2019

Guideline for the Prevention of Mother to Child Transmission of Communicable Infections

South African National Department of Health

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FOREWORD

It is my pleasure to present the Guidelines for the Prevention of Transmission of Communicable infections from mother to child (HIV, Hepatitis, Listeriosis, Malaria, Syphilis and TB).

While the WHO calls for dual elimination of HIV and syphilis, South Africa aspires to eliminate all infections that are transmittable from mother to child by promoting the prevention of such infections, early diagnosis and proper management in order to reduce maternal, neonatal and child morbidity and mortality.

In 2015 Option B+ (lifelong ART irrespective of CD4 count or WHO staging) and birth PCR testing were implemented. The birth PCR test provides an opportunity for early identification of babies who acquired HIV *in utero* and linking them to HIV care and treatment as early as possible. Monitoring of the infant PCR test positive around 10 weeks rate indicated a reduction in the MTCT rate from 1.3% in the FY 2016/17 to 0.9% in the FY 2017/18.

As we are approaching the milestones to elimination of MTCT for HIV, we are now being challenged by the rising of other transmittable diseases from mother to child. It is therefore important that in this guideline other infections such as Hepatitis, Malaria, Syphilis and TB, in addition to HIV, be given due attention. In the period 2014 – 2016, TB was responsible for 9% of all maternal deaths, hepatitis contributed 1.1% and malaria 1.7%. In 2017, the STI sentinel sites survey reported an increase in syphilis amongst pregnant woman to 2% and the recent outbreak of Listeriosis resulted in fatalities in neonates. The integrated approach will allow clinicians to comprehensively screen all pregnant women and their newborn babies and promptly manage those who are diagnosed with these infections.

The challenge that PMTCT is currently facing is an increasing number of babies who acquire HIV infection during the postnatal period. To address this challenge, the guidelines provide guidance on the following:

- Strengthening antenatal and postnatal care for both HIV negative and positive mothers.
- The introduction of a dolutegravir-based ART regimen which is more efficacious in reducing the risks of transmission of HIV.
- Promoting integrated management of the mother-baby pair by aligning PMTCT interventions with BANC visits during antenatal period and EPI visits during postnatal period.

These guidelines provide a framework for a service benefits package steering us towards the implementation of NHI. Therefore, we urge all clinicians, working in both public and private health facilities, to use these guidelines to offer quality, comprehensive services to the public.

Ms MP Matsoso
Director –General: Health

CONTENT

ABBREVIATIONS

3TC	Lamivudine
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARVs	Antiretrovirals
AZT	Zidovudine
BANC	Basic Antenatal Care
BANC Plus	Basic Antenatal Care Plus
bd	Twice Daily
CBP	Child Bearing Potential
CHW	Community Health Worker
CM	Cryptococcal Meningitis
CPT	Cotrimoxazole Prophylaxis Therapy
CrAg	Cryptococcal Antigen
CTX	Cotrimoxazole
DHIS	District Health Information System
DST	Drug Sensitivity Testing
DTG	Dolutegravir
EFV	Efavirenz
EGK	Electronic Gate Keeping
EML	Essential Medicines List
EMTCT	Elimination of Mother to Child Transmission of HIV
EPI	Expanded Programme on Immunization
FGR	Foetal Growth Restriction
FTC	Emtricitabine
GXP	Gene Expert TB Test
Hb	Haemoglobin
HCW	Health Care Worker
HEI	HIV-exposed Infant
HEU	HIV-exposed but uninfected
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IM	Intramuscular
INH	Isoniazid
IPT	Isoniazid Preventative Therapy
IRIS	Immune Reconstitution Inflammatory Syndrome
IUCD	Intrauterine Contraceptive Device
IV	Intravenous
LAM	Lipoarabinomannan
LP	Lumbar Puncture
LPA	Line Probe Assay
LPV/r	Lopinavir/ritonavir
LTBI	Latent TB Infection
MCR	Maternity Case Record
MDO	Missed Diagnostic Opportunity
MIP	Mother-infant Pair
MNCWH&N	Maternal Neonatal Child Women's Health and Nutrition
MTCT	Mother to Child Transmission of HIV
NHLS	National Health Laboratory System
NVP	Nevirapine
NSA	Non-suppression Algorithm
NTD	Neural Tube Defect
OD	Once Daily
OI	Opportunistic Infection
PCP	*Pneumocystis jirovecii* Pneumonia
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PHC	Primary Health Care
PICT	Provider Initiated Counselling and Testing
PMTCT	Prevention of Mother to Child Transmission of HIV
PNC	Postnatal Club
PO	Per os (per mouth)
PrEP	Pre-Exposure Prophylaxis
RfA	Results for Action NHLS Reports
RPR	Rapid Plasma Reagin
RTHB	Road to Health Booklet
Rx	Treatment
SA	South Africa
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infections
sd	Single dose
TB	Tuberculosis
TDF	Tenofovir
TEE	ART Regimen containing Tenofovir, Emtricitabine, and Efavirenz
TLD	ART Regimen containing Tenofovir, Lamivudine, and Dolutegravir
TPHA	Treponema pallidum haemagglutination assay
TPT	TB Preventative Therapy
TST	Tuberculin Skin Test
UTI	Urinary Tract Infection
VMMC	Voluntary Medical Male Circumcision
VL	Viral Load
VLS	Viral Load Suppression
WASH	Water, Sanitation and Hygiene
WLHIV	Woman Living with HIV
WHO	World Health Organization

OVERVIEW OF THE STRUCTURE OF THIS GUIDELINE

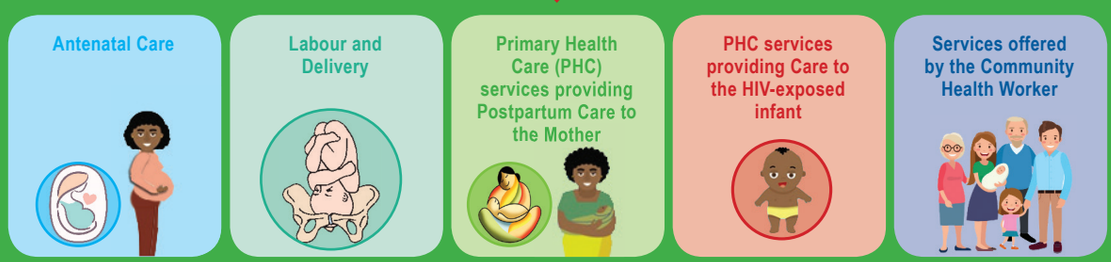
The guideline is divided into four parts:

1 **Part One: Introduction** provides an introduction and background to this guideline

2 **Part Two: Prevention** gives guidance around the universal measures to prevent transmission of infections during pregnancy and breastfeeding, prevent HIV, prevent unintended pregnancies, as well as safe conception.

3 **Part Three: Charts per Service Delivery Area** is structured by service delivery point across the continuum of care. It deals with the care and treatment of the woman living with HIV, her partner and children, and preventing mother-to-child-transmission (MTCT) to her exposed infant.

START BY SELECTING THE SERVICE POINT AT WHICH SERVICES ARE PROVIDED



For each service delivery point **in the facility** the following components of care are outlined:

1. HIV testing,
2. Antiretroviral therapy (ART) as treatment or prophylaxis,
3. Viral load (VL) monitoring and management,
4. Tuberculosis (TB) screening, TB Preventative Therapy (TPT), and opportunistic infection (OI) prophylaxis,
5. Prevention of mother to child transmission of syphilis, hepatitis B virus (HBV) and other infections, and
6. Other care required, e.g. basic antenatal care (BANC) services, immunization services (EPI), growth monitoring and nutrition.

For care provided by the **community** health worker (CHW) at home the following components of care are outlined:

7. Care of the non-pregnant woman of child bearing potential (CBP) at home,
8. Home-based care during the antenatal period, and
9. Home-based care after delivery for the mother and infant

Where additional information is needed you will be redirected to the relevant sections in Part Four.

4 **Part Four: Algorithms and Decision Tools** provides algorithms and decision tools that may apply to any service point, e.g. how to manage an elevated VL, how to screen for TB and initiate TPT, important adherence messages, etc.

1 PART 1 – INTRODUCTION

BACKGROUND

Infections during pregnancy are a major contributing factor to perinatal morbidity and mortality. In utero infections may directly affect the foetus and can lead to intra uterine deaths and still births. The foetus may also be affected indirectly as a consequence of maternal infection leading to premature birth or foetal growth restriction (FGR). Infections that are asymptomatic at birth may present later in life, often within the first five years. In general, primary infections during pregnancy are substantially more damaging than re-infections or reactivations of infection. Likewise, infections acquired at an earlier gestational age tend to lead to more serious infections.[1] HIV, syphilis, TB, HBV, malaria, and more recently, listeriosis, are all infections with significant impact on maternal and child health outcomes in SA. Although all these infections are important, this guideline will focus mainly on preventing mother to child transmission of HIV, syphilis and TB.

OVERALL GUIDELINE OBJECTIVE

This guideline aims to outline the minimum standards for routine care for women of child bearing age and their families relating to:

- the prevention of new HIV cases, TB cases, syphilis cases, and other infections
- the prevention of unintended pregnancies
- the prevention of mother-to-child transmission of HIV, syphilis, and other infections, and
- the care and treatment of the women living with, and their children exposed to HIV, syphilis and other infections

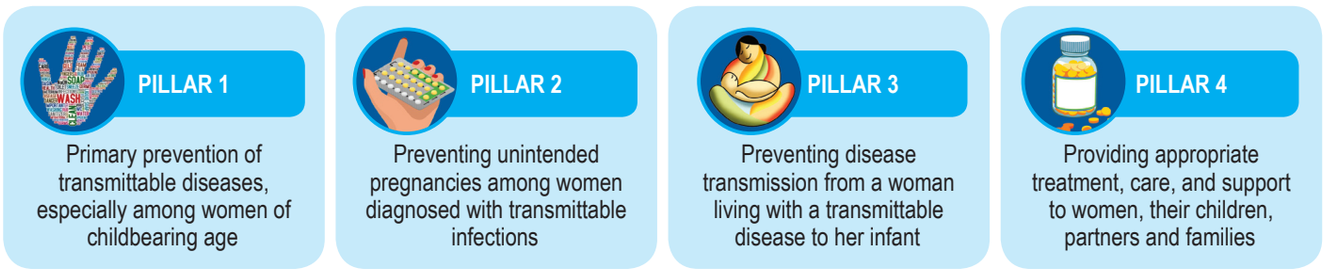


Figure 1 *The Four Pillars for Prevention of Transmittable Infections from Mother to Child*

OVERVIEW OF PMTCT OF HIV

South Africa (SA) is committed to achieving the elimination targets outlined in the Last Mile Plan. Whilst significant progress has been made in preventing HIV infections in children, HIV remains the third leading cause of maternal mortality[2], and a significant contributor to under-five deaths in SA. Therefore, managing the health of women living with HIV and preventing mother-to-child transmission of HIV remains a critical intervention for ensuring that women and children survive and thrive in South Africa. PMTCT Option B Plus entailed initiating ART for life in all pregnant and breastfeeding women regardless of CD4 count or clinical stage and was launched in SA in January 2015. Now, three years down the line, it is necessary to reflect on new evidence, both scientific and operational, to ensure that SA's HIV PMTCT program remains relevant, practical, and evidence based.

The PMTCT program outlines four pillars by which to achieve the targets of zero HIV transmission from mothers to their infants and an HIV-free generation. They are outlined in Figure 2 below.

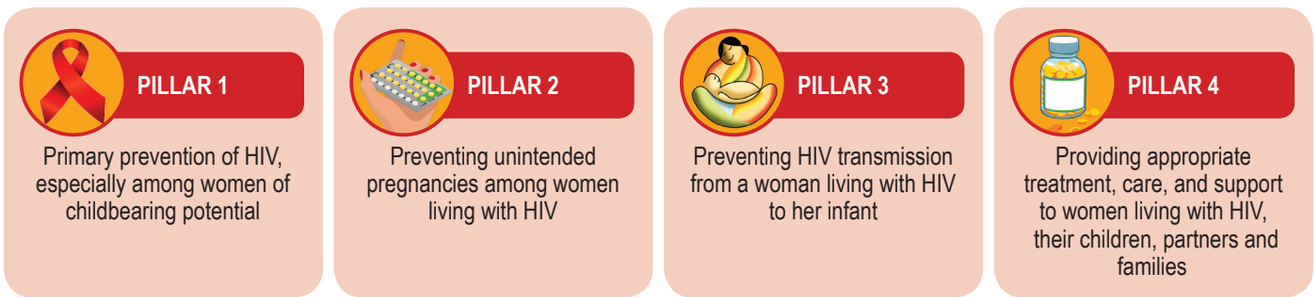


Figure 2 *The Four Pillars of PMTCT for HIV*

SYPHILIS IN PREGNANCY

Syphilis remains a significant cause of preventable perinatal death in SA.[3] The 2015 provincial level syphilis prevalence estimates for women attending ANC ranged form 1.1% (95% CI: 0.8%-1.5%) to 4.6% (95% CI: 3.8%-5.6%). With only an estimated 72% of woman receiving screening for syphilis, many woman may remain undetected and untreated. Adverse pregnancy outcomes occur in up to 80% of syphilis seropositive, untreated pregnant women. South Africa has committed to dual elimination of both HIV and syphilis, and greater emphasis is therefore needed on the process of screening and effectively treating mothers, their partners, and their infants affected by syphilis.

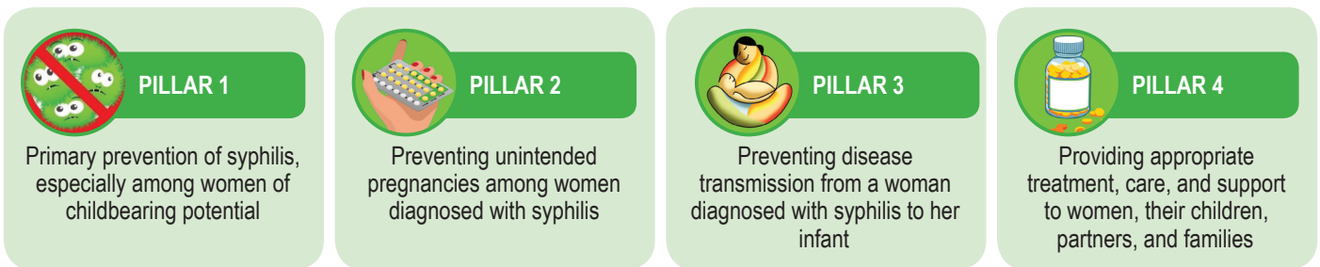


Figure 3 *The Four Pillars of Preventing Mother to Child Transmission of Syphilis*

TUBERCULOSIS IN PREGNANCY

Non pregnancy related infections remains the leading cause of maternal mortality in South Africa and in all provinces. Within this category, respiratory infection remains the most common causes of death, and TB the most common underlying disease. Yet, deaths from TB are likely to be unrecognized, with many deaths due to pulmonary or disseminated TB being attributed to other causes.[4] Furthermore, maternal TB may result in premature birth, low birth weight, and congenital or neonatal TB infection or disease.[5] Preventing, diagnosing and treating women for TB must receive greater emphasis if maternal and child outcomes are to be improved in SA.

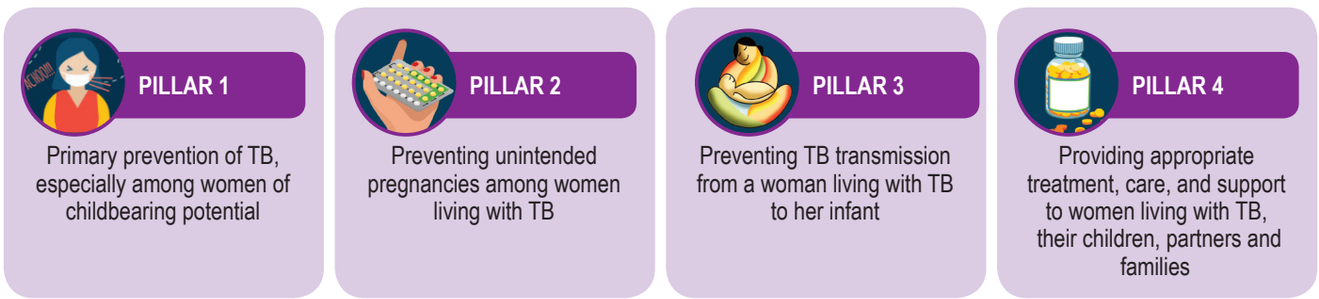


Figure 4 *The Four Pillars of Preventing Mother to Child Transmission of Tuberculosis*

OTHER INFECTIONS

MALARIA IN PREGNANCY

Pregnant women, particularly in the second and third trimesters of pregnancy, are more likely to develop severe malaria and have a higher malaria-related mortality rate than other adults. Malaria in pregnancy is more frequently associated with complications such as cerebral malaria, hypoglycaemia, and pulmonary oedema/adult respiratory distress syndrome. In addition, maternal malaria increases the risk of spontaneous abortion, stillbirth, premature delivery, low birth weight (a leading cause of child mortality) and rarely, congenital malaria. Foetal distress may occur peripartum. The risk of severe malaria extends into the early postpartum period. Pregnant and breastfeeding women living in malaria-endemic areas should therefore be a focal group for malaria prevention interventions. It is important to follow up pregnant women treated for malaria, and their infants, more closely to promptly diagnose and adequately manage any complications of malaria in pregnancy.[6]

HEPATITIS IN PREGNANCY

Worsening of liver disease in HBV-infected pregnant women is uncommon, but case reports have suggested that HBV reactivation, hepatic exacerbations and fulminant liver failure may occur. Furthermore, maternal HBV infection may result in higher rates of preterm births, lower APGAR scores, gestational diabetes and antepartum hepatitis. Whilst horizontal transmission during childhood remains the primary mode of HBV transmission, vertical transmission from mother to child remains an important mechanism of infection in countries with high HBV prevalence.[7] In SA, a large proportion of HBV infected women are also living with HIV and will receive ART during pregnancy. The ART drugs tenofovir and lamivudine treat both HIV and HBV and reduce the risk of mother to child transmission by decreasing the viral load of both HIV and Hepatitis B. Health care workers need to be aware of the required management of a HBV-infected mother and her infant as outlined in the National Guidelines for the Management of Viral Hepatitis.

LISTERIOSIS, ZIKA AND OTHER INFECTIONS

Listeriosis is a disease caused by ingesting food contaminated with the bacterium Listeria monocytogenes. Pregnant women, newborn infants and those with weakened immune systems are particularly at risk and the infection may result in sepsis or meningitis with high mortality. Vertical transmission may result in stillbirth, premature delivery or severe infection in the newborn.[1]

Zika virus in transmitted by mosquitos, sexual contact, and contaminated blood products. While the majority of Zika infections are asymptomatic, infected persons may present with a short-lived febrile illness. There is no evidence that pregnant women are more susceptible to Zika virus, or that they are more likely to develop complications of the disease. However, maternal Zika infection may result in congenital brain abnormalities including microcephaly in the infant.[8]

While Zika virus infections may not be an imminent threat in the South African context, the recent outbreak of Listeriosis highlights the importance of universal measures to prevent infections during pregnancy and the breastfeeding period to prevent any form of infection and their consequences during this vulnerable time.

POPULATIONS TO WHOM THIS GUIDELINE APPLIES

This guideline covers all settings where routine sexual and reproductive health (SRH) services and HIV care and treatment services are offered to HIV-uninfected and HIV-infected women, their partners and their families. It is to be used in all South African health care facilities, and by doctors, nurses and allied health workers at primary, secondary and tertiary care levels where clients may require uncomplicated PMTCT care. This guideline does not cover clients with complex care issues who may require individualised client care approaches.

SUMMARY OF WHAT'S NEW IN THE 2019 PMTCT GUIDELINE

Table 1 *Summary of changes in the PMTCT Guideline*

CONTENTS	2015 CONSOLIDATED GUIDELINE	2019 PMTCT GUIDELINE
Overall approach		• Focus on practicality for the end user • Focus on integration of services, including use of CHWs in the community
Prevention		• Guidance on universal infection precautions, and for preventing HIV in HIV-negative women and serodiscordant couples
Preventing unplanned pregnancies and promoting safe conception		• Guidance for contraception in women living with HIV, as well as safe conception
HIV testing for mother	• At first visit and every three months	• At first visit and at each routine BANC plus visit (eight visits in all)
ART initiation		• Guidance on adherence messages • Guidance on considerations for adolescents • Guidance for use of dolutegravir (DTG) in women of childbearing potential
VL monitoring for Mother	• Guidelines for newly diagnosed mothers, and known positives on ART	• Additional guidance for mothers with previous ART exposure, and who book late for antenatal care • Do a VL at delivery and at six months postpartum for all women on ART, and six-monthly during breastfeeding
ART for the mother presenting in labour	• Stat dose nevirapine (NVP) and Truvada, and zidovudine (AZT) three-hourly during labour	• Once DTG is available, replace previous regimen with a stat dose of tenofovir (TDF), lamivudine (3TC), and dolutegravir in a fixed dose combination tablet (TLD) and a stat single dose of nevirapine (NVP). Start lifelong ART on the following day after appropriate counseling to understand her fertility intentions and contraceptive needs
Infant HIV testing	• HIV-PCR testing at birth, and 10-weeks • 18-week PCR for high risk infants who received extended NVP for 12 weeks • Age appropriate HIV testing six-weeks post cessation of breastfeeding • 18-month HIV rapid testing for HIV-exposed infants, with a second rapid used for confirmation of HIV diagnosis	• Birth HIV-PCR testing and 10-week HIV-PCR testing remain unchanged • No 18-week PCR for high risk infants • Do a six-month HIV-PCR for all HIV-exposed infants • Do an age appropriate HIV test at six-weeks post cessation of breastfeeding, even if breastfeeding continues for longer than 18 months • Universal HIV testing at 18 months (HIV rapid test for ALL infants regardless of HIV exposure, except in those who previously tested HIV positive and are on ART) • HIV-PCR should be used as the confirmatory test for any HIV positive test result up to two years of age
Definition of a "high risk" infant at birth	• Maternal VL ≥ 1000c/ml • Maternal ART < 4 weeks prior to delivery	• Mother with a VL of ≥ 1000 c/ml at delivery (or most recent VL taken during the last 12 weeks of antenatal care), or • a mother with no VL result in the last 12 weeks of antenatal care.
Infant post exposure prophylaxis	• High risk infants: AZT for six weeks and NVP prophylaxis for 12 weeks	• High risk infants at birth: AZT for six weeks and NVP prophylaxis for a minimum of 12 weeks. Stop NVP after 12 weeks only if mother's VL is less than 1000 copies/ml. If the maternal VL is not less than 1000 c/ml by 12 weeks, continue NVP until mother's VL is less than 1000 c/ml, or until four weeks after she is no longer breastfeeding. • Guidance for management of the infant of a newly diagnosed mother during breastfeeding • Guidance on the breastfeeding mother who was previously less than 1000 c/ml and is now found to have a VL ≥ 1000 c/ml
Breastfeeding	• Breastfeeding recommended for 12 months	• Breastfeeding in the context of ART recommended for 24 months or longer, in line with recommendations for general population • Guidance on stopping breastfeeding and indications for formula feeding
TB screening and TPT for pregnant women, mothers, and their infants	• TB Gene Expert (GXP) only if TB symptom screen positive • TST to determine duration of IPT	• Isoniazid Preventative Therapy (IPT) to become known as TB Preventive Therapy (TPT) for Treatment of Latent TB Infection (LTBI) • TB GXP for all newly diagnosed women living with HIV, or known positive women with a new pregnancy diagnosis • No tuberculin skin test (TST) required • If CD4 > 100, defer TPT for pregnant women until 12 weeks postpartum • If CD4 ≤ 100 during pregnancy, initiate TPT for 12 months
Syphilis, HBV, Malaria	• Not featured	• Guidance for screening and treatment of syphilis, HBV, and malaria

2 PART 2 – PREVENTION

UNIVERSAL MEASURES TO PREVENT INFECTIONS DURING PREGNANCY

Table 2 below summarizes the universal preventative measures that all pregnant woman should observe to prevent transmission of infections to her infant during pregnancy or breastfeeding.

Table 2 *Universal Measures to Prevent Infections during Pregnancy*

The Health care provider should advise the pregnant or breastfeeding client about the following practices that may increase or decrease the risks for contracting infections	
Contact with Adults with Respiratory or Flu-Like Symptoms	• Avoid close or intimate contact with adults with communicable respiratory diseases, acute or recent fever or flu like symptoms. To prevent respiratory infections, avoid: - Kissing - Sharing food utensils, drinking from the same container • Wash hands frequently and, if available, use alcohol gel after shaking hands and before eating
Sexual Contact	• Use male latex condoms consistently and correctly. - Carefully handle the condom to avoid damaging. - Put the condom on after the penis is erect and before any genital, oral, or anal contact with the partner - To prevent the condom from slipping off, hold the condom firmly against the base of the penis during withdrawal, and withdraw while the penis is still erect. - Do not use the condom more than once • Use female condoms correctly • Avoid receptive oral sex with a partner with oral herpes or intercourse during the third trimester with men who have genital herpes. • Ensure that all sexual contacts of individuals treated for STIs are linked to care and receive STI treatment.
Blood Contact	• Consider the risks if you are thinking about getting a tattoo or body piercing. Infected tools can transmit hepatitis B or other infections • Do not share personal care items that might have blood on them (razors, toothbrushes). • Avoid using drugs. Do not share needles or other equipment related to drug use.
Contact with Children with Respiratory, Flu-Like Symptoms or Skin Rash	• Careful hand washing with soap and running water and, if available at home, use alcohol gel rub after - exposure to a child's bodily fluids and diaper changes, - bathing the child o handling dirty laundry, - touching the child's toys and other objects • Avoid close or intimate contact with the child such as - kissing on the mouth or cheek (kiss them on the head or give them a hug) - sleeping together, - sharing towels and washcloths, • Avoid contact with baby's saliva while feeding - sharing or tasting foods with the same utensils (spoons, forks) - drinking from the same container
Consuming, Handling, And Processing of Food	• Avoid eating raw or undercooked lamb, pork, beef or poultry. Cook all meat until it is no longer pink, and the juices run clear. Reheat any processed meat until steaming • Do not eat food that has passed its expiry date • Do not eat unpasteurized dairy products (including all soft cheeses), • Peel or wash raw fruit and vegetables thoroughly. • Wash hands, knives, and cutting boards after handling uncooked foods or fluids from their packages. • Wash hands thoroughly after handling raw meat
Protection from Insects	• Always use Insecticide-treated bed nets if you live in a malaria endemic area.

Table adapted from 'Perinatal Infections transmitted by the Mother to her Infant', March of Dimes Foundation, Latin American Center for Perinatology / Women and Reproductive Health - Pan American Health Organization / World Health Organization1

PREVENTION OF HIV

Family Planning (FP) and HIV testing services (HTS) should always be provided together. At every FP visit, offer HTS. At every HTS visit, offer FP

All persons of reproductive age need access to comprehensive information, as well as non-judgmental, confidential, and (as necessary), youth friendly SRH services.

WHO should be offered HIV prevention services?

- All HIV negative women, including adolecent girls, young women, and sex workers
- HIV negative partners and other men
- HIV positive persons

WHAT HIV prevention options should be offered?

BASIC PREVENTION PACKAGE

HTS services
Couples Counselling and partner testing
Screen and treat STI's
Safe sex education*
Post Exposure Prophylaxis (PEP)
Pre-Exposure Prophylaxis (PrEP) as applicable & available #

BASIC PREVENTION PACKAGE + Voluntary Medical Male Circumcision (VMMC) and communication for men

TREATMENT AS PREVENTION

HTS, couples counselling and partner testing, Linkage to Care, ART and VL suppression

Remember, condoms are recommended for all couples regardless of HIV status

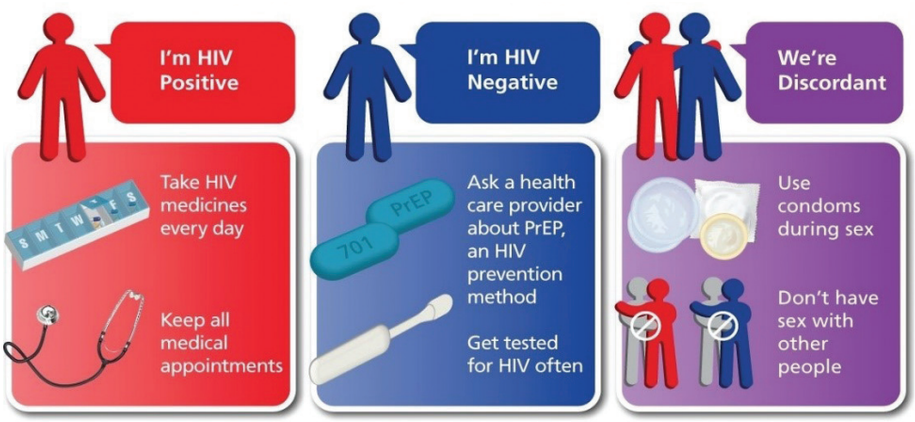
WHERE should HIV prevention services be offered?

At all contact points with the health system, including PHC, SRH services, MNCWH&N services, Chronic and Acute Care services (including hospitals)

Community based services, including mobile/outreach services for sex workers and other working persons

School based prevention (in the context of comprehensive sexuality education)

Ways to prevent HIV transmission within a discordant couple



***Safe Sex Education:**
Counsel the women to avoid the following sexual practices that could put her at risk for contracting HIV and other STI's:

- The woman or her regular partner having new or multiple sexual partners
- Unreliable use of condoms
- Alcohol abuse

***PrEP** is routinely available for adolescent girls and young women, as well as for sex workers. For PrEP in other populations consult the current PrEP guideline.*

PREVENTION OF UNINTENDED PREGNANCIES AND SAFE CONCEPTION IN WOMEN

Family planning should be an integral part of ART services!

Regularly discuss issues of childbearing and contraception to understand current fertility desires and health care needs

Ideally, engage the women living with HIV and her current partner in a couples-based approach, as the health and co-operation of both partners is important for safe contraception or conception

Classify client

A. Currently wanting to conceive

Recommend, discuss, and agree on steps before conception

Optimise HIV treatment in the partner living with HIV (serodiscordant couple), or in both partners living with HIV (sero-concordant couple).

- Continue to use condoms
- Document HIV status of both partners
- Identify and manage co-morbidities, including syphilis and other STIs
- Initiate ART and support good adherence
- Maintain an undetectable VL, ideally for 4-6 months before conception
- Start folate supplementation and do an Hb if clinically pale
- Consider PrEP for the uninfected partner

Initiating **Dolutegravir (DTG)** in women wanting to conceive now or in the future may carry risks. Counsel the mother on use of DTG in pregnancy and allow her to make an informed choice. See **Dolutegravir in Pregnancy** on page 17

Once viral load suppression is achieved in the HIV positive partner(s), the following additional options are available to make conception safer

- timed, limited, peri-ovulatory, sex without a condom
- intravaginal insemination
- male circumcision
- intra-uterine insemination
- sperm washing
- surrogate sperm donation

Not readily available in the public sector

If pregnancy confirmed, counsel the mother to book at ANC before 14 weeks and to continue using condoms consistently during pregnancy and the breastfeeding period

B. Not currently desiring a child, but may do so in the future

Counsel about options for contraception including long-acting reversible contraceptives (IUCD and implants), and barrier methods

C. No desire for a child now or in the future

Counsel about options for contraception including permanent methods (male and female voluntary sterilisation), long-acting reversible contraceptives (IUCD and implants) and barrier methods. If permanent methods are not appropriate, proceed to an alternative dual method as outlined below

Dual method is always recommended:

A hormonal method (including implants) or intra-uterine contraceptive device to prevent pregnancy

A barrier method (male/female condoms) to augment the hormonal method, and prevent STIs and HIV

Discuss the different contraceptive options available for use in the women living with HIV (See PC101, and the National Contraceptive Clinical Guideline, 2018)
Available options include:

- Injectable progestins
- Combined oral contraceptive pills.
- Intra-uterine contraceptive device
- Emergency contraception

All hormonal methods including implants (e.g. Implanon NXT®) and the long acting injectables (e.g. Depo Provera®) are effective when used with Dolutegravir. Women should be counseled about the possibility of reduced efficacy when using **progestin subdermal implants (e.g. Implanon NXT®)** with enzyme inducing drugs such as **Efavirenz, Rifampicin,** and certain epilepsy drugs. Women who are already using an implant should consider an alternative non-hormonal method for contraception e.g. the IUCD, and should continue to use condoms correctly and consistently.

3 PART 3 – CHARTS PER SERVICE DELIVERY AREA

ANTENATAL CLINIC

When caring for a pregnant woman, always be sure to:

- Recognise the pregnant client that requires urgent attention as outlined in BANC Plus and manage/refer as appropriate
- Identify the pregnant client who needs secondary level antenatal care as outlined in BANC Plus and manage/refer as appropriate
- Provide routine antenatal care to the woman not requiring urgent referral.

TESTING for HIV

HIV Testing: Provider Initiated Counselling and Testing (PICT) should be provided to all women with unknown or HIV-negative status:

- Offer an HIV test at ANC first/booking visit.
- Retest the HIV-negative mother at every routine BANC Plus visit.
- Offer couple/partner testing to promote prevention, access to HIV care and treatment, and/or manage discordant results (when one partner is HIV-positive and the other partner HIV-negative).
- If the woman and/or her partner test HIV-negative, provide **HIV prevention** information (Go to **HIV Prevention** on page 8).
- Women who choose not to be tested should be offered 'post-refusal' counselling and offered a re-test at every subsequent visit.
- If a woman tests HIV-positive at any stage, encourage testing of her other children, and linkage to HIV care and treatment as necessary.
- For the **HIV testing algorithm**, including the management of discrepant HIV test results, refer to the HTS Guideline.

TREATMENT for HIV

- Pregnant women already on ART should continue their current ART regimen pending their 1st VL result (see below). If she will now collect her ART at ANC, ensure that she is documented as a transfer-out from her former clinic, and not classified as lost-to-follow-up.
- All newly diagnosed HIV-positive pregnant women are eligible for lifelong ART regardless of gestation, CD4 count, or clinical stage.
- Creatinine and CD4 count should still be done to determine renal function and the need for prophylaxis (TB, PCP and CM).
- TDF, 3TC, and DTG (as a fixed dose combination) is the preferred regimen for women who are newly initiating ART. However, each mother should understand the risks and benefits of DTG and EFV-based regimens, and be enabled to make an informed choice. ART should be initiated on the same day as HIV diagnosis[10], and after contra-indications to ART have been excluded (Go to **ART Initiation Algorithm** on Page 18).
- Pregnant women already on ART should continue their current ART regimen pending the result of their 1st VL (to be done at entry into antenatal care as outlined below). Only if her VL is <50 c/ml, and she is no longer in the 1st trimester, offer her the option of switching to DTG. (If her VL is ≥ 50 c/ml, manage her as per the VL Non-suppression algorithm on page 21) A switch to DTG needs to be preceded by appropriate counseling on the risk for NTDs for subsequent pregnancies, postpartum contraception, and the new side-effects that may be experienced when switching to a new drug (see **DTG in pregnancy** on page 17). If she will now collect her ART at ANC, ensure that she is documented as a transfer-out from her former clinic, and not classified as lost-to-follow-up.
- Known HIV positive women, who are not currently on ART, but are ART-exposed (e.g. previous PMTCT, or previous LTFU on ART) should initiate a DTG-containing regimen. If she has a documented VL that was suppressed while she was previously on ART, start TLD. If no VL result is available, or her VL was not suppressed, start AZT, 3TC, and DTG.
- Appropriate ART literacy education should be given to the woman before she leaves the facility. (Go to **Key Adherence Messages** on page 19)
- All women living with HIV should be referred to a CHW to support adherence, breastfeeding and retention in care pre- and post-delivery.

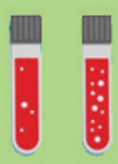
PRIMARY OBJECTIVES

1. Identify HIV infection and achieve viral suppression
2. Identify and treat syphilis and other infections

! Initiating Dolutegravir in pregnant women in the 1st 6 weeks may carry risks. Counsel the mother on use of DTG in pregnancy and allow her to make an informed choice.

Remember to put the PMTCT code: **C#PMTCT** in the EGK code field of the lab form for each VL done to ensure the electronic gatekeeping rules (EGK) do not lead to sample rejection

VL MONITORING and Management (Go to **VL Monitoring Schedule** on page 20)



Newly diagnosed and initiated ART for the first time:
- Do 1st VL at 3 months on ART.
- If VL < 50 c/ml, repeat VL at delivery.

Known HIV-positive women already on ART:
- VL at first/booking visit in ANC,
- If VL < 50 c/ml, repeat VL at delivery.

Known HIV-positive women, who are not currently on ART, but are ART exposed (e.g. previous PMTCT, or ART LTFU) and who are initiating a DTG-containing regimen:
- Do 1st VL at 3 months on ART.
- If VL < 50 c/ml, repeat VL at delivery.

If the VL is ≥50 c/ml in any of the above scenarios, go to **the VL Non-suppression Algorithm on** page 21.

✓ Early referral to community-based services improves adherence to ART, exclusive breastfeeding and retention in care

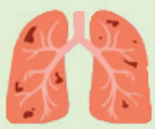
! Pregnant adolescents are at a higher risk for poor adherence and poor viral suppression and require more intense support. Go to **"The Pregnant Adolescent"** on Page 22

! Remember to insert the laboratory barcode sticker and record all VL, TB, and syphilis results in the Maternity Case Record/ANC Card, and the ART Clinical Stationery (if available in that facility)

SCREENING for TB and other OI's

Screen for TB at every visit regardless of HIV status and consider TPT if eligible. Ensure any woman diagnosed with TB is adherent to TB treatment and that she is aware that her newborn may require TB prophylaxis (Go to **TB screening and TPT** on page 27). Initiate Cotrimoxazole Prophylaxis (CPT) if CD4 count ≤ 200 cells/μL, or WHO clin6cal stage 2, 3, or 4.

If CD4 ≤100 cells/uL the lab will automatically perform a Cryptococcal Antigen test (CrAg). CrAg-positive clients who are pregnant should be offered an LP (regardless of symptoms) and discussed with an expert before a decision is made regarding management.



PREVENTION of transmission of Syphilis, HBV and other infections

Syphilis: Test all women for syphilis and screen for other STI's, e.g. gonorrhoea, at their first ANC visit. (Go to **Syphilis** on Page 31)
- If the first test is performed before 20 weeks gestation and is negative, a second test should be done at 32 to 34 weeks.
- Treat all women with a positive syphilis screening test, irrespective of titer (MCG, PC101).

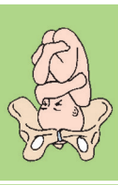
HBV: All woman living with HIV will automatically be treated for HBV when they start routine 1st line ART containing TDF and 3TC/FTC. If she should need to switch to 2nd line ART, HBsAg should be checked. If HBsAg is positive, TDF should be retained as a fourth drug in her new regimen. If a HIV negative pregnant woman is known to have HBV infection, she should be referred for further tests to determine eligibility for treatment. All babies should receive hepatitis B vaccinations in accordance with the EPI schedule.

Malaria: Although MTCT is rare, malaria in pregnancy poses serious risks for both the mother and the baby. Malaria presents as a febrile illness and is often unrecognised or misdiagnosed with severe consequences. The most important aspect of making a diagnosis of malaria is having a high index of suspicion. If a woman presents with fever in pregnancy, always ask about her travel history. Refer any woman with signs of severe illness or danger signs as outlined in PC101. Comprehensive information on Malaria in Pregnancy is available in the Guideline for Maternity Care in South Africa, and the National Guideline for the Treatment of Malaria SA.

Other Care

- Routine antenatal care according to the BANC Plus guideline. Encourage male partner involvement throughout antenatal care.
- Nutritional screening for mother. Refer any woman with a BMI of less than 23 to a dietician
- Counselling on infant feeding. See the **Infant and Young Child Feeding Policy**.
- Mental health screen for mother
- Assist the mother to register on Mom-Connect

! TB and other non-pregnancy related infections remain an important cause of maternal and neonatal mortality



LABOUR AND DELIVERY

PRIMARY OBJECTIVES

1. Safe delivery for mother and infant
2. Prevent MTCT during labour

TESTING for HIV

PICT should be provided to all women presenting in labour ward who are not known to be HIV-positive (including born-before-arrivals [BBAs]):

- Offer couples counselling and partner testing. For the management of the discordant couple, go to the **HIV Prevention** section on page 8.
- Women who choose not to be tested should be offered 'post-refusal' counselling and offered a re-test at every subsequent visit.
- If a woman tests positive at any stage, encourage testing of her other children, and linkage to HIV care and treatment as necessary.
- If a woman has indeterminate or discrepant HIV test results, treat the baby as a high-risk HIV-exposed infant until mother's HIV status can be confirmed. Communicate clearly to the mother and document the results and plan of action in the maternal record and RTHB.

Antiretrovirals

Pregnant women already on ART should continue their current ART regimen at usual dosing times during labour.

Newly diagnosed, or known HIV positive women not on ART:

- Give a stat single fixed dose combination tablet of TDF, 3TC and DTG (TLD) and a stat single dose of NVP.
- Lifelong ART should be initiated the following day after contra-indications to ART have been excluded (Go to **ART Initiation Algorithm** on Page 18). TLD is the preferred regimen, provided the mother has been provided with all necessary information on DTG and EFV-based regimens including the risk of NTDs. A contraceptive method is recommended. Provide her with a choice of contraceptive options as desired.
- Appropriate ART literacy education should be given to the women before she leaves the facility. (Go to **Key Adherence Messages** on Page 19).
- Mothers must understand and anticipate the adherence challenges that may be experienced in the postpartum period.

! An elevated viral load at delivery increases the risk for poor maternal outcomes and MTCT during labour and through breastfeeding.

VL MONITORING and Management

Check if the mother has had a VL result in the last 12 weeks and categorize the risk for the infant:

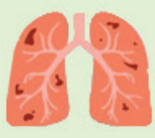
- VL < 1000c/ml = Low risk
- VL ≥ 1000 c/ml = High risk
- No VL result in the last 12 weeks = High risk

All women must have a VL test done at the time of delivery.
Although this VL result will mostly still be unknown when infant prophylaxis is initiated, remember to insert the laboratory barcode sticker into the postnatal discharge form and the RTHB.
The results of the delivery VL must be checked at the 3-6-day postnatal visit, and the management of the mother-infant pair adjusted accordingly.

Remember to put the correct PMTCT code in the EGK code field of the lab form for each VL done to ensure the electronic gatekeeping rules (EGK) do not lead to sample rejection.
Use the code **C#Delivery** for all VLs done at the time of delivery.

SCREENING for TB and other OI's

- Screen all women for TB at entry to the labour ward, and initiate TPT for women living with HIV before discharge, if eligible (Go to **TB Screening and TPT** on page 26).
- Initiate Cotrimoxazole Prophylaxis before discharge if CD4 count ≤ 200 cells/uL, or WHO clinical stage 2, 3, or 4.



Other Care for the Mother living with HIV at delivery

Provide routine labour and delivery management according to the Maternity Guidelines of SA, including safe delivery techniques for the HIV positive mother:

- Avoid episiotomy & assisted delivery unless essential. Avoid prolonged rupture of membranes. Avoid unnecessary suctioning of the infant.
- If C/section required: Provide prophylactic antibiotics for all HIV-positive women according to the Maternity Care Guidelines 2016.

Within 1 hour of delivery

- Encourage skin-to-skin contact with baby and initiate exclusive breastfeeding. Hospitals and labour wards can support mothers to breastfeed by following the WHO **10 Steps to Successful Breastfeeding** on Page 28. In addition, counsel mother on **Breastfeeding Plus** on page 29.

At discharge

- Ensure contraception has been administered after appropriate counselling (go to **Contraception and Safe Conception** Page 9).
- Provide the mother with two-months' supply of ART and six-weeks supply of infant prophylaxis.
- Communicate follow-up appointment dates for the six-day post-natal visit at a named facility. Provide necessary referral letters. Provide an ART transfer-out letter, if she will receive her ART at a different facility. However, it is recommended that the mother-baby pair continue to receive integrated care within the maternal and child health stream until the baby is two years old or no longer breastfeeding.

Care of the HIV-exposed Infant at Delivery

All HIV-exposed Infants should receive a birth HIV-PCR to identify HIV transmission that occurred in-utero.
All HIV-exposed Infants should receive a minimum of six weeks post exposure prophylaxis with NVP.

Identify the high-risk infants for whom additional prophylaxis must be provided:

- Mother with a VL of ≥ 1000 c/ml at delivery (or most recent VL taken during the last 12 weeks of antenatal care), or
- Mother with no VL result in the last 12 weeks.
- These infants should be provided with high-risk prophylaxis until the result of the delivery-VL can be checked at the 3-6-day postnatal visit. When the delivery-VL result is known, the infant can be re-classified as high/ low-risk and prophylaxis adjusted accordingly.

All high-risk infants who are breastfed should receive additional AZT for the first six weeks of life and should receive NVP for a minimum of 12 weeks. NVP should only be stopped when the breastfeeding mother has a VL of less than 1000 c/ml, or until four weeks after she has stopped breastfeeding. All high risk infants who are exclusively formula fed should receive AZT for 6 weeks and NVP for 6 weeks. (Go to **HEI Prophylaxis Infographic and the NVP and AZT dosing chart** on Page 23)

Provide oral polio vaccine, BCG and other routine neonatal care as per the Maternity Care and Neonatal Care Guidelines. Do not give BCG if baby is TB-exposed, and will be receiving TB prophylaxis (Go to **Management of the TB-Exposed Infant** on Page 27).

PREVENTION of transmission of Syphilis, HBV and other infections

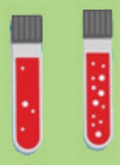
Syphilis: Examine and treat the newborn of the RPR positive mother (go to Syphilis on page 31):
Well (asymptomatic) baby: Treat baby with benzathine penicillin 50 000u/kg IM stat only if:

- Mother was not treated, or
- If the mother has received < 3 doses of benzathine benzylpenicillin, or
- If the mother delivers within 4 weeks of commencing treatment.

Symptomatic baby (hepatosplenomegaly, pseudoparesis, snuffles, oedema, jaundice, anaemia, purpura, desquamative rash -especially involving palms and soles): Refer all symptomatic babies for treatment of congenital syphilis: procaine penicillin 50 000 u/kg IM daily for 10 days, or benzyl penicillin (penicillin G) 50 000 u/kg/dose 12-hourly IV for 10 days.

HBV: All babies should receive hepatitis B vaccinations in accordance with the EPI schedule.

CARE OF THE MOTHER AFTER BIRTH

	6 DAYS	6 WEEKS	10 WEEKS	6 MONTHS	18 MONTHS
TESTING for HIV 	Retest the HIV-negative mother if she was not retested in labour		Retest every HIV-negative mother at the **10-week visit** (~ three months postpartum), the **six-month visit**, and every **three months** whilst breastfeeding Remember to offer partner testing. If no longer breastfeeding, ensure that the mother receives an HIV test at least every year		
Antiretrovirals 	**Mother to continue ART** during the postpartum period and **for life**. If she is **newly diagnosed during the breastfeeding period**, initiate ART after contra-indications to ART have been excluded (Go to **ART Initiation Algorithm** on Page 18). Provide appropriate counselling on available ART options. TDF, 3TC, and DTG (TLD) is the preferred regimen, provided the mother has been given all necessary information on DTG and EFV-based regimens including the risk of NTDs. This is a high-risk period for poor **adherence**. Ensure that the mother understands the importance of continued viral suppression for her own health and that of her baby. She must also understand and anticipate the adherence challenges that may be experienced in the postpartum period. Link the mother to mom-connect, a CHW, a mentor mother, or a support group/club if available (See **Post-natal Clubs** on Page 34). Whether continued ART care is provided at MNCWH services (preferred) or at PHC/Wellness services, ensure that mother is **retained in care, adherent to ART, and maintains a suppressed viral load.**				
VL MONITORING and Management 	Check ART adherence Follow-up on result of **delivery-VL**. (If not yet available, follow-up again in 1 week. If VL not done at delivery, do VL at this visit) **If VL ≥ 50 c/ml:** manage mother as per **VL Non-suppression Algorithm** on Page 21. **If VL ≥ 1000 c/ml:** manage infant as a high-risk infant i.e. add AZT for six weeks, and extend NVP until mother's VL is <1000 c/ml.	Check ART adherence Repeat VL if delivery-VL was ≥ 1000 c/ml. Check mother's ART supply and confirm where she will be receiving her ongoing ART care	Check ART adherence Check, record and act on any earlier VL tests Check mother's ART supply and confirm where she will be receiving her ongoing ART care	Check ART adherence at every visit. Check, record and act on results of any earlier VL tests Do a VL for all HIV-positive mothers on ART at six months. Continue VL monitoring every six months (at 12,18, and 24 months) whilst breastfeeding. Ensure that the results of any VL test are checked within 1 week. If VL ≥ 50c/ml: • Recall the mother-infant pair to the facility • Manage mother as per **VL Non-suppression Algorithm** on Page 21 If VL ≥ 1000 c/ml: • Restart/extend infant prophylaxis if mother is still breastfeeding. Go to **Management of a High Maternal VL after Delivery** on Page 25.	
SCREENING for TB and other OI's	• Routine postpartum care as per the Maternity Care Guideline • TB screening, TPT, and CTMX according to guidelines • Mental Health: Screen for postpartum depression • Contraception and STI screening • Infant feeding counselling and support according to the Infant and Young Child Feeding Policy • Counselling on safe use of water, sanitation and hygiene (WASH) • A papsmear can be done from six weeks onwards		• TB screening, TPT, and CTMX according to guidelines • Mental Health: Screen for postpartum depression • Contraception and STI screening • Infant feeding counselling and support according to the Infant and Young Child Feeding Policy • Counselling on safe use of water, sanitation and hygiene (WASH) • Papsmear (if indicated)		

! Viral Load suppression is critical for the health of the mother, her baby, her subsequent pregnancies, and her partner!

PRIMARY OBJECTIVES

1. Prevent MTCT through Breastfeeding
2. Retain Mother in Care
3. Achieve and Maintain Viral Suppression

CARE OF THE HIV-EXPOSED INFANT AFTER BIRTH

HIV Testing and Early Infant Diagnosis

3-6 DAYS	6 WEEKS	10 WEEKS	6 MONTHS	18 MONTHS	OTHER TESTS (at any time)
Follow-up results of birth PCR and manage accordingly. Any HIV positive neonate should be discussed/referred to a clinician experienced in managing an HIV-positive neonate. ART should be initiated even if the infants weighs less than 2,5 kg.	Ensure that birth PCR and mother's VL results were checked, recorded and acted upon correctly.	HIV-PCR for all HIV-exposed infants who previously tested HIV-PCR negative.	**Known HIV-exposed infants:** • Do HIV-PCR test at 6 months in all HIV-exposed infants, except in those who previously tested positive and are on ART.	Universal HIV testing at 18 months (HIV rapid test for ALL infants regardless of HIV exposure, except in those who previously tested HIV positive and are on ART)	Do an age-appropriate HIV test 6 weeks post cessation of breastfeeding, even if breastfeeding continues beyond 18 months of age. Test a symptomatic child at any age according to IMCI guideline.

! The HIV-exposed but uninfected (HEU) child is at higher risk for poor outcomes and requires careful follow-up. Go to **"Care of the HEU Infant"** on page 30

! Use the **NHLS Results for Action (RfA) Reports for action** to follow up on lab results (See page 34). Any child with a positive, indeterminate, or not-resulted PCR should be traced to come back to the clinic urgently. A clinical audit can provide insight into reasons for the failed PMTCT

Infants not known to be HIV-exposed:
- At six months of age, establish the HIV status of all infants not already known to be HIV-exposed
- Offer an HIV test to the mother. If she tests HIV negative, no infant test is required
- If the mother is not available, or refuses an HIV test, get consent and do an HIV rapid test on the infant
- All positive infant rapid tests need to be confirmed with an HIV-PCR.

Confirmatory test for HIV

Any child under two years with a positive HIV-PCR or a positive HIV rapid test should have their HIV status confirmed with a **HIV-PCR test on a new sample**. At the clinician's discretion, the HIV-PCR may be replaced by a viral load test which has the advantage of both confirming the HIV diagnosis and providing a baseline VL for monitoring the child's response to ART. **Any child who tests HIV positive should initiate ART** according to the Paediatric ART guideline as a matter of urgency. Do not wait for the confirmatory result before initiating ART **but ensure that this result is checked**. For the **Management of Indeterminate HIV PCR results**, go to page 25.

AGE OF CHILD	HIV SCREENING TEST	HIV CONFIRMATORY TEST
Less than 18 months	PCR	PCR
18 months to 2 years	Rapid	PCR
More than 2 years	Rapid	Rapid

Infant Prophylaxis

Check **adherence**/ tolerance to NVP (and AZT, if applicable). Ask the mother to explain how she administers the infant's medication. Check result of mother's delivery-VL.

If necessary re-classify infant as high/ low-risk and adjust prophylaxis accordingly.

See the **Infant Prophylaxis Infographic** and the **NVP and AZT dosing chart** on Page 23.

All HEI's: Start cotrimoxazole prophylaxis therapy (CPT), even if birth PCR was negative. Go to **Cotrimoxazole Dosing Chart** on Page 23

Low-risk infant:
Stop NVP if mother's VL at delivery was <1000 c/ml.

High-risk infants:
- **stop AZT**,
- **continue NVP** for a minimum of 12 weeks, or until four weeks after all breastfeeding has stopped

High-risk infants: Continue NVP prophylaxis. Ask mother to return at 12 weeks to evaluate VL result and stop/ extend NVP as necessary

At every visit, check results of mother's most recent VL. An elevated VL may require high-risk infant prophylaxis (6 weeks AZT twice daily and 12 weeks NVP daily) to be restarted or existing NVP prophylaxis to be extended. Go to **Management of a High Maternal VL after Delivery** on Page 25.

! Remember to adjust NVP dosages according to weight

Stop NVP after 12 weeks only if mother's VL is < 1000 c/ml. If the maternal VL is not suppressed by 12 weeks, continued NVP **until mother's VL is <1000 c/ml**, or until four weeks after all breastfeeding has stopped.

Continue **cotrimoxazole prophylaxis** until infant is confirmed HIV negative six weeks post cessation of breastfeeding. For formula fed infants, CPT may be stopped if the infant is confirmed to be HIV negative at the 10-weeks PCR test, provided that no breastfeeding has occurred in the six weeks prior to the 10-week PCR test.

If a child tests **HIV positive** at any stage, **stop NVP** prophylaxis, **initiate ART**, do a confirmatory HIV PCR, and continue cotrimoxazole prophylaxis according to guidelines.

! For any child that tests HIV-positive ensure that:
- Confirmatory testing has been done and the child is tracked and linked to care,
- The mothers and other significant caregivers are counselled appropriately,
- CHWs are involved,
- The child is registered on Tier.net & retained in care.

If mother diagnosed with HIV after delivery or during the breastfeeding period go to **Management of a High Maternal VL (due to HIV Diagnosis) after Delivery** on Page 24

Other Routine Care

Routine growth monitoring, immunisations, nutritional support. Provide advice to support breastfeeding. Go to **Breastfeeding Plus** on Page 29

Routine growth monitoring, immunisations, vit A, deworming and nutritional support. Provide advice to support **breastfeeding**. Go to **Breastfeeding Plus** on Page 29

THE COMMUNITY HEALTH WORKER

Early referral to community-based services improves adherence to ART, exclusive breastfeeding and retention in care

Care of the non-pregnant woman of child bearing potential (CBP) at home

- Ask if she is using reliable family planning, and if not, refer to the clinic. Discuss the advantages of planned parenthood.
- Screen all woman of child bearing potential (CBP) for pregnancy. If she is not on reliable contraception or her period is late, provide/refer her for a pregnancy test.
- Encourage all girls, boys, women, and men to test for HIV if they are sexually active. Offer an HIV test to the woman and her partner if they have not tested in the last year.
- Discuss healthy nutrition with the family.

Encourage pregnant women to attend at the antenatal clinic

- Identify pregnant woman early.
- Encourage booking at the antenatal clinic before 14 weeks.
- Encourage attendance of all 8 antenatal appointments.
- Track and trace any woman who missed their clinic appointments.

Identify the pregnant woman living with HIV

- Check that she has been offered an HIV test during this pregnancy.
- Encourage partner testing.
- Encourage testing of any other children living in the household if she tests positive for HIV.

Counsel all pregnant women on good nutrition and following a healthy lifestyle

- Discuss infant feeding.
- Follow a healthy diet.
- Avoid tobacco, alcohol, drugs and traditional remedies.
- Wash your hands after using the toilet, before and after preparing food, or after changing a baby's diaper/nappy.
- Practice safe sex and continue to use condoms.

Prevent mother to child transmission of HIV, syphilis and TB

- Provide education on STI's, HIV, ART and the importance of viral load suppression.
- Encourage adherence to ART and all other treatment provided by the clinic.
- Counsel on the importance of exclusive breastfeeding
- Screen all woman for TB and STI's

Promote safety during pregnancy and delivery

- Educate her and her family on danger signs in pregnancy.
- Educate her on the signs of labour.
- Encourage the mother to deliver in a clinic or hospital.
- Encourage her to plan her mode of transport to the delivery site.

Postnatal care for mother and baby

- Check mother for bleeding, infections, mastitis, and depression. Screen the mother for TB.
- Refer mother or baby at any stage if ill, including the jaundiced (yellow-skinned) baby.
- Educate mother on universal infection control practices if either mom or baby are ill (Go to **Universal Measures to Prevent Infections during Pregnancy** on page 7).
- Provide support for exclusive breastfeeding and advise on latching and positioning of baby whilst feeding.
- Educate on hygienic cord care and keeping the baby warm (thermal care).
- Continue to support good adherence to ART, cotrimoxazole (if indicated), and other treatment.
- Make sure that the mother is giving infant NVP (and AZT) correctly (NVP once daily and AZT twice daily).
- Make sure mother and baby attend all postnatal check-ups and immunisation appointments.
- Check that baby is growing well.
- Educate mother on contents of RTHB, including infant nutrition and danger signs in infants and children.

4 PART 4 – ALGORITHMS AND DECISION TOOLS

DOLUTEGRAVIR (DTG) IN PREGNANCY

BENEFITS OF DOLUTEGRAVIR[16]

- ✓ Superior Efficacy
- ✓ Side-effects are mild and uncommon
- ✓ High genetic barrier to resistance
- ✓ Cost effective
- ✓ Small tablet
- ✓ No interaction with hormonal contraceptives
- ✓ Can be used with TB treatment if boosted

! Calcium supplements decrease DTG concentrations if taken together on an empty stomach. To prevent this, DTG and calcium supplements can be taken at the same time after food intake. Magnesium/ aluminium containing antacids decrease DTG concentrations regardless of food intake and should be taken a minimum of 2 hours after or 6 hours before DTG. Iron and calcium supplements should be taken at least 4 hours apart.

Dolutegravir with TDF and 3TC/FTC as a fixed dose combination (TLD) is now the preferred first line regimen in South Africa for all persons except women who actively want to conceive, and women in the first 6 weeks of pregnancy

Standard dose: 50 mg daily

DTG requires **boosting with TB treatment to 50 mg twice daily.** This will require one standard fixed dose combination tablet of TLD to be taken at the normal time, and an additional single tablet of DTG 50 mg to be taken 12 hours later.

! #Never switch only one drug in a failing regimen. Ensure that her VL is <50c/ml before switching from EFV to DTG, or from DTG back to EFV should she desire to become pregnant

Risk of Neural Tube Defects

There are some concerns regarding the risk of neural tube defects (NTD) if a woman should fall pregnant on DTG. Therefore:

- Women should be counseled about the potential risk of NTDs when DTG is taken around the time of conception and be allowed to make an informed choice.
- Any non-pregnant woman taking or starting DTG should be advised to use contraception and folic acid supplements.
- Once a non-pregnant woman is taking DTG, fertility intentions should be discussed at every visit. Should she desire a pregnancy, and she is concerned about the risk of NTDs, she can be offered a switch from TLD to TEE, provided that she has a suppressed VL in the last 6 months.
- Woman who fall pregnant on DTG should be entered into the antiretroviral pregnancy register (http://www.APRegistry.com/)
- Pregnant women already on an EFV containing ART regimen may switch to DTG containing regimen provided that:
  - Her most recent VL in the last 6 months is <50 c/ml.
  - She has been counseled on the risk for NTDs for subsequent pregnancies, and the need for postpartum contraception.
  - She is aware of the side-effects that may be experienced when switching to DTG (insomnia, headache, GIT disturbances). These are usually mild and self-limiting. If she does not feel well, encourage her not to stop her ART, but rather to report to the clinic.
  - She is aware that whilst her previous TEE regimen was taken at night, TLD may be taken in the morning or at night. However, should she experience insomnia, it is recommended that TLD be taken in the morning.

POTENTIAL RISKS OF USING DTG AROUND THE TIME OF CONCEPTION[12]

DTG may increase the risk of neural tube defects (NTDs). The absolute risk is very low and translates into a risk difference of 2 additional NTDs per 1000 periconception exposures to DTG (0.3% risk), compared to EFV ART at conception (0.1% risk). DTG should be avoided periconception and in the first 6 weeks of pregnancy. The neural tube closes by the end of the sixth week of pregnancy (fourth week post-conception). DTG appears to be safe if started after the neural tube has closed. Thus, there is no risk of NTDs with TLD use after this period.

! **Effective contraception**

All women of child bearing potential should be screened for pregnancy before initiating DTG. It is recommended that any non-pregnant woman taking or starting DTG should be provided a choice of contraceptive options, which includes condoms, oral contraceptives, implants, injectables, and intra-uterine contraceptive devices (IUCDs). Dual methods are recommended. DTG does not have any known drug interactions with long acting hormonal contraceptives.

Adult Women and Adolescent Girls ≥ 35 kg[1] and ≥ 10 years of Age

Women or Adolescent Girls of Childbearing Potential?

NO → TLD recommended

YES → Determine current pregnancy status and fertility intentions

Pregnant, up to 6 completed weeks of gestation, or actively wanting to conceive in the near future[2]

Provide all necessary information on DTG and EFV-based regimens including the risk of NTDs for this and subsequent pregnancies
Discuss postpartum contraceptive options[3]

TEE recommended

All other WOCP, including:
Pregnant, from 7 weeks gestation onwards
Not pregnant, and not currently desiring to become pregnant

Provide all necessary information on DTG and EFV-based regimens including the risk of NTDs and recommend contraception. Provide her with a choice of contraceptive options as desired [3]

TLD recommended

Client makes an informed choice after understanding risks and benefits

TEE [1, 4]

TLD [1, 5, 6]

1 For adolescent girls who weigh less than 35 kg, replace tenofovir with abacavir (ABC)

2 Women wanting to conceive should be started on folate and should be counselled to defer attempts to conceive until they are virally suppressed. See also "Contraception and Safe Conception" on page 9 of the PMTCT guideline.

3 Women should be provided a choice of contraceptive options (which includes condoms, oral contraceptives, implants, injectables, and IUCDs)

4 Women who choose to use TEE around the time of conception can be offered a switch to TLD if their VL is suppressed at 3-months on ART.

5 Documentation that the woman has been counselled and consents to receive DTG must be included in the patient's chart/file.

6 If a woman's fertility intentions change and she is concerned about the risk of NTDs, she can be offered a switch from TLD to TEE, provided that she has a suppressed VL in the last 6 months

* For adolescent girls who weigh less than 35 kg, replace tenofovir with abacavir (ABC)

ART INITIATION ALGORITHM

Any pregnant or breastfeeding women with a new HIV diagnosis, or any known positive woman (not currently on ART) with a new pregnancy diagnosis

* Known HIV positive women, who are not currently on ART, but are ART-exposed (e.g. previous PMTCT, or previous LTFU on ART) should initiate a DTG-containing regimen. If she has a documented VL that was suppressed while she was previously on ART, start TLD. If no VL result is available, or her VL was not suppressed, start AZT, 3TC, and DTG

! Timing of ART initiation in pregnancy is critical. Every week a mother is on ART further decreases her risk of MTCT[10]

Take a history and do a clinical examination:
Exclude contra-indications to starting ART on the same day. Ask about TB symptoms, a history of renal disease, or current psychiatric symptoms. Determine the client's WHO Clinical Stage. Start cotrimoxazole (CPT) if eligible.
Do the following tests on ALL HIV positive pregnant women, regardless of symptoms or history: **CD4 count, s-Creatinine, sputum for TB Gene Expert (GXP), and urine dipstix**

TB Symptoms with danger signs:
If the woman appears very ill with any of the following signs, **discuss with a doctor or refer for further assessment. Do not start ART until TB is excluded/diagnosed as these women may be at a higher risk of developing IRIS:** weight loss > 5%, difficulty breathing, respiratory rate >30/min, temperature > 38°C, pulse > 100min, BP < 90/60, coughing up blood, confusion, agitation, or unable to walk unaided.

TB Symptoms without danger signs

History of renal disease

If no abnormal history

Initiate ART same day: TDF, 3TC/FTC, and DTG preferred*
(See algorithm on **Recommendations Regarding the Use of DTG in WOCP** on page 17)
If TDF contraindicated due to history of/suspected renal disease replace TDF with ABC.
Review results in 3-7 days

Ensure a thorough evaluation for TB

TB GXP negative, but still TB symptoms

TB GXP positive

Investigate with CXR, 2nd sputum for culture/line probe assay (LPA) +/- antibiotics as per National TB Guidelines. If CD4 <100, do a urine LAM.

TB Diagnosis confirmed → **Initiate TB Rx**

Review in 2 weeks. If stable and tolerating TB Rx, initiate ART (if not already initiated). DTG requires boosting with TB treatment to 50 mg twice daily. If TB symptoms worsen after ART initiation, consider TB IRIS and refer/discuss with the HIV hotline. If TB meningitis, defer ART for 4 to 6 weeks.

TB GXP negative (or unable to produce sputum), AND no TB symptoms

Continue ART: TDF, 3TC/FTC, DTG*

CD 4 ≤ 100

Do CrAG

CrAG neg

CrAG pos

Initiate TPT for 12 months, if client tolerating ART
Ensure TB GXP and urinary LAM negative.
Exclude other contra indications to TPT.
No TST necessary.
(Go to **TB Screening and TPT algorithm** on page 26)

Refer Urgently for LP

Creatinine > 85 umol/L

Continue/adjust ART to **ABC**, 3TC and DTG.
Adjust dose of 3TC (and any other drugs) as needed.
Discuss with an expert/HIV-hotline re further investigations and management.

No abnormal results and CD4 more than 100

Continue ART

Defer TPT until 6 weeks after delivery

[$]Only switch an existing, stable client from EFV to DTG if her VL is <50c/ml and she is no longer in the first 6 weeks of pregnancy. A switch to DTG needs to be preceded by appropriate counseling on the risk for NTDs for subsequent pregnancies, postpartum contraception, and the new side-effects that may be experienced when switching to a new drug. See DTG in pregnancy on page 17.

For a **Summary of 1st line ART Regimens** go to page 19

KEY ADHERENCE MESSAGES
(NATIONAL ADHERENCE GUIDELINE, 2015)[11]

Step 1 Education about HIV

- What does HIV do to your body?
- How taking ART can help you?
- The importance of VL suppressions for mother and baby.
- Risks of poor adherence.
- Side-effects of ART.

Step 2 Identify Life Goals

- What are the things that make you want to stay healthy and alive?

Step 3 Identify Support Systems

- Who could support you in taking your treatment?
- Would you agree to have a CHW visit you at home?

Step 4 Coming to your appointments

- What will you do if something prevents you from coming to your appointment (such as no money for transport, raining when you usually walk, taxi strike or a sick child, or any other reason)?
- Go to the clinic as soon as possible if you do miss an appointment or run out of ART
- Always take your medication with you to your clinic appointments to enable the HCW to better assist you

Step 5 Assess readiness to start ART

- Do you feel ready to start treatment as soon as possible?

If not, stay supportive. Invite client to express their beliefs or concerns.Correct misconceptions (avoiding judgments).

! Do not turn away an ART client who reports to have run out of treatment and presents without a transfer letter!

Step 6 Medication schedule

- According to your schedule, what would be the best time for you to take your treatment?

Step 7 Reminders

- What could you use to remind you to take your medication? (e.g. alarm, someone to remind them, when "Generations" is starting on TV, etc.)

Step 8 Missed Doses

- What will you do if you miss a dose?

Advise them to take the treatment as soon as they remember.

Step 9 Storing your medication and extra doses

- Do you worry about people seeing or stealing your treatment?
- Which safe place could you identify to store your treatment? Check that it is outside the reach of children.
- In case you don't have access to your treatment at the time you are supposed to take it, how can you always carry 1 or 2 doses with you?

Step 10 Managing Side-effects

- Side-effects such as dizziness, nausea, headache or diarrhea can happen when starting treatment. Most side-effects go away after a few weeks. If you vomit up to one hour after taking the medication, take your treatment again. Severe side-effects are rare. If you don't feel well, it is important you don't stop your treatment and come to the clinic.

SUMMARY OF 1ST LINE ART REGIMENS FOR ADOLESCENTS GIRLS (10 – 19 YEARS) AND ADULT WOMAN

Any WOCP with normal renal function, with or without TB, and who chooses to use DTG after understanding the risk and benefits	Weight ≥ 35 kg	TDF 300 mg, 3TC 300 mg, DTG 50 mg (TLD) as a single fixed dose combination tablet taken once daily
	Weight < 35 kg	Replace TDF with Abacavir 300mg bd (or 600mg once daily)
	DTG requires boosting with TB treatment to 50 mg twice daily. This will require one standard fixed dose combination tablet of TLD to be taken at the normal time, and an additional single tablet of DTG 50 mg to be taken 12 hours later.	
Clients who currently wish to conceive and are concerned about the risk for NTDs on DTG	Weight ≥ 40 kg	TDF 300 mg, FTC 200 mg, EFV 600 mg (TEE) as a single fixed dose combination tablet taken once daily in the evening
	Weight < 40 kg	TDF 300 mg daily, 3TC 300 mg daily, Efavirenz 400 mg daily
Abnormal renal function	Tenofovir (TDF) is contraindicated	Replace TDF with Abacavir 300mg bd (or 600mg once daily), or dose-adjusted AZT
Active psychiatric illness	Efavirenz (EFV) is contraindicated	Replace EFV with DTG. If DTG not suitable and CD4 < 250, give Nevirapine (NVP) 200 mg daily for 2 weeks, then 200 mg twice daily, or, if CD4 > 250, give LPV/r
Known HIV positive women, who are not currently on ART, but are ART-exposed (e.g. previous PMTCT, or previous LTFU on ART)	VL < 50 c/ml while previously on ART	TDF 300 mg, 3TC 300 mg, DTG 50 mg (TLD) as a single fixed dose combination tablet taken once daily
	Unsuppressed VL, or no documented VL while previously on ART	AZT 300 mg twice daily, 3TC 150 mg twice daily (or 300 mg once daily), and DTG 50 mg daily

For further information see the **2019 Consolidated ART Guideline**

MONITORING BLOODS ON ART

These monitoring bloods are in addition to the **VL monitoring schedule** on Page 20

Time on ART	Creatinine (only if on TDF)	CD4	FBC (only if on AZT)	ALT (only if on NVP)
At ART Initiation	✓	✓	✓	Only if client develops rash or symptoms of hepatitis
Month 3	✓		✓	
Month 6	✓		✓	
At 1 year	✓	✓		
Annually	✓	If clinically indicated	✓	

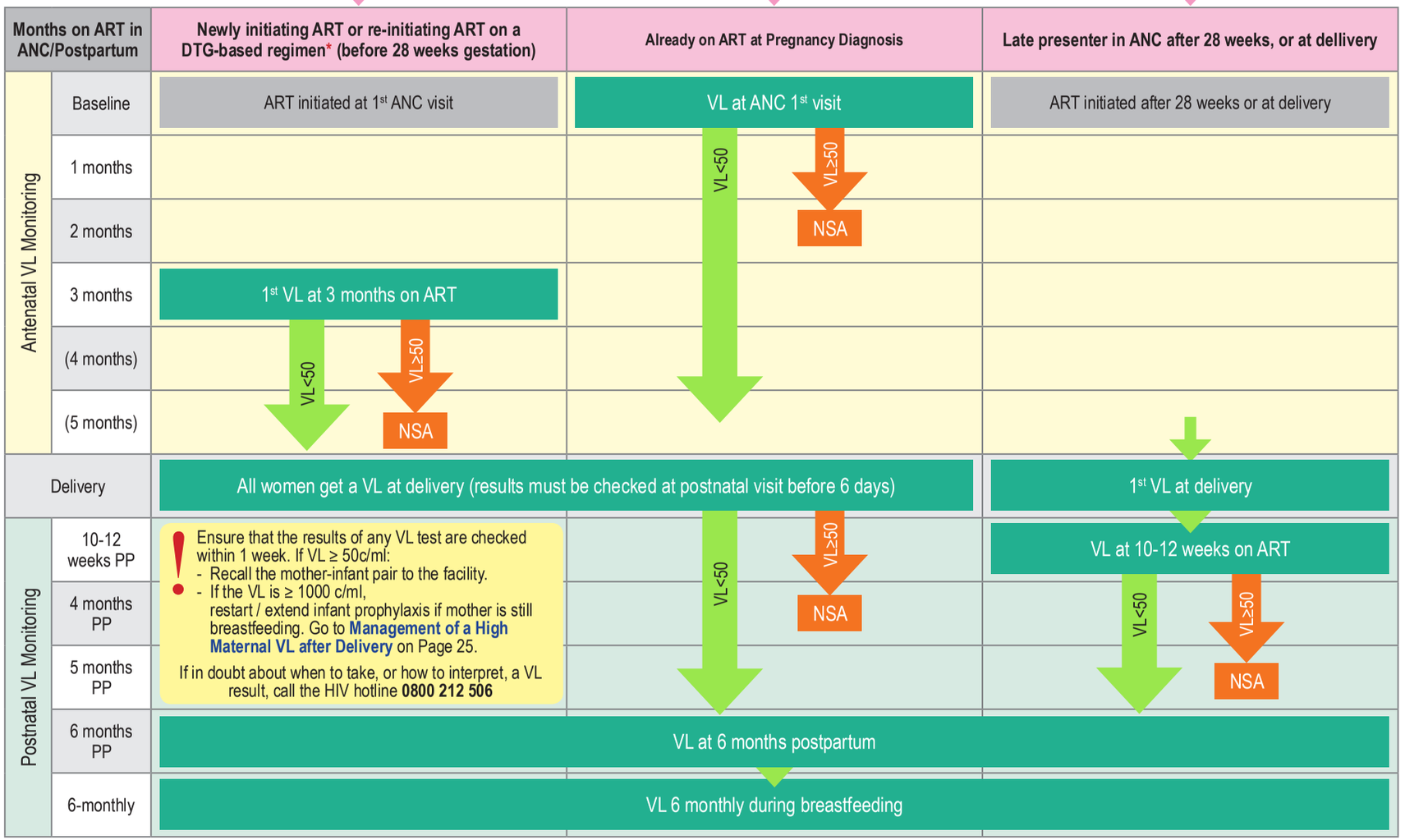
Do HB and HBsAg if switching from 1st to 2nd line ART

NSA refers to the **VL Non-Suppression Algorithm** on the next page

Remember to put the correct PMTCT code in the EGK code field of the lab form for each VL done to ensure the electronic gatekeeping rules (EGK) do not lead to sample rejection.
Use the code **C#PMTCT** for all VLs done during ANC or the breastfeeding period.
Use the code **C#Delivery** for all VLs done at the time of delivery.

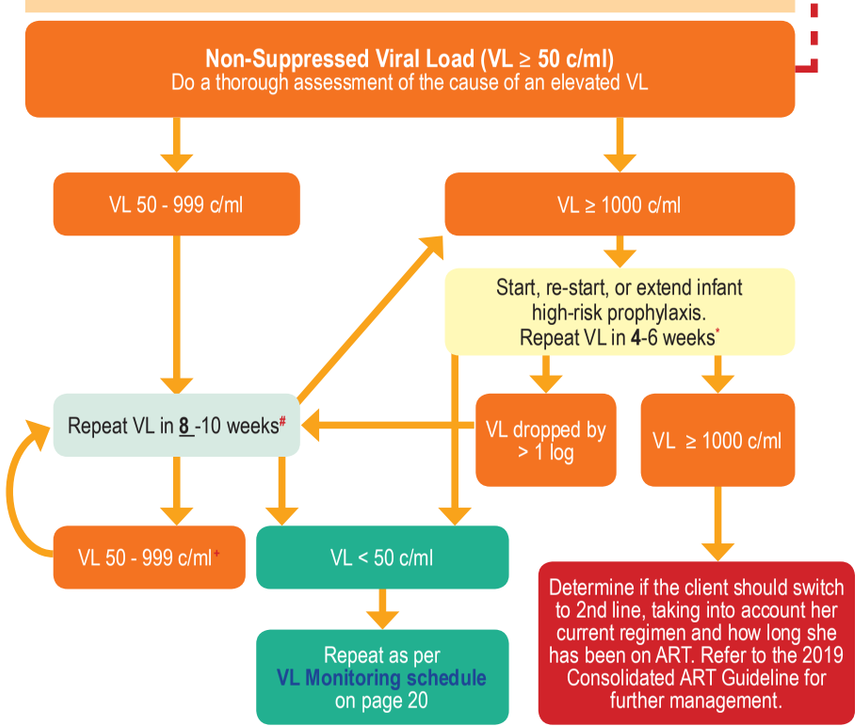
START HERE

Select a category for the woman starting ART from the pink blocks below:



* If a women who is previously ART exposed chooses to re-initiate EFV rather than DTG, do a VL before re-starting ART. Repeat the VL in one month. If more than one log drop in VL is achieved, continue current regimen and repeat VL in two months. If VL < 50 c/ml, repeat VL at delivery. If the repeat VL is ≥ 50 c/ml, manage according to the **VL non-suppression algorithm** on page 21

VIRAL LOAD NON-SUPPRESSION ALGORITHM (NSA)



* The shorter 4-week interval between the first VL above 1000 and the repeat VL is preferred wherever possible. However, if the first elevated VL is the **delivery-VL**, the next visit may only occur at the 6-weeks post-natal visit. A HBVsAg and HB can also be done at the same time to inform the switch to 2nd line if this becomes necessary.

\# The shorter 8-week interval between the first VL of 50 - 999 c/ml and the repeat VL is preferred wherever possible. However, if the first elevated VL is the **delivery-VL**, and the mother opts to remain in the maternal and child stream for follow-up ART care, the closest coinciding visit will occur at the 10-week EPI visit.

* Women on an EFV-containing regimen who have a second VL result of between 50 and 999 c/ml may be considered for a switch to a DTG-containing regimen, provided she has been thoroughly assessed for her elevated VL, and has been appropriately counseled as outlined on page 17.

Breastfeeding with an Elevated VL

It is recommended that women with a VL ≥ 1000 c/ml on 1st line ART continue to breastfeed. Infant prophylaxis should be extended / restarted while a concerted effort is made to re-suppress the mother's VL (see **Management of a High Maternal Viral Load after Delivery** on page 24). Breastfeeding in women who are failing 2nd and 3rd line ART is not recommended. These women should be referred or discussed with a team of experts as outlined in the orange box to the right. See also **Stopping Breastfeeding and Indications for Formula Feeding** on page 30

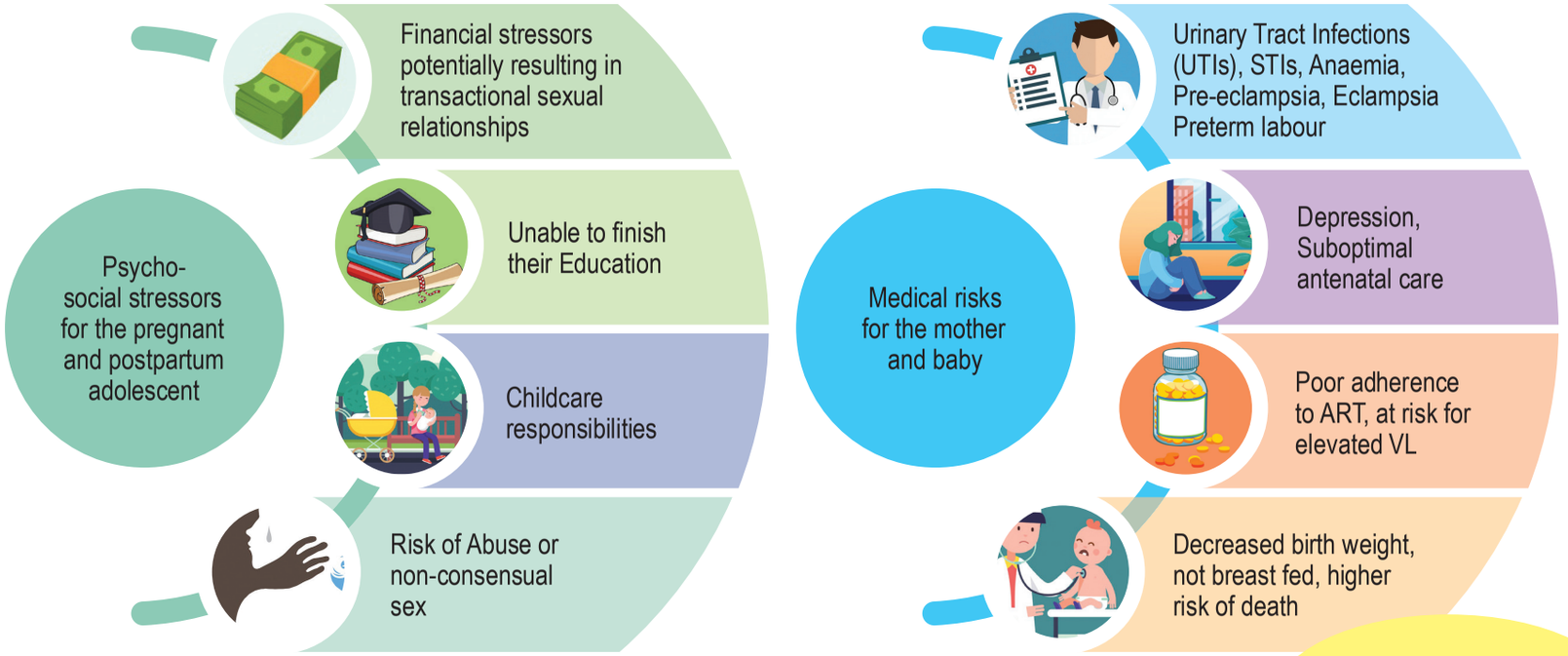
A thorough assessment is essential for any client with a viral load measuring ≥ 50 c/ml

A Adherence	Is adherence to medication poor? Ask about factors that may influence adherence e.g. • Medication side-effects, • Depression, • Alcohol or substance abuse, • Poor social support or • Non-disclosure. Pregnant women may experience nausea, heartburn, and constipation. Assess the need for symptomatic treatment with an anti-emetic, anti-diarrhea agent, or fiber supplement.	**Tips** Ask open ended questions e.g. "What makes it difficult for you to take your treatment?", and "How many doses have you missed this week?" Be non-judgemental. Statements like "we all miss a dose now and then" can encourage a client to be more open.
B Bugs (Infections)	Check for symptoms and signs of infection. Do a TB and STI screen.	Remember that immune compromised and pregnant clients may not exhibit overt symptoms of TB. If in doubt, do a TB GXP.
C Correct Dose	Is the client on the correct dose for her weight? This is especially applicable to young or malnourished girls who may have recently gained weight, or clients with previous renal impairment.	
D Drug Interactions	Are there any potential drug interactions? Consider: • Other prescribed treatment e.g. rifampicin, anti-epilepsy drugs • Over the counter treatment e.g. antacids • Supplements and herbal/traditional medications e.g. St John's wort	If in any doubt, call the **HIV Hotline** **0800 212 506**
E RE-sistance	Consider HIV drug resistance if other causes of virological failure have been excluded and the client is adherent to their medication. The need for 2nd-line ART is determined by her current regimen and how long she has been on ART.	Refer to the 2019 Consolidated ART Guideline for further management

Remember, an elevated VL in a pregnant or breastfeeding mother is a **MEDICAL EMERGENCY!** Every week she continues with an elevated VL increases her risk for MTCT!

Women who fail to suppress despite switching to second line, or who are failing 2nd or 3rd line should be discussed with an expert/HIV hotline or referred. These women may be experiencing complex clinical and/or psychosocial challenges beyond the scope of this primary care guideline, and may require a tailored approach to maternal management, infant prophylaxis and recommendations for breastfeeding.

Pregnant adolescents are a vulnerable group that have psycho-social stressors and medical risks that may result poor health outcomes[14]



For a **Summary of 1st line ART Regimens** applicable to adolescents go to page 19

The pregnant adolescent requires non-judgmental, confidential, and quality youth friendly SRH services that are sensitive to the challenges and stressors experienced by adolescents. This care should include:

A determination of whether or not the pregnancy was intended/unintended? wanted/unwanted? Provide counselling about options in terms of proceeding/not proceeding with the pregnancy?

High quality basic antenatal care, considering the additional medical risks in an adolescent.

Intensive ART adherence support during ANC, breastfeeding and there-after. If available, she should attend a peer-led support group.

Education and intensive support for **breastfeeding and PMTCT**. Adolescent are more likely not to breastfeed.

Counselling on **contraceptives, STIs** as well as **re-entering the education system**. Long-acting reversible contraceptive methods are preferred.

An exploration of the **possibility of abuse or non-consensual sex** to ensure that she is in a safe environment. If not, the involvement of the police and social services should be facilitated.

Risk Profile	Antenatal	Labour and Delivery	Postnatal Period (6 weeks PP / 12 weeks PP)
Low-Risk Mom	Mom booked early in ANC, and is adherent to treatment	**Delivery VL < 1000 c/ml**	Mom's VL: Continue the VL monitoring and management schedule on page 20
Low-Risk Infant	Keeping the mom's VL suppressed is the best way to protect her infant	Infant gets Birth PCR	**NVP** Once daily: Baby gets NVP for 6 weeks only → STOP NVP → Start cotrimoxazole from 6 weeks onwards ★★
High Risk Mom	Mother with a VL of ≥ 1000 c/ml (most recent VL taken during the last 12 weeks of antenatal care), or a mother with no VL result in the last 12 weeks.	**Delivery VL ≥ 1000 c/ml**	Mom's VL: Get the mom's VL suppressed as a matter of urgency! Even though NVP prophylaxis to the infant can be stopped if her VL is < 1000 c/ml, any detectable VL ≥ 50 c/ml means the virus is replicating and puts her at risk for developing resistance mutations. Follow the **VL Non-suppression algorithm** on page 21 → Mom's VL < 1000c/ml
High Risk Infant	Any situation that causes mom to have an elevated VL puts her infant at risk for HIV infection	**Infant gets Birth PCR.** If at discharge no VL result is available (delivery-VL or a VL in the last 12 weeks), initiate the baby on high risk prophylaxis until result can be checked at 3-6-day postnatal visit	**NVP** Once daily: The breastfed baby gets NVP for a minimum of 12 weeks, and if needed, ongoing until mothers VL is < 1000 c/ml, or until 4 weeks after cessation of all breastfeeding. The exclusive formula-fed baby will receive NVP for 6 weeks. → STOP NVP **AZT** Twice daily: Baby gets AZT for 6 weeks only, whether breastfed or formula fed → STOP NVP → Start cotrimoxazole from 6 weeks onwards ★★

Summary of Infant Prophylaxis Regimens		
Risk Profile	**NVP**	**AZT**
Low risk, whether breastfed or formula fed	6 weeks	no AZT
High Risk, and breastfed	minimum of 12 weeks	6 weeks
High risk, and exclusively formula fed	6 weeks	6 weeks

The PMTCT guideline uses two VL thresholds. If any client on ART, including mothers, surpasses the first VL threshold of 50 c/ml, action is required to timeously assess for possible causes that may lead to confirmed virological failure. Once the maternal VL exceeds 1000 c/ml, the risk for MTCT warrants the use of high-risk prophylaxis.

! Certain babies are at higher risk of developing anaemia on AZT e.g. premature and malnourished infants. Closer monitoring is recommended. If in doubt, discuss with an expert and refer as needed.

Prophylactic doses

Zidovudine (AZT)		
Age	**Current weight**	**Twice daily dose**
Birth to 6 weeks	< 2 kg, > 35 weeks gestation★	4 mg/kg/dose twice daily
	2,0 to 2,49 kg	1 ml (10 mg) twice daily
	> 2,5 kg	1,5 ml (15 mg) twice daily
> 6 weeks (doses according to ART Drug Dosing Chart for Children)	< 3 kg	4 mg/kg/dose 12 hourly (0.4 ml/kg/dose 12 hourly)
	3,0 to 5,9 kg	6 ml (60 mg) twice daily
	6 to 7,9 kg	9 ml twice daily
	8 kg to 13,9 kg	12 ml twice daily

Nevirapine (NVP)		
Age	**Current weight**	**Once daily dose**
Birth to 6 weeks	2,0 - 2,49 kg★	1 ml (10 mg) daily
	> 2,5 kg	1,5 ml (15 mg) daily
> 6 weeks to 6 months		2 ml (20 mg) daily
> 6 to 9 months		3 ml (30 mg) daily
9 months until 4 weeks after all breastfeeding has stopped		4 ml (40 mg) daily

Cotrimoxazole syrup (200/40 mg per 5 ml)	
Weight	**Once daily dosage**
2,5 to <5 kg	2,5 ml
5 to <14 kg	5 ml

STOP ★★ Stop cotrimoxazole when PCR is negative ≥6 weeks after full cessation of breastfeeding AND infant is clinically HIV negative

★ *Premature infants <35 weeks gestational age should be dosed using expert guidance.*

- *For infants weighing <2000 g, the suggested NVP dose is 2 mg/kg/dose (0.2 ml/kg/dose) once daily from birth – 2 weeks of age followed by 4 mg/kg/dose (0.4 ml/kg/dose) once daily from 2 – 6 weeks of age.*
- *If the infant still weighs <2 kg at 6 weeks of age, continue with dosage of 4 mg/kg/dose (0.4 ml/kg/dose) once daily until reaches 2kg.*

Follow **ART Initiation Algorithm** for mother on page 18, and the **VL Monitoring schedule** on page 20

A Mother may have a high VL after delivery due to:

A new HIV diagnosis after delivery

or

An elevated VL of ≥ 1000 c/ml after previously being suppressed on ART.

Get mother's VL re-suppressed as a matter of urgency! Follow the **VL Non-suppression algorithm** on page 21

See **NVP, and CPT dosing charts** on page 23.

Infant currently breastfeeding, or has breastfed in the last week

Immediate Infant HIV-PCR

Provide High-risk Infant Prophylaxis: AZT twice daily for 6 weeks, and NVP for a minimum of 12 weeks regardless of infant's age. Clearly document the prophylaxis start date. If infant > 6 weeks old provide CPT

Infant HIV-PCR negative

Complete 6 weeks of AZT and a minimum of 12 weeks of NVP. If needed, continue NVP for longer until mothers VL < 1000 c/ml.

Do HIV-PCR 6 weeks after stopping NVP

Breastfeeding never started or stopped more than 1 week ago.

Immediate Infant HIV-PCR

No prophylaxis needed as baby is no longer being exposed to HIV

Infant HIV-PCR negative

Do all routine HIV tests according to the age and schedule for HIV exposed Infants:

- HIV-PCR at age 10 weeks
- HIV-PCR at age 6 months
- HIV-PCR 6 weeks post cessation of breastfeeding
- HIV Rapid test at age 18 months
- Test anytime baby is unwell

Enquire as to why breastfeeding was stopped or never started. Ensure that the mother understands the risks of not breastfeeding, and that she has made an informed choice as to whether she will continue breastfeeding or not. See also the Infant and Young Child Feeding Policy.

Women who fail to suppress despite switching to second line, or who are failing 2nd or 3rd line should be discussed with an expert/HIV hotline or referred. These women may be experiencing complex clinical and/or psychosocial challenges beyond the scope of this primary care guideline, and may require a tailored approach to maternal management, infant prophylaxis (including LPV/r) and recommendations for possible stopping of breastfeeding and the prescription of infant formula to be supplied by the DoH (see **"Stopping Breastfeeding"** om page 30.

If Infant tests HIV-PCR positive at any stage.

Confirm positive result with a 2nd PCR on a new sample. Stop any NVP prophylaxis. Initiate ART. Start cotrimoxazole (CPT) if not already started.

For any child that tests HIV-positive ensure that:

- A confirmatory HIV test was done
- The child is tracked and linked to care
- The mothers and other significant caregivers are counselled appropriately,
- CHWs are involved
- The child is registered on Tier.net & retained in care

MANAGEMENT OF INDETERMINATE PCR RESULTS IN INFANTS

Indeterminate HIV-PCR result
(This result is not positive, but not negative either)

Check for prior HIV-PCR and VL results

- Prior HIV-PCR is positive or indeterminate And/or Prior HIV VL is detectable → Treat infant as HIV infected Initiate ART
- Prior HIV-PCR or VL is negative or undetectable, or No prior HIV-PCR or VL done → Repeat HIV-PCR and HIV VL urgently
  - HIV-PCR is positive or indeterminate and/or HIV VL is detectable → Treat infant as HIV infected Initiate ART
  - HIV-PCR is negative and HIV VL is undetectable # → Further HIV testing as per PMTCT guidelines

Final HIV status cannot be determined until the infant has stopped all antiretroviral prophylaxis and is at least 6 weeks post-cessation of breastfeeding. In cases where clients have been initiated on ART and diagnosis remains uncertain, clients should be referred for further management by a specialist clinical and laboratory team. ART should never be stopped without specialist supervision.

! If in doubt, discuss with a virologist, or contact the NICD at HIV@nicd.ac.za
Document all test barcodes in the RTHB and referral letters

PCR, polymerase chain reaction; VL, viral load; ART, antiretroviral therapy

THE ABANDONED INFANT

Abandoned infant with unknown HIV exposure
Treat infant as a high-risk, HIV-exposed infant

Perform an HIV-PCR and HIV rapid test[$].
Provide high-risk infant prophylaxis.

Start NVP once daily for 6 weeks and AZT twice daily for 6 weeks

- HIV-PCR is negative → Do HIV-PCR at 10 weeks of age or 4 weeks after stopping NVP
  - HIV- PCR is negative → Go to **Management of HEU infant** on page 30
  - HIV-PCR is positive → Initiate ART as per guidelines and confirm with a second HIV-PCR or VL.
- HIV-PCR is positive → Stop NVP (and AZT) → Initiate ART as per guidelines and confirm with a second HIV-PCR or VL.

[$] A positive HIV rapid test will confirm HIV exposure and assist clinical management. However, a negative HIV rapid test may be falsely negative. Due to the unavailability of the mother, the HIV-exposure status of an infant with a negative rapid test can therefore not be definitively established. For this reason, all abandoned infants should have an HIV-PCR test performed and be managed as a high-risk HIV-exposed infant. An HIV rapid test therefore adds value if it is positive but does not change the management of the infant if it should be negative.

ALL women should be screened for TB at every visit

IPT is now known as **TPT** (TB Preventive Therapy)
TPT treats Latent TB Infection (LTBI)

At 1st / Booking visit in ANC

All pregnant women with a new HIV diagnosis, or
All known HIV positive woman with new pregnancy diagnosis (whether on ART or not on ART)

Assess TB symptoms and clinical condition:
If TB symptoms without danger signs, or no TB symptoms present, **initiate ART**.
If the woman appears very ill with any of the following signs, **discuss with a doctor or refer for further assessment. Do not start ART until TB is excluded/diagnosed as these women may be at a higher risk of developing IRIS:**
weight loss > 5%, difficulty breathing, respiratory rate >30/min, temperature > 38°C, pulse > 100min, BP < 90/60, coughing up blood, confusion or agitation, or unable to walk unaided.

Do a TB GXP for all women at 1st visit in ANC, due to the lower sensitivity of the symptom screen in pregnant women.

- GXP neg, but TB symptoms still present → Additional investigations as per National TB Guidelines
  If CD4 ≤ 100, do a urine LAM
  - TB diagnosis confirmed → Initiate TB Rx
  - CD4 more than 100 → Defer TPT until 6 weeks after delivery
  - CD4 100 or less → Initiate TPT after contra-indications have been excluded*
- GXP positive → Initiate TB Rx
- TB GXP negative (or unable to produce sputum) AND no TB symptoms → Initiate/continue ART

Review in 2 weeks: If stable and tolerating TB Rx, continue TB Rx and initiate/continue ART:
TDF, 3TC/FTC, EFV/DTG$
If TB meningitis, defer ART for 4 to 6 weeks

At Follow-up visits

HIV positive woman currently on TPT

Check:
1. Adherence to TPT, ART and CPT
2. Side-effects of TPT
3. TB symptoms

- 1 or more TB symptoms present → Investigate as per National TB Guideline
  - If TB diagnosed, stop TPT, initiate full TB Rx and send a sputum sample for LPA, or culture and drug sensitivity test (DST)
- No TB symptoms present → Continue TPT for a total of 12 months

All HIV positive women from 6 weeks after birth who had TPT deferred in pregnancy (CD4 count above 100 during antenatal care)

TB symptom screen

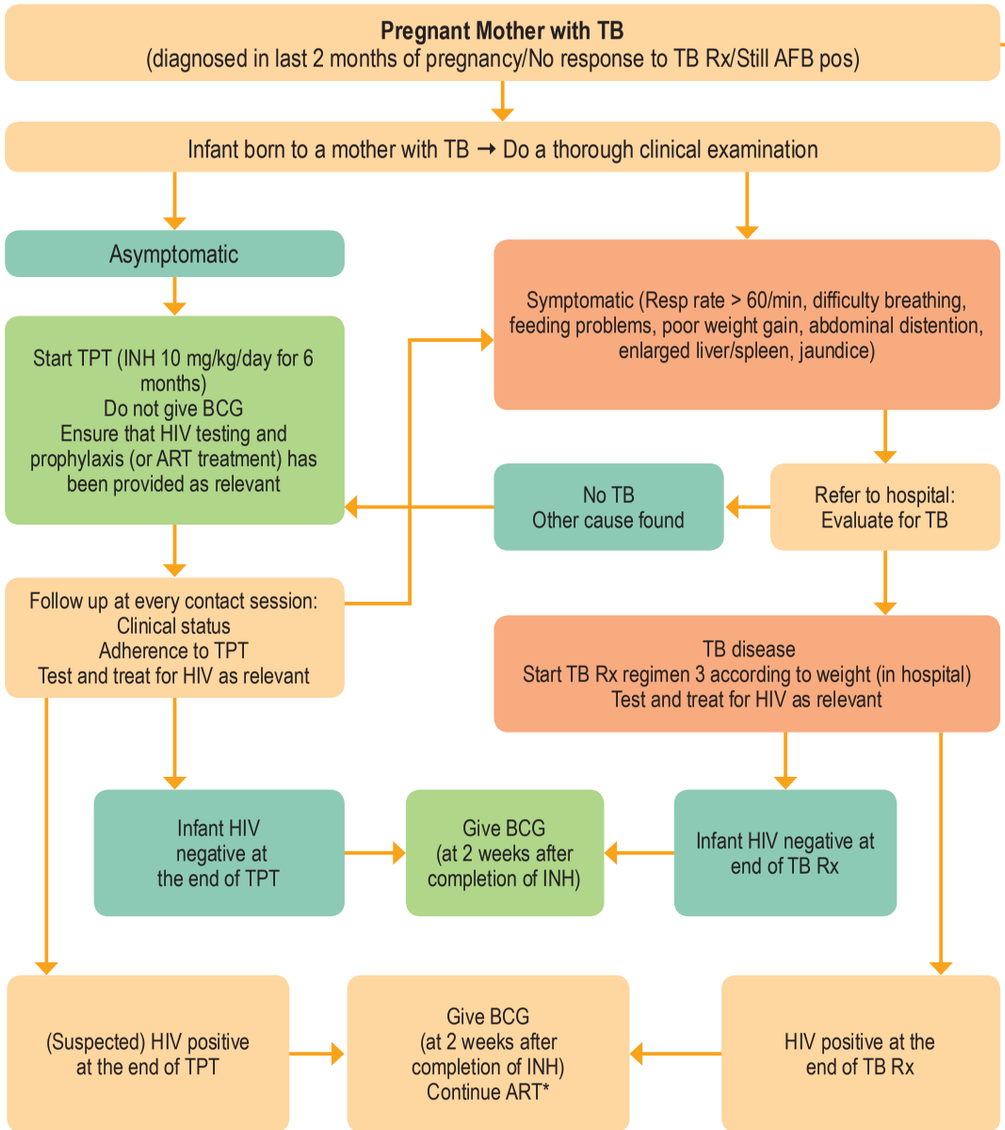
- No TB symptoms present → Initiate TPT for 12 months (after excluding other contra-indications to TPT *)
  Record start date of TPT
- 1 or more TB symptoms present → Investigate as per **National TB Guideline (2014)** page 28

***Contra-indications to TPT**
- Positive TB symptom screen
- Alcohol abuse
- Liver disease
- Known hypersensitivity to INH

TPT dosage: Isoniazid (INH) 300 mg daily PO, and Pyridoxine 25 mg OD PO x 12 months

The **APPRISE** randomised control trial found a higher incidence of adverse pregnancy outcomes in mothers who used TPT in pregnancy

$DTG requires boosting with TB treatment.
See **DTG in pregnancy** on page 17



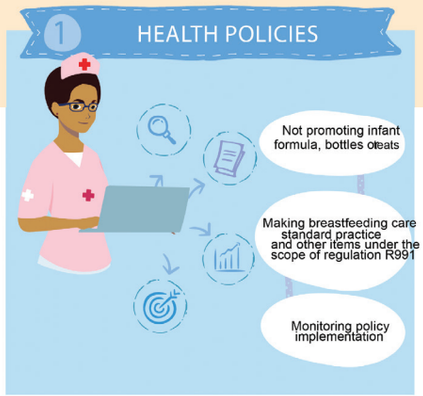
Refer/discuss any mother diagnosed with **drug resistant TB** with an expert or call the HIV Hotline 0800 212 506

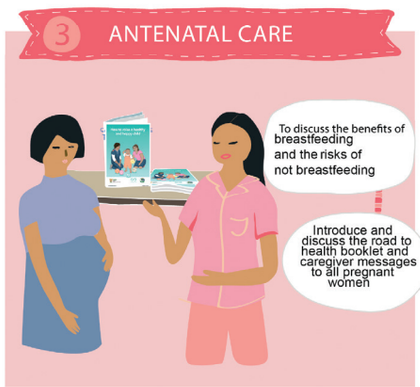
INH Dosing Chart	
Isoniazid (INH), oral, 10 mg/kg daily for 6 months. Maximum dose 300 mg daily	
Weight (kg)	**Daily INH (100mg tablet)**
>2-3,4 kg	¼ tablet
>3,5-6,9 kg	½ tablet
>7-9,9 kg	1 tablet
>10-14,9 kg	1 ½ tablets
>15-19,9 kg	2 tablets
>20-24,9 kg	2 ½ tablets
>25 kg	3 tablets

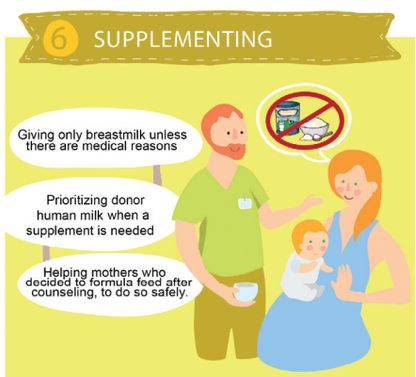
*If ART is delayed due to other clinical complications, discuss with an expert or the HIV Hotline to determine the best course of action regarding BCG vaccination

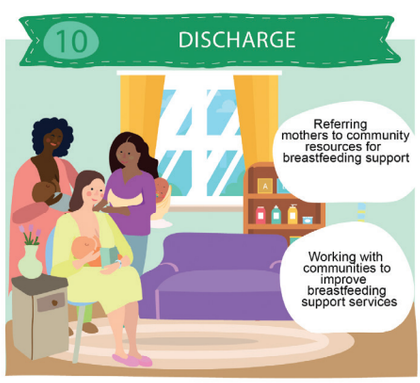
The **TEN STEPS** to Successful Breastfeeding

All Health Facilities must support mothers to breastfeed as a standard of care by implementing the following...









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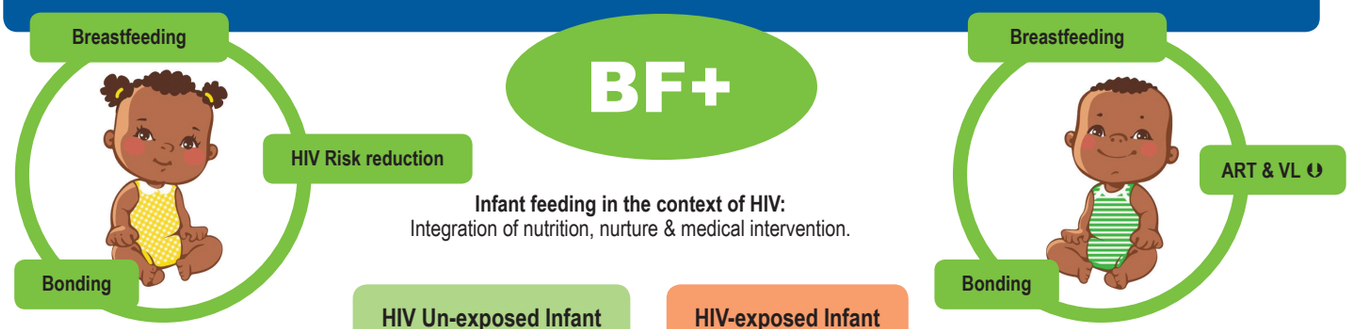
Breastfeeding Plus



Infant feeding in the context of HIV:
Integration of nutrition, nurture & medical intervention.

HIV Un-exposed Infant

HIV NEGATIVE WOMEN

1. HIV Risk Reduction
   - Number of sexual partners
   - Condom use
   - Partner testing
   - Partner ART and viral suppression
   - PrEP (as available and applicable)
2. Regular HIV Testing
3. Infant Feeding advice and support

HIV-exposed Infant

WOMEN LIVING WITH HIV

1. ART and VL suppression
2. Infant prophylaxis
3. Infant testing
4. HIV Risk reduction (re-infection and risk to partner)
   - Number of sexual partners
   - Condom use
   - Partner testing
   - Partner ART and viral suppression
5. Infant Feeding advice and support

Whether a woman is living with HIV or HIV-uninfected, recommendations for Infant feeding remain the same

! HIV VL suppression in mother is essential to prevent MTCT through breastfeeding!

Infant Feeding Advice

For all women, exclusive breastfeeding (EBF) is recommended for the 1st six months of life. Thereafter, breastfeeding should continue for two years or longer, with the introduction of nutritionally adequate, appropriate and safe complementary feeding. Women living with HIV should be fully supported for ART adherence during the breastfeeding period and thereafter

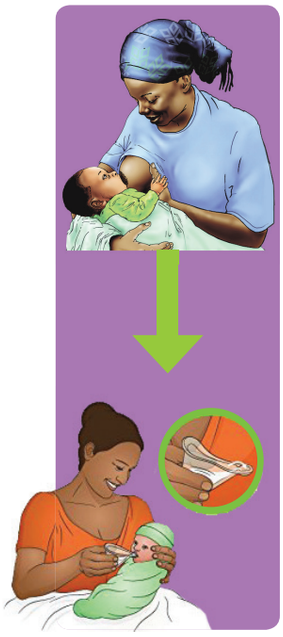
Antenatal	6 months	12 months	18 months	2 years
Counselling on the benefits of breastfeeding should start during the antenatal period	Early initiation of BF within 1 hour after birth. EBF for 1st 6 months of life	**Continue breastfeeding until 2 years of age or longer**		
		Start introducing age appropriate solid foods from 6 months onwards as outlined in the RTHB		

! Introducing solids before 6 months is strongly discouraged! The younger the infant, the higher the risk to the infant's health.

WHO Practice Statements for Women Living with HIV

- Any mother that is mixed feeding in the first 6 months should be encouraged to return to exclusive breastfeeding.
- However, mothers living with HIV and health-care workers can be reassured that ART reduces the risk of postnatal HIV transmission in the context of mixed feeding. Although exclusive breastfeeding is recommended, practicing mixed feeding with formula milk is not a reason to stop breastfeeding in the presence of ARV drugs.
- Mothers living with HIV and health-care workers can be reassured that shorter durations of breastfeeding of less than 12 months are better than never initiating breastfeeding at all.

STOPPING BREASTFEEDING



Stopping Breastfeeding

Mothers living with HIV who decide to stop breastfeeding should do so gradually over a period of a month. Abrupt cessation of breastfeeding is not recommended and may increase the VL in breastmilk. If subsequent intermittent breastfeeding should occur, the infant is at increased risk of becoming HIV infected.

Infants who have been receiving ART prophylaxis should continue prophylaxis for four weeks after all breastfeeding has stopped.

Children must receive an adequate diet following cessation of breastfeeding as outlined in the Infant and Young Child Feeding Policy.

Indications for Formula Feeding to be provided by the Dept of Health Supplementation Scheme

1. Infants of mothers who are failing second or third-line ARV treatment (VL ≥1000 copies/ml) should be advised not to breastfeed.
2. The mother has died, or the infant has been abandoned.
3. Other individual circumstances deemed necessary by a multidisciplinary team including certain metabolic conditions in the infant, medical conditions in the mother, or certain maternal medications as outlined in the PHC EML.

CARE OF THE HIV-EXPOSED BUT UNINFECTED INFANT

More than 25% of the total infant population in SA are HIV-exposed and more than 98% of these infants are HIV negative. Yet, having escaped HIV infection, they may still suffer the consequences of being born to a woman living with HIV. HIV-exposed but Uninfected (HEU) children still require:

Routine Child Health Management

- Manage and treat acute problems according to the IMCI guidelines
- Provide feeding counselling and support
- Monitor growth and development
- Provide routine immunizations, Vit A, and deworming
- Screen for TB symptoms and TB index cases and manage accordingly
- Ask about mother's health, ART adherence, and family planning needs
- Provide social support and counselling for age-appropriate parental disclosure

Routine Management for the HIV-Exposed Infant

- Ongoing interventions to prevent vertical transmission through breastfeeding
- All routine HIV tests as indicated in this guideline for HIV-exposed infants

Additional Management for the HEU Infant

HEU infants may experience poorer outcomes despite being HIV uninfected, and may require more regular follow-up.
Identify high-risk HEU infants who may require closer monitoring, including those with:

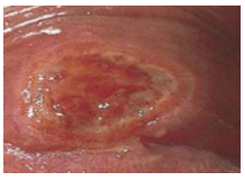
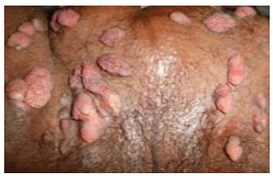
- Poor birth outcomes
- Symptoms of anaemia
- Impaired growth and/or neurodevelopment
- History of hospitalisation
- Maternal illness or death

Ongoing Care for the Mother and her Family

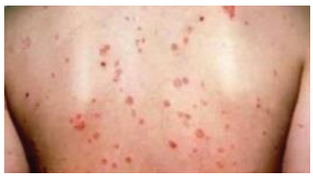
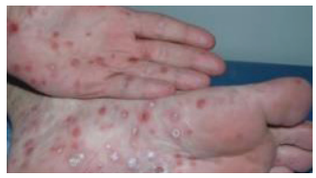
- Remember to provide appropriate ongoing care to the women living with HIV and her family.
- If a breastfeeding mother is sick or hospitalised, consider appropriate ways she can continue breastfeeding. If not, ensure that baby receives appropriate care whilst mother is hospitalised.
- Screen partner and other children for HIV and other infectious disease as indicated (e.g. TB)

SYPHILIS

Syphilis is a sexually transmitted infection that can have multiple different presentations but also be asymptomatic. The signs of secondary syphilis occur six to eight weeks after the primary ulcer (chancre) and include a generalized rash (including palms and soles), flu-like symptoms, flat wart-like genital lesions (condylomata lata), mouth ulcers and patchy hair loss. Tertiary syphilis occurs many years later and affects skin, bone, heart and nervous system.

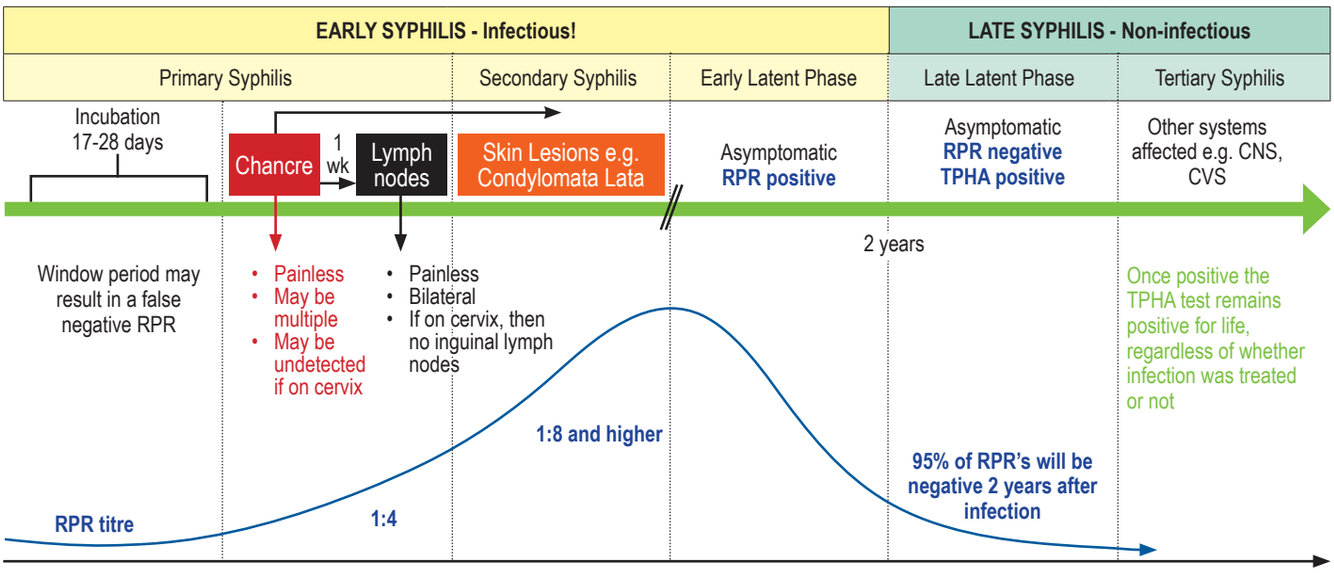



Painless ulcer/chancre and condylomata lata on genitals

Rash involving palms and soles

The stages of disease progression of syphilis are illustrated in the figure below, together with the typical clinical presentation in each stage, and the level of the RPR titer (blue graph). Note that a genital ulcer caused by syphilis will resolve spontaneously within four to six weeks without treatment; however, the syphilis infection persists, and the ulcer resolving does not represent cure.



Testing for Syphilis	First test	Confirmatory test
Use of RPR	RPR (rapid or laboratory)	TPHA (laboratory)
If rapid syphilis testing used (dual and standalone)	TPHA (HIV-syphilis combination or standalone syphilis test)	RPR (rapid or laboratory)

Testing for Syphilis

It is important to know what type of test is being used to test for syphilis. Older syphilis tests are of the RPR type (non-treponemal test). False positive RPR's can occur. It is therefore good practice to confirm any positive RPR with a TPHA/FTA test (treponemal test). TPHA remains positive for life, but an RPR changes in titer in response to treatment or disease progression. Consider re-infection if the RPR titer increases by four times or more. Conversely, if a TPHA is used as the first test (as what is used in the HIV-syphilis combination or standalone syphilis rapid test), the positive result should be confirmed using an RPR. The RPR will determine if the positive TPHA result indicates a current active infection or an earlier infection.

Congenital Syphilis

Vertical transmission occurs in 40% of mothers with untreated syphilis, and can result in miscarriage, still birth, non-immune hydrops fetalis and congenital syphilis of the newborn. Signs of congenital syphilis are desquamative rash (red/blue spots or bruising especially on soles and palms), jaundice, pallor, distended abdomen due to enlarged liver or spleen, low birthweight, respiratory distress, large, pale placenta, and hypoglycaemia.

Treating the Newborn Infant

Examine and treat the newborn of the mother with syphilis:
Well (asymptomatic) baby: Treat baby with Benzathine penicillin 50 000 u/kg intramuscularly (IM) stat only if:

- Mother was not treated, or
- If the mother has received less than three doses of benzathine benzylpenicillin, or
- If the mother delivers within four weeks of commencing treatment.

Symptomatic baby:

- Refer all symptomatic babies for treatment of congenital syphilis:
- Procaine penicillin 50 000 u/kg IM daily for 10 days, or benzyl penicillin (penicillin G) 50 000 u/kg/dose 12-hourly intravenously (IV) for 10 days
- Erythromycin does not reliably cure syphilis in either the mother or the baby

SYPHILIS IN PREGNANCY

All pregnant women at first visit and repeat testing at 32-34 weeks for women testing negative in the first trimester

Take history and examine, explain needs for syphilis screening, do pre-test counselling for HIV

Do a syphilis test, an HIV test, and any other tests according to the BANC Plus protocol

Any STI syndrome or illness?

Y

Use appropriate flowchart, manage appropriately

Syphilis positive?

Y

Treat pregnant woman with:

- **Benzathine penicillin** 2.4MU imi once weekly for 3 weeks. Reconstitute with 6mL of lidocaine 1% without epinephrine (adrenaline)

OR In case of penicilin allergy:

- Refer for penicillin desensitisation

HIV test positive?

Y

Post test counselling, same day TB screen, HIV education, CD4 count, creatinine, clinical staging, support, and same day ART start

N

Repeat HIV testing **monthly** at every full BANC Plus visit throughout pregnancy, at labour/delivery, at 10-week EPI visit, and every 3 months throughout breastfeeding

Symptomatic newborns of mothers with positive syphilis test during pregnancy:

- Refer all symptomatic babies

Notify: Notification of medical conditions, form GW17/5

Treat asymptomatic newborns of mothers with positive syphilis test if mother was not treated, ***OR*** if mother received < 3 doses of Benzathine penicillin, ***OR*** if mother delivers within 4 weeks of commencing treatment, with:

- **Benzathine penicillin** (depot formulation), IM, 50,000 units/kg as a single dose into lateral thigh*

** Benzathine penicillin (depot formulation) must never be given IV*

Follow up at 3 months after the last injection to confirm a fourfold (i.e. 2 dilution) reduction in RPR litres, provided the initial litre was >1:8. If the initial litre was <1:8, further reduction may not occur.

All pregnant women:

- Educate, ensure compliance and counsel; promote couple-counselling if applicable
- Explain the risk of vertical transmission
- Promote consistent condom use particularly during pregnancy, demonstrate condom use, provide condoms
- Stress the importance of partner treatment, issue one notification slip for each sexual partner
- Promote HIV counselling and testing of partner

Source: Sexually Transmitted Infections Management Guidelines 2015,
Adapted from: Standard Treatment Guidelines and Essential Drugs List PHC

DATA MANAGEMENT

DOCUMENTATION IN THE CLIENT RECORD

Document all clinical findings, results and decisions clearly, and insert the barcode stickers of any blood tests taken in the following client records as applicable:

1. The Maternity Case Record
2. The Adult Clinical Record (ART Stationery) for HIV positive women, if available in that facility
3. The Road to Health Booklet for the HIV-exposed infant

USING NHLS REPORTS FOR QUALITY IMPROVEMENT AND CLIENT TRACKING

These reports are compiled from NHLS HIV laboratory data and are e-mailed in different formats depending on the user's requirements. The purpose of these reports is to assist with monitoring of the HIV PMTCT program, identify HIV-infected pregnant women with high viral loads and link HIV-infected infants to care.

REPORT NAME	REPORT NO.	DESCRIPTION	USEFUL FOR
HIV PCR Facility Report	RPT01001	• Provincial level data disaggregated per facility • Number of PCR tests and results at each facility per age range • Reported per month with comparison to previous year • Can be used to check accuracy of DHIS stats • Total MDOs per facility reported	▲●
HIV National Report (Birth Testing)	RPT01008	• National monthly report • Number of PCR tests done within 7 days of birth with results and MDOs • Reports intra-uterine infection case rates	▲●
HIV PCR RfA Report	RPT01002 W/D	• All verified PCR results (with client identifiers) since the previous weekly (W)/daily (D) report • To assist with tracing HIV-exposed infants and linkage to care • All previous HIV PCR results per client are also reported (within limitations of demographic linking)	●■
HIV VL RfA Report (all ages)	RPT00001 W/D	• All VL ≥ 1000 c/ml (with client identifiers) since previous weekly (W)/daily (D) report • Previous consecutive VL ≥ 1000 c/ml per client are also reported (within limitations of demographic inking)	●■
HIV PCR MDO Report	RPT01004/5/6/7 (monthly)	• Facilities with the highest number of MDOs are listed at either National, Provincial, District or Facility level • The 10 facilities with the most MDOs in a region receive a detailed report of their MDOs (e.g. rejection type, rejection reason and test result text) • A laboratory report is also available for laboratorians • To improve the quality of specimen collection and processing	▲●■★

RfA, Results for Action; MDOs, Missed Diagnostic Opportunities = registered HIV PCR tests that are neither positive or negative (includes rejections, invalid and indeterminate results); DHIS, District Health Information System

DESCRIPTION	DESCRIPTION
▲	National/ Provincial/ District Manager
●	Facility Manager
■	Clinical Healthcare Worker
★	Laboratorian

Registering on the self-service portal and requesting reports
STEP 1: Go to **www.nicd.ac.za**
→ Click on the "M&E Dashboards" and "HIV"
→ Select "Guest User"
→ Click on "Self Service Registration"
→ Self-Service Portal Landing Page
STEP 2: Select "New User Registration" → Complete the registration form, and follow further instructions

Please direct any queries to **HIV@nicd.ac.za**

ANNEXURE 1 – POST NATAL CLUB (PNC) MODEL

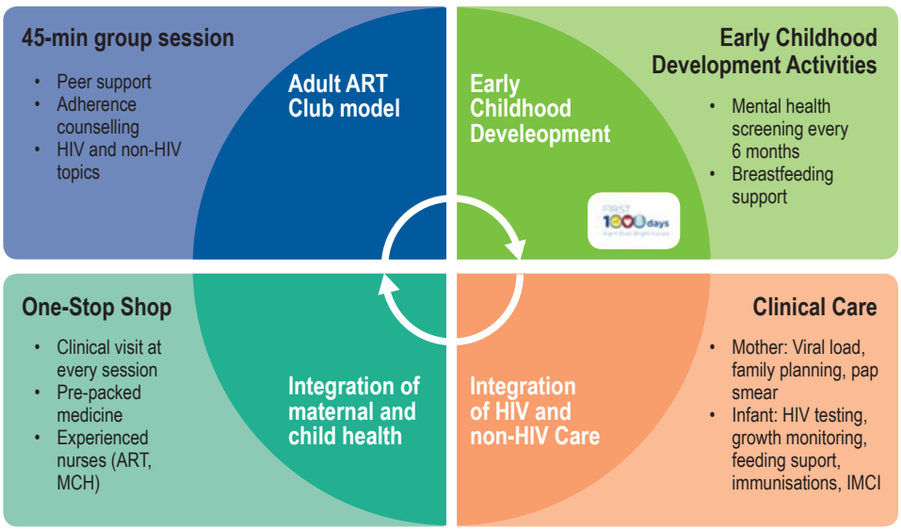
PNCs were developed in the Western Cape Province due to the need for reducing MTCT during the postnatal period and for retaining mother-infant pairs (MIP) in care. It is a holistic client-centred model of care that:

- addresses both the medical needs of a mother living with HIV and her HIV-exposed infant.
- provides peer support, psychosocial support and early childhood development support.

For more info on the PNC model including stationery, the club register and monitoring and evaluation go to **www.bit.ly/PNCtoolkit**

VL = Viral load
FP = Family planning
ART = Antiretrovaral theraphy
IMCI = Integrated management of childhood illness
MCH = Maternal and child health

THE KEY COMPONENTS OF A CLUB SESSION

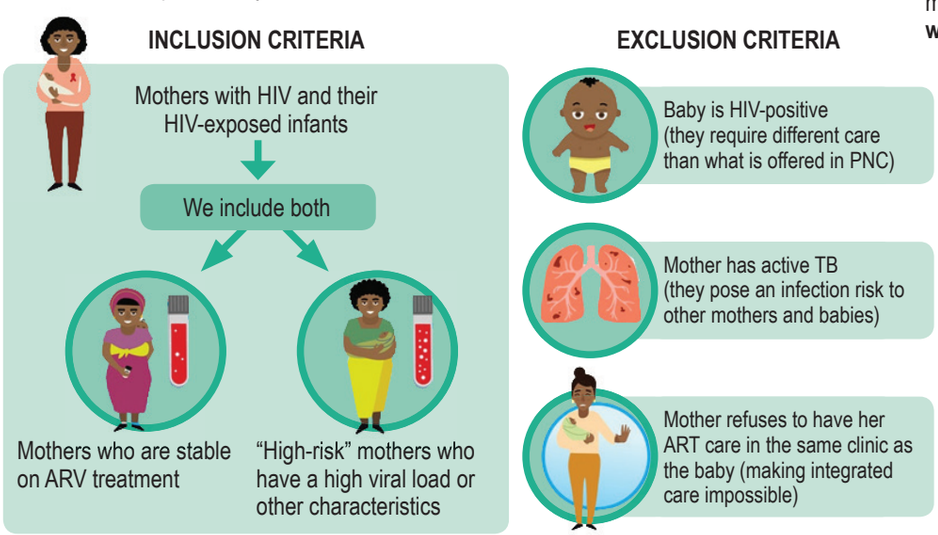


PNCs aim to provide high quality care to both mother and infant and have been shown to:

- Improve retention in care,
- Improve maternal viral load suppression rates, and
- Increase the uptake of infant HIV tests and vaccinations.

WHO CAN BE RECRUITED FOR A PNC

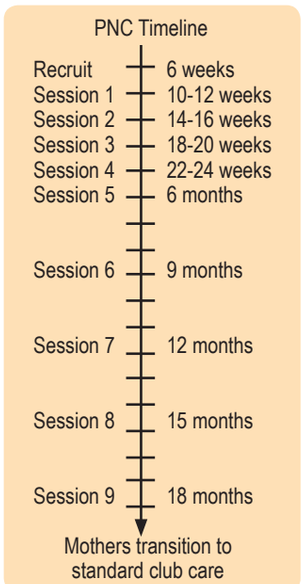
The mother living with HIV is given the option of joining PNC when she first presents to the clinic (usually around six-weeks post natally). She is then given a date and time for the first session of the PNC. The recruitment is usually done either by the m2m mentor or by the nurse seeing the mother-infant pair. Babies are grouped per same month of age and PNCs start around ten weeks post natally.



In the first six months, babies are seen monthly because of their higher mortality and morbidity risk in this period. After six months of age, clubs are held three-monthly until 18 months of age (following the "Road to Health" card clinical appointments). At 18 months, children go back to the standard of care and mothers are encouraged to join an adult ART club (facility or community based).

WHAT HAPPENS AT EACH CLUB?

As in the adult club model, PNC starts with a peer support session, which is led by peer-educators, following a session guide. Early childhood development (ECD) activities and promoting the "First 1000 Days" campaign are included. Mother-infant pairs (MIPs) will have an integrated clinical session provided by the nurse. Each visit's interventions will depend on the age of the baby. The mother's clinical care schedule is adapted around the baby's visits.
More info on the PNC model including stationery, the club register and monitoring and evaluation go to **www.bit.ly/PNCtoolkit**



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