes of a child that begins from birth and continues into early childhood. It is imperative that healthcare workers are diligent in completing this record at every point that an infant and young child is seen at a health facility. Information regarding HIV exposure and PMTCT interventions are **CRITICAL** for the continued management of mothers and infants.

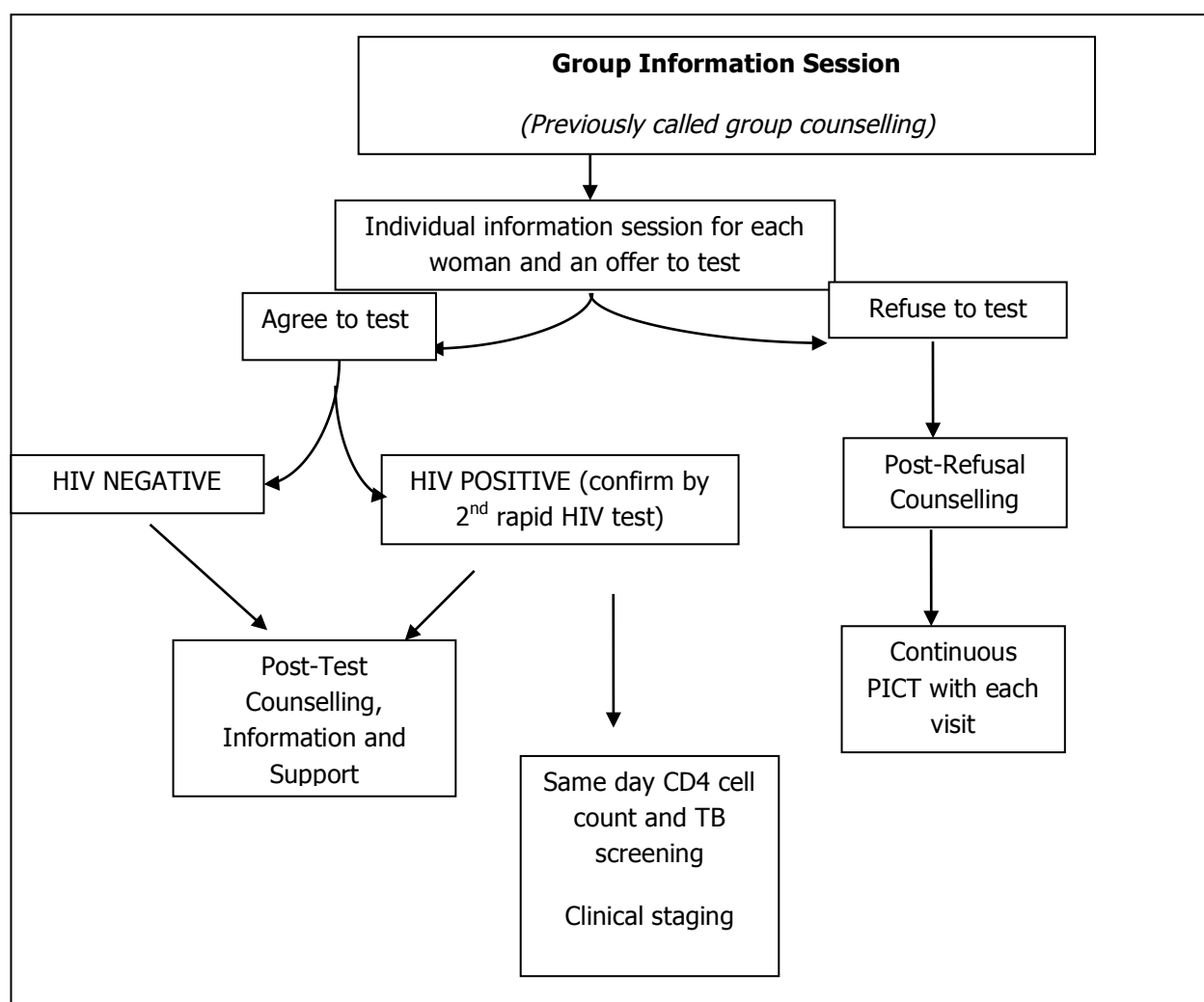
CHAPTER 4

PROVIDER-INITIATED COUNSELLING AND TESTING FOR WOMEN AND INFANTS

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 with another test type.
- 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 below summarises the processes involved in provider-initiated counselling and testing.

Figure 5: 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*
 - *Emphasis that both partners need testing*
- *Benefits to the foetus and infant:*
 - *Information about mother-to-child transmission of HIV and possible measures to reduce this*
 - *Information on interventions that can keep HIV-exposed infants healthy, such as cotrimoxazole and INH prophylaxis and antiretroviral therapy*
 - *Advantages of breastfeeding as well as measures to reduce risk of transmission via this route*
 - *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*
 - *Importance of bringing infant in for attention and testing prior to 6 weeks if any suspicion*
 - *Importance and relevance of the Road To Health Booklets*

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. Treatment will be provided for all women living with HIV until 1 week after breast feeding cessation. Ongoing treatment is determined by CD4 cell count and clinical stage and condition of the woman.

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*
 - *Verbal consent for HIV testing for current test and subsequent tests in pregnancy*

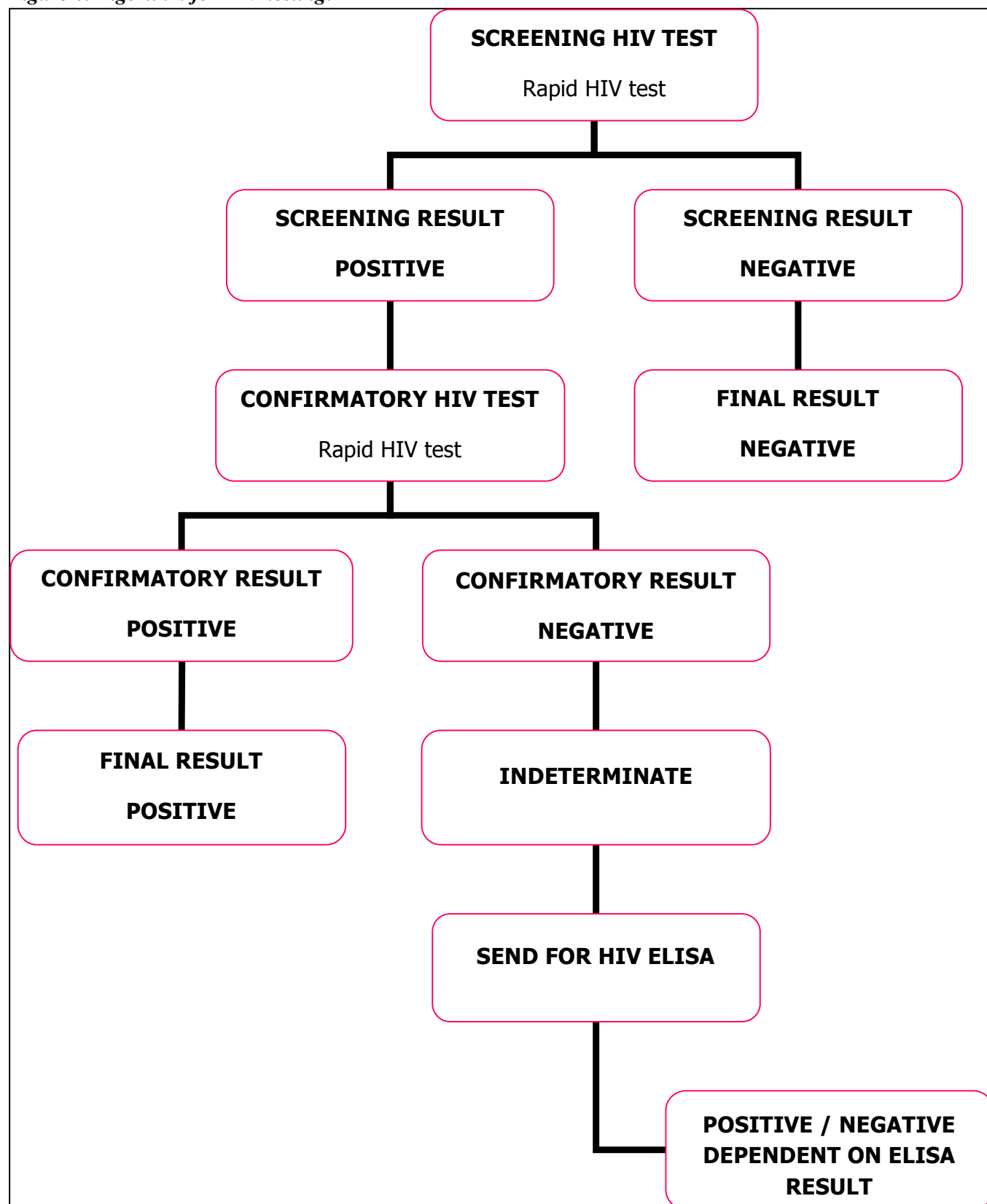
4.2 TESTING ALGORITHM FOR PREGNANT WOMEN

- 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 and serum creatinine, if the rapid HIV tests are positive.
 - 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, intra partum and post partum every 3 months to detect late sero-conversion or late infection.
 - **If the rapid HIV test is positive, a second confirmatory HIV test** should be done utilizing 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 healthcare 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, serum creatinine and TB screening should follow the HIV test and

should be done at the same visit and women asked to return in 7 days for the results.

- 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 6: 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:*
 - *Risks for HIV transmission*
 - *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*
 - *TB symptoms*
 - *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 infection 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*
 - *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*
- *Provide ongoing follow up and counselling*

POST-TEST COUNSELLING ISSUES FOR HIV POSITIVE WOMEN

- *All HIV-positive women should be clinically staged, have their CD4 cell count and creatinine checked and be screened for TB preferably on the same day as the confirmation of their HIV-positive status.*
- *All women living with HIV should be initiated on ART (FDC) on the same day.*
- *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*
 - *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*
 - *Information on disclosure*
 - *Shown the RTHB and informed of the benefits and need for this document*
- ***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 FOR HIV NEGATIVE WOMEN

- *HIV negative women should be offered routine antenatal services, as stipulated in the DOH Guidelines for Maternity Care in South Africa. A repeat HIV test is done after 12 weeks of an initial negative HIV test, and/or 32 weeks or later gestation, at the time of delivery and 6 weeks, 3, 6, 9 and 12 months after delivery.*
- *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*
 - *The benefits of exclusive breastfeeding for the first 6 months and continued breastfeeding thereafter and introduction of complementary foods.*
 - *Shown the RTHB and informed of the benefits and need for this document*

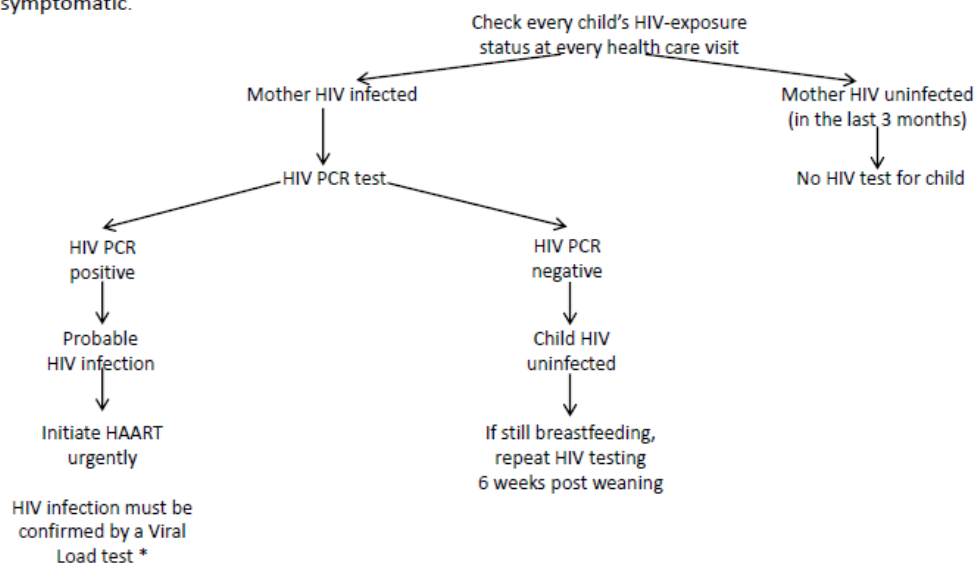
4.4 TESTING ALGORITHM FOR INFANTS

The below diagrams show the testing algorithms for infants < 18 months of age, and infants > 18 months of age.

Diagnosis of HIV infection in infants and children

1. Children <18 months old

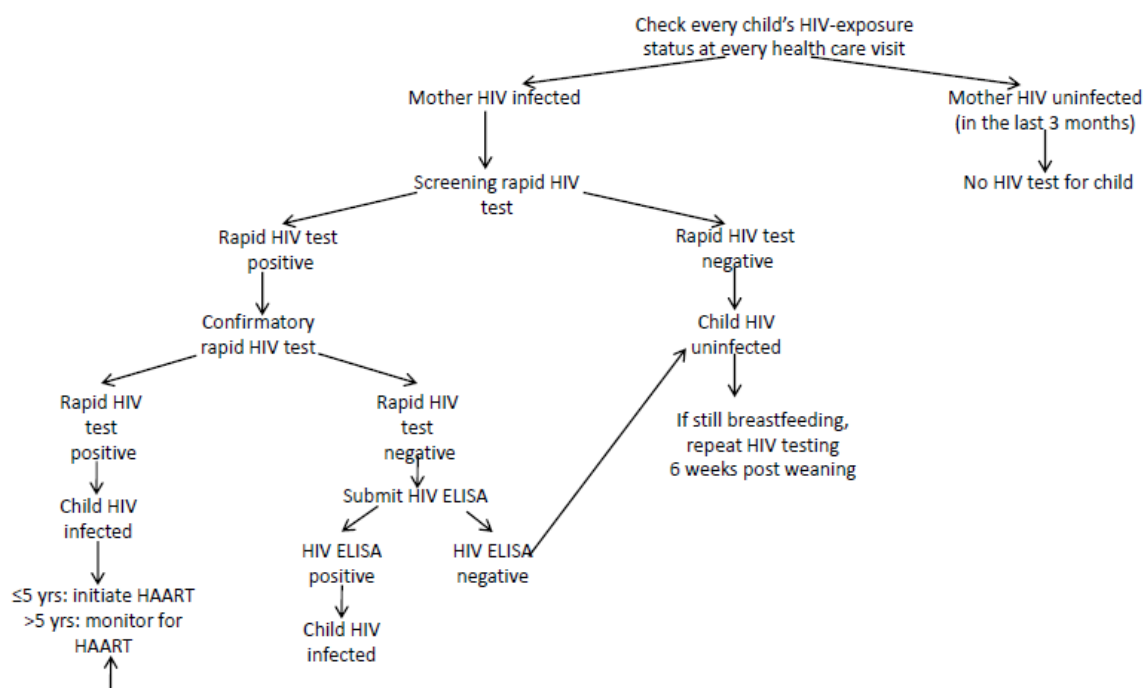
- All HIV-exposed infants require PCR testing at 6 weeks of age, 6 weeks post weaning and at any age if the child is symptomatic.



- A detectable Viral Load confirms HIV infection. HAART initiation should not be delayed by waiting for the Viral Load result.
- If the HIV infection status of an infant initiated on HAART is in doubt, discuss further HIV testing required with your nearest HIV PCR laboratory

2. Children ≥18 months old

- All HIV-exposed children require a rapid test at 18 months of age, except HIV-infected children on HAART



CHAPTER 5

ROUTINE CLINICAL CARE FOR HIV-POSITIVE PREGNANT WOMEN

HIV positive pregnant women require all components of routine antenatal, labour and delivery and post natal care. These include: iron and folate supplementation; haemoglobin testing; the provision of antiretroviral drugs for prophylaxis and/or treatment; the diagnosis, prevention and management of opportunistic infections including TB; the modification of obstetric practices, especially during labour and delivery; counselling on infant feeding, safer sex, family planning, and contraception.

5.1 ANTENATAL MANAGEMENT

INITIAL ASSESSMENT

At their first antenatal clinic visit all HIV positive women should undergo ~~have~~ the following,:

- 1 Routine testing for Haemoglobin, Rh, RPR
- 2 CD4 cell count
- 3 HIV clinical staging
- 4 Clinical screening for TB and STIs
- 5 Clinical & laboratory screening for renal disease, including serum creatinine
- 6 Screening for active psychiatric illness
- 7 Initiation of antiretroviral prophylaxis and/or treatment

CD4 CELL COUNT

- CD4 cell count testing should be done at the first antenatal visit, but initiation of an antiretroviral regimen should not be delayed for the CD4 cell count or other investigations.
- Laboratory turnaround times for CD4 cell counts should be under one week. CD4 results are not required before initiation of a triple-drug antiretroviral regimen. However CD4 results should be reviewed at the next antenatal visit to decide whether triple-drug antiretrovirals are to be given as prophylaxis until one week after cessation of breastfeeding or as lifelong therapy and whether the women requires co-trimoxazole prophylaxis.

HIV CLINICAL STAGING

Clinical assessment and staging of all HIV positive women should be conducted at their

first antenatal visit.

CLINICAL & LABORATORY SCREENING FOR RENAL DISEASE

Use of tenofovir is contraindicated in individuals with renal disease. Renal disease is uncommon in HIV-infected pregnant women. At the first antenatal visit, women at increased risk of renal disease may be identified through a pre-pregnancy history of diabetes or hypertension, a previous kidney condition requiring hospitalization, or $\geq 2+$ proteinuria on urine dipstick.

At the first antenatal visit, blood for serum creatinine testing should be sent together with CD4 cell count and other bloods. Serum creatinine results should be available within one week, and may be needed to adjust antiretroviral medications. A serum creatinine of $>85 \mu\text{mol/L}$ is considered abnormal in pregnancy (other methods of estimating renal function, including estimated glomerular filtration rate from the Cockcroft-Gault equation, are inaccurate in pregnancy).

CLINICAL SCREENING FOR TUBERCULOSIS

Active TB disease is common in women living with HIV. All pregnant women should be actively screened for TB symptoms. If an HIV positive patient has symptoms suggestive of TB, a sputum specimen must be collected for GeneXpert testing, and the TB Xpert diagnostic algorithm followed. Although it is important to investigate patients for TB before starting ART, in most pregnant patients initiation of ART prophylaxis or lifelong treatment should not be delayed for TB investigations.

The healthcare provider should suspect TB in a woman living with HIV if any of the following 4 symptoms are present:

- 1 Current cough of any duration.
- 2 Fever
- 3 Night sweats
- 4 Weight loss or poor weight gain

Any woman living with HIV who has none of these symptoms can be considered for eligibility for isoniazid preventive therapy by performing a tuberculin skin test (TST).

CLINICAL SCREENING FOR NEUROPSYCHIATRIC ILLNESS

Use of efavirenz is contraindicated in individuals with active psychiatric illness. In practice, any woman with an **active** psychiatric illness should not receive an efavirenz-containing antiretroviral regimen without consultation. Mild depression is not a contraindication to efavirenz.

INITIATION OF ANTIRETROVIRAL PROPHYLAXIS OR TREATMENT

It is important to avoid unnecessary delays in initiating antiretroviral medications during

pregnancy and all HIV-infected pregnant women should receive antiretroviral prophylaxis or treatment from their first antenatal visit regardless of gestational age.

Under the revised guidelines, the first-choice ARV regimen for prophylaxis and lifelong treatment are the same (TDF+3TC/FTC+EFV, ideally as an FDC). As a result, unless there is a contraindication to TDF+3TC/FTC+EFV, all women can start this regimen as an FDC, at the first antenatal clinic visit.

Identifying women who are eligible for lifelong treatment early in pregnancy is important to ensure adequate counselling. All 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 TDF+3TC/FTC+EFV throughout pregnancy until 1 week after cessation of breastfeeding to reduce mother-to-child transmission. In women for whom TDF+FTC+EFV is contraindicated, AZT during pregnancy and intrapartum is the alternative antiretroviral regimen with extended daily infant NVP until breast feeding cessation.

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. As per the adult guidelines, TDF+3TC/FTC+EFV is the preferred regimen for lifelong antiretroviral therapy unless contraindicated due to active psychiatric illness or renal disease.

Note that eligibility for lifelong antiretroviral treatment may be determined at the first antenatal visit (based on clinical staging) or at a later antenatal visit when CD4 cell count results are reviewed.

ANTIRETROVIRAL PROPHYLAXIS

HIV positive pregnant women who are not eligible for lifelong ART are given an antiretroviral regimen for prophylaxis to reduce mother-to-child transmission.

The maternal prophylaxis regimen is: TDF+3TC/FTC+EFV (ideally as a fixed drug combination tablet, FDC) taken once daily, from the first antenatal visit. This regimen is continued during labour and delivery, and into the postpartum period throughout the period of breastfeeding until one week of breastfeeding cessation.

In women with a contraindication to TDF+3TC/FTC+EFV (eg, renal disease or psychiatric illness), antenatal AZT should be initiated from the first antenatal visit, unless laboratory findings indicate that the mother is severely anaemic (i.e. Hb<8g/dl). Iron and folate supplementation should be provided to all antenatal women routinely.

Antiretroviral prophylaxis should be dispensed at regular intervals from the antenatal clinic setting.

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 count of 350cell/mm³ 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. Monitoring for treatment failure and toxicity should follow the recommendations in the adult ART guidelines.

Antiretroviral treatment for pregnant women should be initiated in the antenatal clinic and dispensed regularly throughout pregnancy and postpartum.

Women on lifelong ART who become pregnant continue with treatment as per adult ARV guidelines (including those on second line regimens). A viral load test should be performed by the HIV clinic as soon as pregnancy is diagnosed. Ongoing adherence advice is recommended regardless of result. If the viral load is high, appropriate interventions to improve adherence and or diagnose resistance with appropriate regimen change is important. If the VL is high, the women should be referred back to the HIV clinic for appropriate management.

Women who initially test negative and subsequently test positive during pregnancy should be initiated onto TDF+3TC/FTC+EFV as an FDC immediately. A CD4 cell count and serum creatinine should be taken, clinical staging and TB screening done. As for other women starting TDF+3TC/FTC+EFV, serum creatinine should be reviewed within one week to determine the safety of long-term tenofovir use, and CD4 cell count should be reviewed to determine the need for prophylaxis versus lifelong antiretroviral therapy.

TUBERCULOSIS DISEASE

Tuberculosis is a WHO stage 3 disease and as such, HIV positive pregnant women with active TB disease qualify for lifelong ART regardless of CD4 cell count. HIV positive women with TB disease should be initiated on TB treatment along with AZT prophylaxis.

Lifelong antiretroviral therapy (typically TDF+FTC/3TC+EFV) should replace AZT prophylaxis approximately 2 weeks after the start of TB therapy. The early introduction of ART increases the risk of TB associated immune reconstitution inflammatory syndrome (TB IRIS). Patients should be counselled regarding TB IRIS and staff should be alert to the symptoms of TB IRIS as per adult guidelines. Initiation of ART should not be delayed while waiting for the results of TB investigations.

Pregnant women who develop TB while on lifelong ART should continue their existing ART regimen, unless they are taking LPV/r. In this case, the LPV/r dose should be doubled.

Isoniazid Preventive Therapy (IPT)

All HIV positive pregnant women should undergo a symptom screen for TB at each visit. If they have no cough, fever, night sweats or weight loss they should be considered for a TST (tuberculin skin test) and if this is positive started on IPT (isoniazid preventive therapy) once stable on ART. If the woman is on lifelong ART IPT should be continued for 36 months. If the woman is on prophylactic ART IPT should be continued for 12 months only. If TST cannot be performed IPT should be deferred until TST can be performed. IPT should only be started once the patient is

stable on ART.

OI PROPHYLAXIS

For women with CD4 <200 cells/mm³ or WHO stage 3/4 disease: start Co-trimoxazole 80/400mg, 2 tablets daily until CD4 >200 cells/mm³.

ANAEMIA

A woman is said to be anaemic when her haemoglobin level is below 11g/dl, but treatment usually only occurs when haemoglobin is below 10g/dl. An Hb < 7g/dl is a severe anaemia.

Anaemic women have an increased risk of pregnancy complications, including death. If anaemia is corrected, the woman would be able to better withstand the complications of haemorrhage and sepsis. Anaemia is a very common condition, and is more common in women infected with HIV.

Screening for anaemia

- Measure haemoglobin level at first ANC visit, at 32 weeks gestational age and near time of delivery (36 weeks gestational age)
- Look for conjunctival pallor
- Look for palmar pallor
- Ask pregnant women at each visit: do you tire easily or get short of breath doing routine tasks?

What immediate action should be taken if there is anaemia?

If Hb <7g/dl: start supplementation of ferrous sulphate (FeSO₄) 1 tablet three times a day and folate 5mg daily and send blood to the laboratory for a full blood count (FBC) (see below).

Hb between 7 and 10g/dl: FeSO₄ 1 tablet three times daily and follow them 2 weekly and check Hb.

If Hb is 10 and 11g/dl, give FeSO₄ one tablet twice a day and check Hb again 4 weeks later.

All women should be counselled on the importance of taking their tablets and nutritional advice should be given.

How to prevent anaemia:

All pregnant women should receive ferrous sulphate 170 200mg (1 tablet) daily, and folic acid 5 mg (1 tablet) daily throughout their pregnancy.

If Hb<7g/dl: Blood needs to be sent to the laboratory for a Full Blood Count (FBC) and the women referred.

- Iron deficiency is likely if: the FBC shows a low mean corpuscular volume (MCV <80fl)) (microcytic anaemia) with normal white cell count (WCC) and platelets.
Treatment: Iron supplementation if not due to another cause such as an inherited haemoglobinopathy
- Folate deficiency is likely if: there is a high MCV (>115fl) and normal WCC and platelets **Treatment:** folic acid supplementation
- In women infected with HIV, it is common to have a mixed picture, indicative of chronic disease. If the **WCC, platelets and Hb are all decreased**, the patient has a **pancytopenia** and should be **referred to a hospital**.
- If the patient is symptomatic (short of breath at rest or mild exertion, oedema, syncope), she should be referred to a hospital immediately.

RENAL DISEASE

At the first antenatal visit, women identified through their history as being at increased risk of renal disease, or who have $\geq 2+$ proteinuria on urine dipstick, should not receive a tenofovir-containing regimen without prior review of serum creatinine results. These women should start AZT immediately and return for review of CD4 cell count and serum creatinine within one week.

- Women who have a normal serum creatinine ($\leq 85 \mu\text{mol/L}$) should switch from AZT to TDF+FTC/3TC+EFV immediately
- Women who have an elevated serum creatinine ($>85 \mu\text{mol/L}$) should be managed according to their eligibility for lifelong antiretroviral therapy based on CD4 cell count and clinical staging:
 - Women who do not require lifelong antiretroviral therapy can continue AZT prophylaxis throughout pregnancy and their infant should receive daily NVP until breast feeding cessation
 - Women who require lifelong antiretroviral therapy should be managed according to adult guidelines for lifelong antiretroviral therapy (and receive a triple-drug antiretroviral regimen that does not contain tenofovir, eg, AZT+3TC+EFV).

For women who start a TDF+3TC+EFV at their first antenatal visit, a serum creatinine $>85 \mu\text{mol/L}$ indicates the need to stop this regimen immediately. The CD4 cell count and clinical staging should be reviewed to identify the best antiretroviral option for these women:

- Women who are not eligible for lifelong antiretroviral therapy can be switched to AZT prophylaxis
- Women who require lifelong antiretroviral therapy should be managed according to adult guidelines for lifelong antiretroviral therapy (and receive a triple-drug antiretroviral regimen that does not contain tenofovir, AZT with 3TC+EFV).

For women taking TDF+FTC/3TC+EFV who develop renal complications during pregnancy, the regimen should be stopped if repeated serum creatinine exceeds 85 µmol/L. In these instances, AZT should be used in the place of TDF+FTC/3TC+EFV for women who are not eligible for lifelong antiretroviral therapy. In women who are eligible for lifelong antiretroviral therapy, an alternate triple-drug regimen should be prescribed per adult antiretroviral guidelines.

PSYCHIATRIC ILLNESS

Women identified as having active psychiatric illness at the first antenatal visit should start AZT immediately and return for review of CD4 cell count within one week. Women determined to be eligible for lifelong antiretroviral therapy based on CD4 cell count <350 or clinical staging should be managed according to adult guidelines for lifelong antiretroviral therapy (eg, substituting NVP or Lopinavir/ritonavir for EFV). Women who require prophylaxis only should continue to receive AZT twice daily throughout pregnancy.

HEPATITIS B INFECTION

TDF and 3TC/FTC are both active against Hepatitis B. When available, Hepatitis B surface antigen testing should be conducted in women before stopping TDF+3TC/FTC+EFV prophylaxis. If a woman has evidence of hepatitis B infection, she qualifies for lifelong ART treatment and must remain on TDF + 3TC/FTC to prevent a hepatitis flare if ARVs stopped.

LABORATORY MONITORING FOR ANTIRETROVIRAL PROPHYLAXIS OR TREATMENT

Following initiation of TDF+3TC/FTC+EFV for prophylaxis or treatment, all women require serum creatinine testing after 3 months, 6 months and 12 months. Because standard methods for the estimation of glomerular filtration rate are inaccurate in pregnancy, serum creatinine values <85µmol/L should be considered normal before delivery. After delivery, interpretation of serum creatinine values should be based on the modified Cocroft-Gault equation per adult antiretroviral guidelines.

All women who are not eligible for lifelong ART during pregnancy (and receive antiretrovirals as prophylaxis) should have a repeat CD4 cell count 6 months after the end of maternal antiretroviral use. In the case of women taking TDF+3TC/FTC+EFV throughout breastfeeding, this means a CD4 cell count 6 months after the end of breastfeeding.

All women who receive AZT for prophylaxis (because TDF+FTC+EFV is contraindicated) require regular (see table below) haemoglobin monitoring during pregnancy.

All women who receive TDF+FTC+EFV or another triple-drug regimen for antiretroviral treatment require standard monitoring per adult antiretroviral guidelines, including Viral Load testing 6 months and 12 months after initiation and CD4 cell count 12 months after initiation.

<i>For women taking</i>	<i>Monitoring if on lifelong therapy</i>	<i>Monitoring if on prophylaxis only</i>
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TDF+3TC/FTC+EFV(FDC)	Creatinine at 3, 6 and 12 months post-initiation	Creatinine at 3, 6 and 12 months post-initiation
	Viral Load at 6 and 12 months post-initiation; CD4 at 12 months post-initiation	
AZT only		Haemoglobin 1, 2, 3 and 6 months post-initiation
Other triple-drug regimens	Per adult ARV guidelines	

5.2 INTRAPARTUM MANAGEMENT

The woman's HIV 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 OR TREATMENT

All HIV-positive women who started TDF+3TC/FTC+EFV or another triple-drug regimen during the antenatal period should continue to receive this regimen throughout labour and delivery. For women who received AZT during pregnancy (ie, with a contraindication to TDF+3TC/FTC+EFV and not eligible for lifelong ART) AZT should be given 3-hourly during labour with a single dose of nevirapine (NVP) and stat dose of TDF+FTC at onset of labour.

WOMEN NEWLY DIAGNOSED HIV POSITIVE DURING LABOUR

Women who are newly diagnosed as HIV positive during labour should receive a single dose of NVP and TDF+FTC and 3 hourly AZT. For women who plan to breastfeed, the regimen TDF+3TC/FTC+EFV should be initiated (with CD4 cell count and serum creatinine testing conducted) as soon as possible thereafter.

INTRAPARTUM SPECIAL CIRCUMSTANCES

Caesarean sections should be performed for obstetric indications and are not recommended to reduce mother-to-child transmission. Women who initiated TDF+3TC/FTC+EFV during the antenatal period should continue this regimen throughout the intrapartum period and treatment should not be omitted. In the case of an emergency Caesarean section in a woman who is not already on an antiretroviral regimen for prophylaxis or treatment, ensure that the woman receives single dose NVP + 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 POSTDELIVERY 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, almost immediately.
- All infants should start feeding (exclusive breastfeeding is recommended).
- Initiate HIV-exposed infants on NVP prophylaxis immediately after birth or very soon after (within 72 hours window).

Before leaving the health facility immediately postpartum:

- All women must be counselled on the ongoing risk of HIV transmission to the infant through breastfeeding, and the need for maternal antiretroviral use for prophylaxis and/or treatment, as well as infant prophylaxis.
- All women taking TDF+3TC/FTC+EFV should have at least 6 weeks' supply of medications and should know the name and location of the health facility where they can receive additional medications, as well as the procedures for this ongoing care.
- All women should have 6 weeks' supply of daily NVP prophylaxis for their newborns.
- All women, whether on antiretroviral prophylaxis or treatment, and their infants should receive follow-up at the health facility within the first 3 to 6 days postpartum, and should be seen again at the health facility at 6 weeks postpartum.
- In order for the recommendation above to be followed through correctly all RTHBs (Road To Health Booklets) need to be correctly completed prior to discharge with all relevant information regarding HIV exposure and PMTCT recorded for ALL babies on pages 7 & 8 of the RTHB. This is a mandatory requirement and NOT optional.
- Infants should be vaccinated per EPI guidelines. BCG vaccine must be given unless the mother has active TB and has been on treatment for less than 2 months prior to delivery. If the mother has active TB, the infant must be screened for congenital TB* and INH prophylaxis or TB treatment started as appropriate (per National TB guidelines) and BCG vaccination deferred.
- Infant testing should be done at 6 weeks (see section on infant testing).
- Contraception and cervical screening should be discussed and offered to all women after delivery before discharge and at subsequent visits
- Ongoing psychosocial support should address the following:
 - Maternal adherence to antiretroviral regimen TDF+3TC/FTC+EFV regardless of

whether this is for prophylaxis or treatment

- Adherence to infant daily nevirapine prophylaxis for 6 weeks
- Safe infant feeding, including exclusive breastfeeding
- Social security issues
- Child health
- Positive prevention for HIV & AIDS

STOPPING MATERNAL PROPHYLAXIS

Women who initiated TDF+FTC+EFV (FDC) for prophylaxis during pregnancy or immediately postpartum should continue this regimen until 1 week after the cessation of all breastfeeding. Prior to discontinuation hepatitis B infection should be excluded and HIV staging, including screening for TB disease, completed. Women with stage 3 or 4 disease or hepatitis B infection should continue ART lifelong.

Repeat CD4 cell counts should be done in case the last CD4 count was done more than 12 months ago.

INFANT PROPHYLAXIS

Antiretroviral prophylaxis given immediately or 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.

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

- **If birth weight \geq 2500 grams: 15mg**
- **If birth weight 2000-2500 grams: 10mg**
- **If birth weight <2500 grams: 2mg/kg**
- **Infant prophylaxis should be initiated as soon as possible after delivery.**

ABANDONED INFANTS should receive NVP as soon as possible (<72 hours) after birth and continued until HIV-exposure status has been determined, using a rapid test or an HIV ELISA test. If the infant has been HIV-exposed, NVP should continue until 6 weeks of age and followed by a PCR at 6 weeks. In instances where an HIV test cannot be determined within 2 hours of encountering an abandoned baby, a stat dose of NVP is warranted.

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 rapid test) to inform further management of the infant.

WHERE THE MOTHER IS KNOWN TO BE HIV-POSITIVE, BUT SHE REFUSES ANY ARV PROPHYLAXIS FOR THE INFANT, a counsellor must intervene to explain the risks of mother-to-child transmission and the benefits of antiretroviral prophylaxis and 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 healthcare 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).

INFANTS BORN TO MOTHERS ON AZT: should continue NVP prophylaxis for the entire duration of breastfeeding, until one week after cessation of breastfeeding.

PATIENT EDUCATION AND COUNSELLING FOR WOMEN RECEIVING ANTIRETROVIRAL PROPHYLAXIS OR TREATMENT

Provision of appropriate patient education, counselling and support to HIV-infected women throughout pregnancy and the postpartum period is a central component of effective PMTCT services. A phased approach to patient education and counselling is recommended that takes into account the women's individual circumstances and her need for prophylaxis and/or treatment. Particular attention is required to patient education, counselling and support during the postpartum period.

1. At the first antenatal visit, in addition to counselling related to their HIV diagnosis, women should receive patient education and counselling on: prevention of mother-to-child transmission; the distinction between ART use for prophylaxis (against transmission) and lifelong treatment (for maternal health); an introduction to the ARV regimen they are starting that day (including dosing and common side effects); information on the timing and determination of eligibility for lifelong treatment; and the importance of long-term adherence.
2. At follow-up antenatal visits, patient education and counselling messages can be tailored to individual women based on their eligibility for lifelong treatment and the ART regimen they are receiving. In addition to ongoing adherence support, preparation for the postpartum period should begin with introduction of issues around infant feeding (including the need for women on prophylaxis only to continue until the end of breastfeeding), infant prophylaxis and family planning.
3. Immediately after delivery, patient education and counselling messages should include infant feeding and prophylaxis, infant testing, and the importance of ongoing maternal adherence for women receiving prophylaxis or treatment.
4. The postpartum period is an important time to ensure appropriate patient education, counselling and support to HIV-infected women. Counselling sessions should reinforce safe infant feeding practices, the timing of infant testing, and the importance of continued maternal adherence to treatment. Throughout, patient education and counselling should be tailored to individual women based on their eligibility for lifelong treatment: women who are taking prophylactic regimens should be counselled on when and how to stop prophylaxis, while women taking lifelong therapy should be counselled on the importance of long-term treatment adherence.

5. The importance of inter-facility transfer of information is critical to the success of this programme. The reliance on the mothers of this programme to be the link between the facilities in terms of carriage of vital health information both written and not has to be emphasized through all education and counselling sessions. She has to be provided with a 'Road Map' of the PMTCT cascade and which points present particular challenges that we rely on her to navigate through with our assistance.
6. The vital role that the **Road To Health Booklet** plays in conveying key and essential information of the mother and infant across facilities and a range of healthcare providers from birth into early childhood. This booklet must be introduced to mothers in the ANC and they should see this as an essential and infant only reliable communication tool that all healthcare workers across the country recognize as a routine document. Taking ownership of the information required in this booklet by mothers provides them with an empowering sense of keeping their infants alive.

CHAPTER 6: REGIMENS

Maternal regimens		
Woman	Regimen	Comment
1 st antenatal visit		
All women at first antenatal visit (any gestational age)	FDC initiated immediately	If there is a contraindication to the FDC: Start AZT immediately and review within a week. (see figure 2-algorithm)
Currently on lifelong ART	Continue the ART regimen If the woman is on a compatible regimen (EFV, 3TC TDF) change to FDC	Check a VL when pregnancy diagnosed
2 nd antenatal visit (1 week later)		
Creatinine ≤85µmol/l Any CD4 cell count	Continue FDC	
Creatinine > 85 µmol/l TDF contraindicated (renal disease)	AZT + 3TC + EFV	If haemoglobin <7g/dl AZT is contraindicated. Use D4T instead of AZT. Refer for investigation for cause of renal disease
Contraindication to EFV (active psychiatric illness) CD4 ≤ 350cells/mm ³	TDF + FTC + NVP	Substitute LPV/RTV for NVP in women with CD4 counts > 250cells/mm ³
Contraindication to EFV (active psychiatric illness) CD4 > 350cells/mm ³	AZT in pregnancy	
	sdNVP + sd TDF + FTC and AZT 3hrly in labour	
Labour		
Unbooked and presents in labour and tests HIV positive	sdNVP + sd TDF + FTC and AZT 3hrly in labour	Assess maternal ART eligibility before discharge
	start FDC after delivery if woman will breast feed	

Infant regimens		
Infant	Regimen	Comment
Mother on lifelong ART or antenatal prophylaxis received (including TDF + 3TC/FTC + EFV or AZT)	NVP at birth and then daily for 6 weeks	If mother is breast feeding and not virally suppressed e.g. late booking or AZT mono-therapy continue NVP for infant throughout breast feeding until one week post cessation of breastfeeding,

Mother did not get any ART before or during delivery and tests HIV positive post delivery	NVP as soon as possible and daily for 6 weeks	Assess ART eligibility as soon as possible
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
Mother on AZT regimen (due to any contraindication to the FDC regimen)	NVP at birth and then daily for 6 weeks.	Test infant with 6 week DNA PCR test. If negative and breastfeeding continue NVP till one week after complete cessation of breastfeeding

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

ARV Adult Dosing Guide

Drug	Dosage	Notes
TDF (Tenofovir)	300mg daily	Tenofovir is contraindicated if serum creatinine >85µmol/L during pregnancy (or creatinine clearance of <50ml/min in non-pregnant adults)
d4T (Stavudine)	30mg 12hrly po	All adult patients now receive 30mg regardless of weight
3TC (Lamivudine)	300mg daily	
FTC (Emtracitabine)	200mg daily	
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 be used with caution with TB treatment Avoid NVP if CD4 count >250cells/mm ³
EFV (Efavirenz)	600mg nocte	Avoid if active psychiatric illness
Aluvia® (lopinavir 200mg /ritonavir 50mg)	2 tabs 12 hourly (Lop400mg/Rit100mg)	Preferably taken with food. Boosting required with TB treatment
AZT (Zidovudine)	300mg 12 hourly po	Avoid if severe anaemia (Hb <8g/dl)

NVP Infant Dosing Guide

	Birth Weight	Dose	Quantity
NVP syrup (10mg/ml)	<1.0kg	2mg/kg initially	0.2ml/kg
	Birth to 6 weeks 1.0-2.5kg birth weight	10mg/d	1ml
	Birth to 6 weeks ≥ 2.5kg birth weight	15mg/d	1.5ml

Suggested oral NVP dosage for babies < 2000g birth weight.

NVP syrup (10mg/ml) Administered orally or per NGT with 1ml syringe. NVP sticks to plastic: Flush NGT with 1ml Normal Saline after dose. Do regular ALT with routine blood tests.	<u>Daily NVP prophylaxis for 42 days</u> <ul style="list-style-type: none"> • Give first dose ASAP after birth (especially if no intrapartum maternal NVP). • Only one dose per 24 hour period; can repeat first dose once if baby vomits. • If HIV PCR positive, confirm with viral load, stop dNVPp and refer for ART. • If mother does not qualify for ART, continue dNVPp for duration of breastfeeding and only stop 1 week after final breastfeed. • If mother qualifies for ART but has not yet started or is on ART with inadequate viral suppression* feed pasteurised breastmilk and continue dNVPp beyond 42 days. Consult expert. 					
	Birthweight 1800 – 1999g			Birthweight < 1800g		
	Age	Dose (mg)	Dose (ml)	Age	Dose (mg)	Dose (ml)
	Day 0 to 14	**5mg daily	0,5 ml daily	Day 0 to 14	2mg/kg	0,2ml/kg
	Day 15 to 42	**10mg daily	1ml daily	Day 15 until discharge	4mg/kg	0,4ml/kg
				At discharge home		
				<14 days old	***5mg daily	0,5ml daily
				>14 days old	10mg daily	1ml daily

**Inadequate suppression: ART duration < 3 months, inadequate ARV doses, poor compliance or drug resistance.*

***Birthweights 1800 - 1999g: round off NVP dose to 5mg for weeks 1 and 2 and 10mg for weeks 3 to 6.*

****A discharge dose of 5mg should be increased to 10mg from 2 weeks of age.*

CHAPTER 7

ESTABLISHING EXCLUSIVE BREASTFEEDING

7.1 BACKGROUND

- The South African national PMTCT programme adopts an approach to infant feeding that maximizes child survival, not only the avoidance of HIV transmission. South Africa actively promotes, protects and supports exclusive breastfeeding.
- Mothers with HIV should exclusively breastfeed their infants for six months, with continued breastfeeding up to 12 months, and should receive ART to prevent HIV transmission.
- Formula feeds will no longer be provided at public health facilities solely for the purpose of PMTCT.
- Formula feeds will be available on prescription by appropriate healthcare professionals for mothers, infants and children with approved medical conditions. Nutritional supplements will be provided to the supplementation guidelines.

Antenatal Infant Feeding Counselling for HIV-negative women or women with unknown HIV status

- Each pregnant woman should receive at least four antenatal counselling sessions on infant feeding.
- 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 encouraged to continue breastfeeding for up to 2 years and beyond.
- Every effort should be made to test all pregnant and breastfeeding women for HIV as outlined in the testing section of this document.
- Pregnant HIV negative women or women of unknown HIV status should be counselled to avoid mixed feeding their infants during their first six months of life as exclusive breastfeeding improves child survival.

Antenatal Infant Feeding Counselling for HIV-positive women

- Each pregnant woman should receive at least four antenatal counselling sessions on infant feeding including exclusive breastfeeding, risks of not breastfeeding, appropriate complementary feeding, and feeding the sick child and ART prophylaxis.
- At every antenatal visit, HIV-positive women should be counselled on exclusive breastfeeding. Mothers living with HIV (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first 6 months of life while introducing appropriate complementary foods from 6 months of age, and continue breastfeeding for the first 12 months of life while the breastfeeding mother continues ART. Breastfeeding should only stop once a nutritionally adequate and safe diet

without breast milk is available

- Pregnant women living with HIV should be counselled to avoid mixed feeding during the first six months of the infant's life.
- HIV-infected mothers who choose not to breastfeed their infants should only give appropriate breast milk substitutes (i.e. commercial infant formula milk) as a replacement feed to their HIV uninfected infants when specific conditions are met namely;
 - a) are able to provide sufficient infant formula, safely feed their infants for the first 6 months of age
 - b) safe water and sanitation are assured at the household level and in the community; and,
 - c) the mother, or other caregiver can reliably provide sufficient infant formula milk to support normal growth and development of the infant; and,
 - d) the mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition; and
 - e) the mother or caregiver can, in the first six months, exclusively give infant formula milk; and,
 - f) the family is supportive of this practice; and,
 - g) the mother or caregiver can access health care that offers comprehensive child health services.

Formula feeding

- Breastfeeding is the feeding recommendation to maximise child survival, there may be instances where HIV infected women choose to 'avoid all breastfeeding.
- Pregnant women living with HIV should know that formula feeds are not routinely provided as part of the PMTCT programme at public health facilities. Nutritional supplements including formula feeds will be available on prescription by appropriate healthcare professionals for mothers, infants and children with medical conditions.
- Mothers living with HIV who choose a breastmilk substitute (commercial infant formula milk product) that is appropriate for the infant's age and circumstances:
 - 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 full 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 South African Regulations Relating to Foodstuffs for Infants, Young Children, and Children.
- At every visit women who choose to formula feed
 - should receive practical support, including demonstrations on how to safely prepare formula and how to feed the infant. These discussions / demonstrations should include:
 - how to prepare formula milk (volume of milk powder and water including temperature of the water),
 - how to feed formula milk (volume needed at each feed and frequency of feeds),

- how to sterilise cups and feeding bottles and teats (cup feeding is preferable to bottle feeding).
- These demonstrations should be done privately, with the specific mother or with mothers who have chosen to formula feed.

Infant feeding and postnatal care for HIV exposed infants

- HIV-exposed infants whose mothers are receiving triple-drug antiretroviral prophylaxis or lifelong therapy should receive NVP prophylaxis for six weeks, providing their mothers is adherent to ART.
- Mothers living with HIV should continue ART throughout breastfeeding, regardless of whether this is for prophylaxis or as part of lifelong therapy.
- Mothers living with HIV taking ART as prophylaxis (who are not eligible for lifelong therapy) should stop antiretrovirals one week after breastfeeding cessation
- Infants with or at risk of poor growth should be referred for continued nutritional monitoring and dietary assistance.

Infant feeding and postnatal care of HIV infected infants

- Infants with confirmed HIV infection should exclusively breastfeed for the first six months, and continue breastfeeding for 24 months with the introduction of complementary foods from age of six months.

CHAPTER 8

MOTHER-INFANT FOLLOW-UP

A full plan for the mother-infant pair follow up should be finalised before the pair is discharged after delivery. Ideally all mothers and their infants should receive health care at the same consultation regardless of service point. The mother should understand the treatment and follow-up plan for herself and her infant. The **RTHB** should be completed prior to discharge after delivery, including recording HIV treatment/prophylaxis interventions received by mother during pregnancy, maternal illnesses, infant HIV prophylaxis and intended feeding method.

CARE FOR THE HIV EXPOSED INFANT

- If a mother/care giver is concerned about the infant's health, including poor feeding, lethargy or jaundice, they should urgently present to a health care facility.
- The 1st postnatal visit is scheduled for day 3 but should take place within 6 days of life at the health facility.
- EPI scheduled visits for vaccination at 6, 10 and 14 weeks at EPI clinic and a routine health check must be performed.
 - At the 6 weeks EPI visit,
 - infant HIV PCR testing should be conducted
 - Discontinue NVP syrup
 - Results for HIV PCR within the week. If positive initiate ART urgently while doing viral load tests.
 - If PCR test result is negative and infant is breastfeeding, start co-trimoxazole syrup.
 - Cotrimoxazole syrup should be continued until the infant is confirmed HIV uninfected and is fully weaned.

Note: Infants who present before 6 weeks and are unwell should have an earlier HIV PCR test. If an infant tests HIV PCR positive, ART must be initiated urgently and a viral load should be sent. This policy of an earlier PCR applies to low birth weight and premature infants who can be regarded as high risk cases that need an urgent diagnosis.

- At the **10 weeks** and **14 weeks** EPI visit:
 - check adherence to cotrimoxazole syrup
 - check maternal adherence to ART
 - growth monitoring
 - infant feeding
- after the 14 weeks, schedule a visit every month:
 - check adherence to cotrimoxazole syrup
 - check maternal adherence to ART
 - growth monitoring
 - infant feeding
- A **6 month visit** should be conducted. At this visit, on-going infant feeding counselling should be provided and a routine health check performed. Mothers still breastfeeding should be

advised to continue and advised on complementary feeding. Infants who have stopped breastfeeding more than 6 weeks earlier should have an HIV PCR test, which if negative, co-trimoxazole must be discontinued. Mothers should be advised to return 6 weeks after breastfeeding cessation for infant HIV testing. If an infant tests HIV PCR positive, ART must be initiated urgently and a viral load should be sent.

- At **9 months** (EPI scheduled visit), on-going infant feeding counselling should be provided and a routine health check performed. Mothers still breastfeeding should be advised to continue breastfeeding if feasible and advised on complementary feeding. Infants who have stopped breastfeeding more than 6 weeks earlier should have an HIV PCR test, which if negative co-trimoxazole must be discontinued. Mothers should be advised to return 6 weeks after breastfeeding cessation for infant HIV testing. If an infant tests HIV PCR positive ART must be initiated urgently and a viral load should be sent.
- At 12 months, a routine health check and on-going feeding counselling should be done. Infants who have stopped breastfeeding more than 6 weeks earlier should have an HIV PCR test, which if negative co-trimoxazole must be discontinued. Mothers should be advised to return 6 weeks after breastfeeding cessation for infant HIV testing. If an infant tests HIV PCR positive ART must be initiated urgently and a viral load should be sent.
- At 18 months (EPI scheduled visit), all HIV-exposed infants, except those with positive PCR test results and on ART, should have a rapid HIV ELISA test. If two HIV rapid ELISA tests are positive, the infant is HIV infected and ART must be initiated urgently.
- **At any visit if the infant is failing to thrive or is unwell, an infant HIV PCR test should be conducted immediately.**

Routine Infant Health Check

- Plot weight and height in RTHB to screen for failure to thrive or obesity.
- History focussed on **IMCI danger signs and main symptoms**
- **TB screening:** persistent cough or wheeze >2weeks, loss of weight or failure to thrive, reduced playfulness and fatigue, fever for 14 days, household TB contact.
- Monitor developmental milestones. (See RTHB for a guide)
- Check history of intercurrent illnesses. (RTHB)
- Check immunisation status. (RTHB)
- Assess feeding pattern; assess feeding difficulties and discuss ways of overcoming them
- Conduct a clinical examination where indicated, and refer to a higher level of care if needed.
- **NOTE:** In women who are breastfeeding and not receiving triple-drug prophylaxis or lifelong therapy, the infant should receive on-going nevirapine syrup until 1 week after cessation of breast feeding. Infant care and testing continues as described above.

CARE FOR THE MOTHER

Women on life-long ART (On-going access to ART and monitoring)

Women on triple-drug antiretroviral therapy for their own health must continue this treatment life-long. Adherence is critical for her own health and to reduce HIV-transmission to her infant. At each infant follow-up visit health care workers should ensure that the mother is accessing on-going ART with appropriate monitoring. Women should be offered on-going infant feeding counselling, contraception and safe sex messaging, and cervical cancer screening services should be integrated into their routine care.

Women on ART for PMTCT prophylaxis

Women on triple-drug prophylaxis to prevent MTCT (and who do not qualify for lifelong ART) should continue the triple-drug prophylaxis until 1 week after cessation of breastfeeding. Adherence is critical to reduce HIV-transmission to her infant, as well as to prevent resistance in future ART regimens. On-going triple-drug prophylaxis and renal toxicity monitoring needs to be routinely provided and continued as life-long therapy if the woman has any WHO stage 3 or 4 disease, or has hepatitis B infection.

- Women who are not on triple-drug prophylaxis and who are breastfeeding should have received AZT during pregnancy, a single dose of NVP and TDF-FTC and AZT 3 hourly intrapartum, and their infants should receive nevirapine syrup until 1 week after post breast feeding cessation.
- All women should receive 6-monthly CD4 cell counts after the end of maternal prophylaxis.
- Women should be offered on-going infant feeding counselling contraception, safe sex messaging and cervical cancer screening services.

Women not yet on ART (either diagnosed in or after labour or while breastfeeding)

If the woman intends to breastfeed, a triple-drug antiretroviral regimen (ideally as FDC) must be started immediately, with a CD4 cell count and serum creatinine taken. She should return within a week for results.

- If $CD4 \leq 350 \text{ cells/mm}^3$, Clinical stage III/IV she should continue ART life-long.
- If $CD4 > 350 \text{ cells/mm}^3$ she should continue FDC until 1 week post breast feeding cessation.

Women should be offered on-going infant feeding counselling, contraception and safe sex messaging, and cervical cancer screening services should be integrated into their routine care.

HIV negative women

All women who test negative during pregnancy should have an HIV test 3 months after delivery while breastfeeding as a strong recommendation. This should be linked to the infant EPI visit (10 week, 6 month, 9 month, 12 month and 18 month scheduled visits). Exclusive breast-feeding for the first 6 months should be encouraged. Women should be offered on-going infant feeding counselling, contraception and safe sex messaging, and cervical cancer screening services should be integrated into their routine care.

CONTRACEPTION AND FAMILY PLANNING

All HIV positive mothers and HIV negative mothers should receive safe sex and family planning advice at each visit during pregnancy and in the post natal period. See Appendix for contraceptive options.

CERVICAL SCREENING

Should be offered to all women from 6 weeks post-delivery.

HOME CARE

Weekly home visits through the PHC ward based outreach teams with referral into care if infant not thriving.

Appendix: Postpartum contraceptive options for HIV-positive women

For Mothers who are **not** breastfeeding:

- The Intrauterine contraceptive devices (IUCD copper 380) can be inserted immediately post-partum after the delivery of the placenta, or within the 1st 48 hours, by a provider trained in postpartum IUCD insertions. It should otherwise be delayed until 4-6 weeks post-partum when the uterus has contracted to its normal size.
- A progesterone-only method can be started immediately after delivery.
- Combined hormonal contraception should be delayed until 3 weeks postpartum when risks of thrombo-emboli are reduced. This delay should be extended for up to 6 weeks if the woman has additional risk factors for thrombo-emboli such as smoking, immobility, transfusion at delivery, postpartum haemorrhage, or eclampsia.
- Female Sterilization can be done immediately when a woman is having a caesarean section or seven days thereafter. If sterilization is not done in this time, it should be done 6 weeks later and other methods should be used in the interim.

For Mothers who are breastfeeding:

- IUCD can be inserted immediately post-partum after the delivery of the placenta or within the 1st 48 hours, by a provider trained in postpartum IUCD insertions. It should otherwise be delayed until 4-6 weeks post-partum when the uterus has contracted to its normal size.
- Female Sterilization can be done immediately when a woman is having a C/S or seven days thereafter. If it is not done in this time, then it should be done 6 weeks later and other methods should be used in the interim.
- **NOTE:** Oestrogen-containing methods (such as the combined oral contraceptive pill) should be delayed until either the infant is weaned, or after 6 months postpartum, whichever comes first.

NOTE: For All HIV Positive Women

- The IUCD is safe to use in HIV positive patients and may be the most suitable contraceptive for women on ART.
- Progesterone-only pills and combined hormonal contraceptive are safe to use in HIV positive women except if they are on the antiretroviral ritonavir (which reduces the effectiveness of combined oral contraceptives and progesterone only pills).
- However, Progesterone only injectable can be used safely in these patients (CD4<200 or WHO Stage 3/4) and is **not** taking lifelong antiretroviral therapy.
- Dual method use (condoms and a non-barrier form of contraception) is advised in all HIV-positive patients.