MINISTRY OF HEALTH
KINGDOM OF SWAZILAND

swaziland integrated HIV management guidelines

World Health Organization

SWAZIS AND AMERICANS IN PARTNERSHIP TO FIGHT HIV/AIDS

2015

Swaziland is at a tipping point with regards to turning the tide against the HIV epidemic. This is due to successful implementation of the 2010 HIV guidelines, which focused on extensive decentralization of HIV services, especially antiretroviral therapy (ART) through the implementation of Nurse-Led ART Initiation (NARTIS), provider initiated testing and counselling (PIHTC), and roll out of the WHO recommended option A for Prevention of Mother To Child Transmission (PMTCT) of HIV. To sustain these gains and maximise the benefits of ART, we must take advantage of best practices and evidenced-based recommendations.

Antiretroviral therapy has been identified as one of the interventions that can help lower the risk of HIV transmission from one person to another. The protective nature of ART was demonstrated in the HPTN 052 study, but this protection is at the individual level and translating this to the entire population is a functionof ART coverage and efficiencies at the national level. Swaziland has achieved universal ART coverage under the previous treatment guidelines (CD4 <350 cells/mm^3),however the benefits of early ART initiation (CD4<500cells/mm^3) in reducing opportunistic infections and other co-morbidities have also been demonstrated. It is also recognised that HTC is the gateway to treatment and prevention and there should be a deliberate move to expand the reach of our HIV testing services. As part of Swaziland's vision to prevent AIDS-related morbidity and mortality, and to eliminate new HIV infection, the country has adopted the 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. This includes providing lifelong ART to pregnant and lactating women to maximise the contribution of ART in eliminating paediatric HIV, and to keep the mothers alive and healthy. In line with this vision, Swaziland is strengthening its policies to ensure that all children receive early HIV diagnosis and are linked immediately to appropriate care. Other key innovations in this document include ART for all children under 5 years and the HIV-positive partner of a sero-discordant couple.

The new integrated guidelines takes a more public health approach to address the country's HIV epidemic at the population level while maintaining the individual benefits of early HIV diagnosis and access to quality care and treatment services. The Government of the Kingdom of Swaziland is also investing in enhanced patient monitoring to improve treatment outcomes such as retention in care and viral suppression.

With the achievements under the previous guidelines - massive decentralization of HTC, PMTCT and ART services, universal coverage of PMTCT and ART, over 85% 12-month retention on ART and MTCT of less than 5% at 6-8weeks - Swaziland is in a unique position to eliminate AIDS and significantly reduce new HIV infections.

If we can ensure that 90% of those who are HIV-positive know their status, 90% of those who are eligible are put on ART, and 90% of those on ART achieve viral suppression under these new integrated guidelines, it will bring the country in line with the 90/90/90 UNAIDS targets for the end of AIDS campaign. This is by all means a daunting task. However, with the right investment, and commitment at all levels of the health care delivery system, we are confident that Swaziland will see the end to AIDS through a successful implementation of these guidelines.

These Integrated HIV Management Guidelines provide the standards and recommendations to move Swaziland forward in achieving the Government of the Kingdom of Swaziland's vision of zero new infections and ending AIDS. To achieve this vision we need a concerted effort from all stakeholders and at all levels of service delivery to translate these guidelines into action while ensuring delivery of quality services and efficient use of limited resources.

May I take this opportunity to thank the MOH program leads, technical working group members, and our key stakeholders and partners for their contribution and support in developing and implementing these guidelines.

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3TC	Lamivudine
ABC	Abacavir
AFB	Acid fast bacilli
AIDS	Acquired immunodeficiency syndrome
ALT/AST	Alanine aminotransferase / Aspartate aminotransferase
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral (drug)
ATV	Atazanavir
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine (also known as ZDV)
BCG	Bacilli Calmette-Guérin
BMI	Body mass index
BUN	Blood, urea, nitrogen
CBC	Complete blood count
Cd4	T–lymphocyte cell bearing CD4 receptor
CDC	United States Centers for Disease Control and Prevention
CIHTC	Client initiated HIV testing and counselling
CK	Creatinine kinase
CNS	Central nervous system
COC	Combined oral contraceptive
CTX	Co-trimoxazole
CYP3A4	Cytochrome P3A4
d4T	Dtavudine
DBS	Dried blood spot
ddI	Didanosine
DNA	Deoxyribonucleic acid
DNA PCR	DNA polymerase chain reaction
DOTS	Directly observed therapy
DRV	Darunavir
DRV/r	Darunavir/ritonavir
DST	Drug susceptibility test
EC	Expert client
EFV	Efavirenz
eGFR	Estimated glomerular filtration rate
EID	Early infant diagnosis
EIMC	Early infant male circumcision
ELISA	Enzyme-linked immunosorbent assay
ETV	Etravirine
FBC	Full blood count
FDC	Fixed dose combination
FP	Family planning
FTC	Emtricitabine

Hb	Haemoglobin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCW	Health care worker
HIV	Human immunodeficiency virus
HIV –ve	HIV negative
HIV +ve	HIV positive
HIVAN	HIV associated nephropathy
HMIS	Health management information system
HTC	HIV testing and counselling
IM	Intramuscular
INH	Isoniazid
IDV	Indinavir
IPT	Isoniazid preventive therapy
IRIS	Immune reconstitution inflammatory syndrome
IUD	Intrauterine device
IV	Intravenous
KS	Kaposi's sarcoma
L&D	Labor and delivery
LAM	Lactational amenorrhea method
LFT	Liver function test
LIP	Lymphoid interstitial pneumonitis
LPV	Lopinavir
LPV/r	Lopinavir/ritonavir
MDR	Multidrug-resistant TB, resistant to at least isoniazid and rifampicin
MDT	Multi-disciplinary team
M&E	Monitoring and evaluation
MTCT	Mother-to-child transmission (of HIV)
NCD	Non-communicable disease
NFV	Nelfinavir
NNRTI	Non-nucleoside reverse-transcriptase inhibitor
NRL	National Referral Laboratory
NRTI	Nucleoside reverse-transcriptase inhibitor
NtRTI	Nucleotide analog reverse transcriptase inhibitor
NVP	Nevirapine
OI	Opportunistic infection
OST	Opioid substitution therapy
PCP	Pneumocystis (jirovecii) pneumonia
PCR	Polymerase chain reaction
PCS	Psychological care and support
PEP	Post-exposure prophylaxis
PGL	Persistent generalised lymphadenopathy

PHDP	Positive health, dignity and prevention
PI	Protease inhibitor
PICO	Population, Intervention, Comparison and Outcomes
PIHTC	Provider initiated HIV testing and counselling
PLHIV	Person/people living with HIV
PMTCT	Prevention of mother-to-child transmission of HIV
PrEP	Pre-exposure prophylaxis of HIV
PSS	Psychosocial support
RAL	Raltegravir
RBV	Ribavirin
RIF	Rifampicin
RNA	Ribonucleic acid
RTV	Ritonavir
sd-NVP	Single-dose nevirapine
SMZ	Sulfamethoxazole
SQV	Saquinavir
STI	Sexually transmitted infection
SUAC	Stepped up adherence counselling
TB	Tuberculosis
TDF	Tenofovir disoproxilfumarate
TEN	Toxic epidermal necrolysis
TMP	Trimethoprim
TPV	Tipranavir
ULN	Upper limit of normal
VCT	Voluntary counselling and testing
VL	Viral load
WHO	World Health Organization
XDR-TB	Extensively drug resistant TB

Adherence: The standard clinical definition of adherence has been 'taking >95% of medications in the right way at the right time'. Over time, this definition has broadened to include additional factors related to continuous, comprehensive care such as following a care plan, attending scheduled clinic appointments, picking up medicines on time and getting regular tests.

Adolescent: a person aged 10 – 19 years inclusive.

Adult: a person aged over 14 years (this definition is strictly for program and data management purposes).

Child: a person aged 14 years and younger.

Couple: two people involved in an intimate relationship.

Exposed infants: is an infant born to an HIV-positive mother.

HIV Presumptive diagnosis: adults and children with signs and symptoms of HIV who are waiting for confirmation of test results.

Infant: a child less than one year of age.

Key populations: sex workers and their clients, men who have sex with men, injecting drug users, prisoners, mobile populations and young girls 15-24 years of age.

Multi-Disciplinary team: an approach to managing patients that involves a team of healthcare workers applying their varying skills sets in the management of complex HIV patients or program issues e.g. switching to second line treatment, or managing co-infection/ comorbidity.

Non-Adherence: characterized by missing one or more doses of medicine, missing one or many appointments at the clinic, lab or pharmacy, not following the care plan, stopping medicine for a day or many days and taking treatment breaks, taking medicines at the wrong times, taking medications without following instructions, mixing ARVs with traditional and alternative medicines or remedies.

Provider-initiated testing and counselling: an approach to HIV testing and counselling, where HIV testing is offered to all patients attending health care facilities.

Rights-based approach: consciously and systematically paying attention to human rights and rights principles in the provision of services.

Serodiscordant couple: a couple in which one partner is living with HIV and the other is HIV-negative.

Stepped-up adherence: an approach to maximising adherence in patients with elevated viral load, who are suspected of failing treatment, designed to rule out poor adherence as the cause of the elevated viral load and may lead to re-suppression once adherence is optimised.

Treatment experienced patients: patients with loss or lack of virologic response to at least two ARV regimens, including at least one member of each of the three drug classes (NRTI, NNRTI, PI)

Undetectable Viral Load: in the Swaziland setting, refers to viral load less than 50 copies/ml.

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Chapter 1:
Introduction

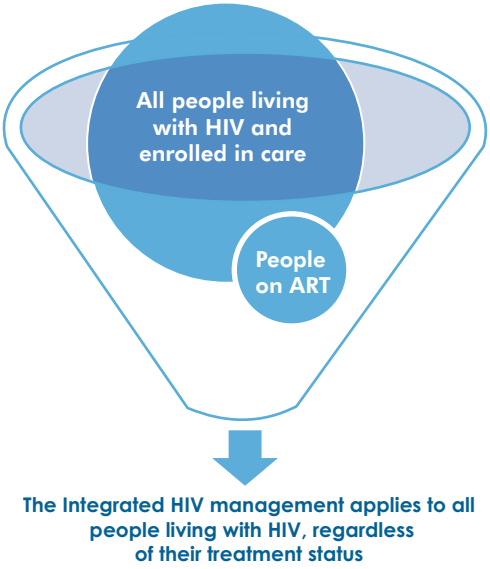
1.1 Background

This Integrated HIV Management Guidelines document is aligned to the WHO consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Prevention of HIV Infections, June 2013. It replaces the Swaziland Ministry of Health National Comprehensive HIV Package of Care, for adults and adolescents, 2010, and the Swaziland Paediatric HIV Management Guidelines 2010.

The Treatment, Care and Support Technical Working Group (TWG) oversaw the development of these guidelines by providing leadership, coordination and reviews. Four sub committees, HTC, Adult Care and Treatment, Paediatric Care and Treatment and PMTCT drafted the respective sections of the guidelines. The sub committees consisted of experts from Ministry of Health, bilateral, multilateral and implementing partner organizations.

These guidelines follow the continuum of care of a patient, from diagnosis to management and are designed to be used at all levels of health care delivery in the country.

Figure 1.1: All People Living with HIV Need Comprehensive Care



1.2 How to Use These Guidelines

The following images will appear throughout the guidelines to highlight:

Children	
Pregnant and breastfeeding women	
Changes to guidelines	
Outside reference	
Reference within guidelines	
Important messages	
Guidance tools	
Dosing Information	

1.3 Summary of Major Changes

Table 1.1: Summary of Major Guideline Changes

HTC: Children • All children with negative or unknown status should be tested at 9 months and 18-24 months (or 8 weeks after cessation of breastfeeding) to determine exposure status and rule out infection (regardless of status of the parents) • All HIV-exposed children should be tested at 6-8 weeks, 9 months, 12 months and 18-24 months (or 8 weeks after cessation of breastfeeding) • Test all children who have signs and symptoms suggestive of HIV • Age of consent is 12 years • Children who come without the primary caregiver should still be tested and primary caregiver invited to come for results
HTC: Key Populations • HTC issues with respect to Key Populations are specifically highlighted.
HTC: Self-testing • The guidelines offer guidance on self-testing, especially in the event of a positive result. This approach is not endorsed by the Ministry of Health and over the counter tests kits are not yet available in the country.
ART Initiation: Adults ART should be initiated in all HIV-positive adults with CD4 cell count <500 cells/ mm^3 regardless of WHO clinical stage. ART should be initiated regardless of CD4 cell count or WHO clinical stage in the following: • The HIV-positive partner in a sero-discordant couple • Patients with tuberculosis • Patients with HBV co-infection • Patients with HIV Associated Nephropathy (HIVAN)

Table 1.1: Summary of Major Guideline Changes (continued)

ART Initiation: Children

- Children <5 years: Initiate on ART regardless of WHO clinical stage or CD4 count
- Children ⩾ 5 years: Initiate on ART, if CD4 <500 cells/mm^3, or WHO stage 3 or 4

ART Initiation: Pregnant and Lactating Women

- All pregnant and lactating HIV-positive women should be initiated on lifelong ART regardless of CD4 and WHO clinical stage, preferably on the day of HIV diagnosis.
- ART initiation should be done at any gestational age (while waiting for the CD4 result and other baselines).
- A once-daily fixed-dose combination of TDF + 3TC+ EFV is recommended as first-line ART in pregnant and breastfeeding women, including pregnant women in the first trimester of pregnancy and women of childbearing age.

Combining ANC, PNC and ART Services:

- All HIV-negative women need to retest at every ANC visit and PNC visit until infant is weaned off breastfeeding
- Mother and baby should be seen jointly as a pair until 18-24 months
- ART services for pregnant women should be provided within ANC settings
- All infants with negative or unknown HIV status should be tested for HIV at 9 months and at 18-24 months regardless of HIV exposure status
- ART follow-up in pregnant and lactating women includes routine monitoring of viral load at baseline and every 6 months until the infant is weaned

Viral Load and CD4 Monitoring:

- Introduction of annual routine viral load monitoring for all patients on ART
- Use of CD4 for patient monitoring will be scaled down

Third-Line Treatment

- Third-line treatment now available in Swaziland

Chapter 2:
HIV Testing and Counselling

HTC (HIV testing and counselling) is the entry point to prevention, care and treatment services. Testing is a process and does not stop at the test itself: results need to be provided to the client and clients need to be linked to either prevention or HIV care and treatment services– ideally on the same day of testing.

> It is essential to offer HTC at all possible points of contact with clients in the health system and community structures

2.1 HIV Testing and Counselling Settings and Approaches

2.1.1 Guiding Principles of HTC

Both CIHTC (client initiated HIV testing and counselling) and PIHTC (provider initiated HIV testing and counselling) are voluntary and the guiding principles of HTC, known as "5 Cs" outlined on the following page, must be respected and adhered to by all HTC service providers and in all settings.

Table 2.1: The Five Guiding Principles of HTC

Guiding Principles	Key Points
Informed Consent	• Clients should be made aware of the indication for, the process of, the benefits as well as the implications of being tested for HIV. • Swaziland has adopted the opt-out approach for obtaining consent for HTC purposes: after HTC is offered, consent is assumed unless an individual explicitly declines the HIV test. In that case, testing is not done. • Verbal consent is recommended; written consent is also accepted (relevant for infants). • Inform clients that refusing an HIV test will not affect their access to other services.
Confidentiality	• Maintain confidentiality of health records at all times. • Access, and access provided to other health workers, to a client's health record should be on a "need to know" basis after relevant assessment. • Document results in a standard, confidential manner (R for reactive (positive) and NR for non-reactive (negative)). • Discuss shared confidentiality during pre-test information and counselling sessions and re-enforce during post-test sessions.
Counselling	• Accompany testing with appropriate and high-quality pre-test information/counselling, and post-test counselling. • Provide follow-up supportive counselling and appropriate referrals as needed.
Correct test results	• Ensure that clients are given correct test results. • Perform testing according to the algorithms included in this guideline and to the national quality assurance standards. • Communicate results to the person tested unless that person refuses to receive the results.
Connection/linkage to prevention, care and treatment	• After testing, link all clients to appropriate HIV prevention, treatment, care and support services, according to their result. • Refer to appropriate follow up services, and ensure that referral information reaches the receiving site. • After receiving the referral, endeavour to make sure that clients link to services.

2.1.2 HTC Approaches: CIHTC and PIHTC

Client-Initiated HTC (CIHTC)

In CIHTC, an individual voluntarily seeks HIV testing and counselling. This approach emphasizes individual risk assessment and management by counsellors, and the development of an individualized risk reduction plan. CIHTC is available in the settings detailed below:

- **Mobile and Outreach Services:** Services provided from fully equipped mobile caravans/vehicles and other movable structures.
- **Integrated sites:** Services integrated or co-located within the health care system in government and non-governmental facilities.
- **Home Based HTC through Door to Door Services:** Services provided in a home setting with a family focus to increase the access and uptake of services.
- **Stand-alone VCT sites:** Sites where only HIV testing and counselling services are provided, with referral for any other needed services.

Provider-Initiated HTC (PIHTC)

In PIHTC, HTC is routinely offered by health care providers to persons attending health care facilities as part of normal standard of care. PIHTC should be made available in different facilities and settings including but not limited to:

- **In-patient and out-patient facilities**
- **Tuberculosis (TB) clinics:** TB patients should be offered HIV testing and all HIV-positive clients should have access to TB screening services.
- **Sexually Transmitted Infection (STI) or sexual health services:** All patients seeking STI services must be routinely offered HIV test as part of the package of STI services.
- **Family planning (FP) services:** HTC should be offered to everyone presenting for FP services. FP, other than condoms, does not offer HIV prevention benefits and dual contraception (condom + other FP method) should be encouraged with promotion of HTC services in this context.
- **Antenatal, delivery and postpartum health services:** HTC must be offered to all women of unknown HIV status during pregnancy, in labour, as soon as possible after delivery or in the postpartum period until breastfeeding is completed.
- **Child Welfare services:** Determine exposure status for all infants and offer routine testing to all exposed infants at the six-week visit or the child's first contact with the health system.
- **Home based HTC services through index clients:** Counsellors providing follow up care to their index client and tracking referrals should provide comprehensive HIV prevention messages and offer HTC.
- **National Blood Transfusion Service:** All persons donating blood must be offered HTC.

2.1.3 Family Testing

Family testing is a successful approach to reach clients who are not attending health facilities or outreach events. A family testing approach involves utilizing the index patient (client testing at that time) to identify and bring HIV prevention, care and treatment services to family members that they are living with. Each client tested in PIHTC or CIHTC settings should be encouraged to visit any testing point with their family, and anyone who is co-habiting with them.

2.1.4 Who Performs an HIV Test

Health workers and lay HTC counsellors who have been trained and certified can perform point of care HIV tests, and collect dried blood samples for infant testing. Training institutions must be recognised by the Ministry of Health as providing sufficient quality of training before they can certify health care workers or lay people to perform HTC, and only those either trained as health practitioners and registered with a Nursing or Medical Council in Swaziland or certified to perform HTC as a lay person should perform HTC.

2.2 HTC Target Groups

Specific guidelines for testing different populations are outlined below.

Table 2.2: Population Specific HTC Guidelines

Population	Key Points
General population	• People should be offered an HIV test at every contact with a health facility and through other CIHTC approaches outlined above. • Everyone should be assumed to be exposed to HIV.
Couples	• Services should be offered to married and cohabiting couples, premarital couples, polygamous unions and any other sexual partnerships. • HIV testing and counselling should be voluntary. • Be aware of intimate partner–based violence and support individuals when they do not want to test with their partners.

Table 2.2: Population Specific HTC Guidelines (continued)

Population	Key Points
Pregnant and Lactating Women	• Re-testing is recommended routinely.
	Before delivery: • At initial ANC visit. If initial test is HIV-negative, repeat at 8 weeks and every ANC visit throughout pregnancy.
	At delivery: • Test women who have never tested or are due for retest.
	After delivery: • Encourage testing at 6 week PNC visit, and every visit mother attends with infant thereafter. • Recommended times are: 10 weeks, 14 weeks, 6 months, 9 months, 12 months, 15 months and 18 months (aligned with baby immunization schedule). • For women who are not bringing their children for immunization, arrange to retest them every 8 weeks pending risk assessment results.
Key Populations	• Key population groups are at higher risk for HIV and include sex workers and their clients, injecting drug users, men who have sex with men, prisoners, mobile populations and young girls 15-24 years of age • Encourage re-testing every 8 weeks, as these groups are at a particularly high risk for HIV infection. • Health care providers should be especially aware to uphold standards of informed consent and confidentiality for these groups.

Table 2.2: Population Specific HTC Guidelines (continued)

Population	Key Points
Children and Adolescents	• Paediatric HIV testing should be conducted in all HTC settings such as Child Welfare Departments, paediatric OPDs or paediatric wards as well as in adult testing points. • Return of results (for DNA PCR) and rapid initiation of treatment is essential. • **HIV-exposed infants** should be tested within 6-8 weeks of birth. Subsequent tests are detailed in the early infant diagnosis algorithm on page 42 • **All children** should be tested routinely **regardless of the HIV exposure** at 9 months and 18-24 months (after cessation of breastfeeding) to determine exposure status and rule out infection at that time. • For children under 18 months of age, HIV infection can only be definitively confirmed using a DNA PCR test on dried blood spots (DBS) because of the presence of persisting maternal HIV antibodies. • **Guiding principle is that "the best interests of the child shall be the primary consideration" in all actions concerning children.**
People with disabilities	• Provisions should be made for persons to access HTC in a manner that meets their specific needs. For individuals unable to consent for themselves, the process of obtaining consent for other medical procedures and diagnostic tests should apply.

2.3 Ethical and Legal Considerations in HTC

2.3.1 Age of consent

The age of consent for HIV testing in Swaziland is 12 years. Individuals 12 years or older may give informed consent for testing for themselves, their children or children they have primary guardianship over.

2.3.2 Mandatory testing

Mandatory HIV testing is not endorsed in Swaziland. It may only be considered in special circumstances where the good of others is in jeopardy, for example, for blood donation and rape perpetrators. In such cases where clients require the results, the testing shall be accompanied by counselling or referral to an HTC site.

2.3.3 Ethical disclosure

HIV test results should be disclosed in person, and only to the client or client's caregiver. Disclosure of results to anyone else should only be done with the client's or caregiver's consent. HCWs are permitted to access a client's HIV status when it relates to care and treatment of the client.

2.3.4 Partner notification

Couples counselling and testing should be promoted. All clients in sexual partnerships presenting for or being offered testing should be encouraged to test together or inform their sexual partner(s) about their HIV test results and encourage them to also get tested. Clients who are reluctant or fearful to disclose their results should schedule a disclosure counselling session with the counsellor to facilitate disclosure. In no case may a health care worker disclose an individual's status to their partner without that individual's consent.

2.3.5 Issues relating to sexual violence

All persons who have been sexually violated should be offered HTC. For those victims who are HIV-negative, post-exposure prophylaxis (PEP) should be offered as soon as possible after exposure but within 72 hours. If the client is HIV-positive, referral must be made to ART services and management must follow the Swaziland Integrated HIV Management Guidelines. Refer to PEP Guidelines. Mandatory testing and counselling for the sexual violence perpetrator can only be performed with a court order, and the results disclosed to the magistrate or judge handling the case.

2.3.6 Legal Issues

HIV testing can only be conducted when it is in the best interest of the child. The Child Protection and Welfare Act of 2012 provides guidance on who can consent for HIV testing of children under 12 years.

2.3.7 Self-testing

Self-testing is not encouraged and test kits are not available from government managed health facilities for this purpose. However, for clients who present to the facility having tested themselves, HCWs should provide proper education, repeat the HIV test (due to concerns about quality) and provide appropriate pre- and post-test counselling (as indicated in this chapter) and link to appropriate prevention or care and treatment services.

2.4 HIV Testing and Counselling Process

2.4.1 General Population

When to test

The general adult and adolescent population should initially be tested at sexual debut, and be tested at **minimum annually thereafter**, provided they test negative. At first testing, or after a known recent exposure, a second test should be offered in 8 weeks to account for the window period.

In CIHTC, a client should be tested whenever presenting for a test, unless a known positive diagnosis is available or the client has tested negative within the current year without a recent exposure.

In PIHTC, a client should be offered a test at any time they present in a health facility for services,unless a known positive diagnosis is available or the client has tested negative within the current year without a recent exposure.

> It is always better to offer HIV testing more often than needed rather than less often. When in doubt, offer the HIV test.

Pre-test information

Pre-test information giving and/or counselling shall be offered to all clients presenting in all health facilities and HTC sites, including in home-based testing settings. Depending on the setting, this can be done in the form of individual counselling, individual information giving sessions and in group health information sessions.

Group pre-test information sessions can be conducted in both PIHTC and CIHTC. They should be conducted by skilled HTC providers and utilized in settings with high client flow. The goal of these sessions should be to discuss general information about HIV and AIDS, HTC services, encourage HTC through sharing the benefits of knowing your own HIV status, and correct any misconceptions about HIV and AIDS.

Table 2.3: Summary of Pre-Test Information

Pre-test information included in both CIHTC and PIHTC:	
• Clinical and prevention benefits of HIV testing • Explain the HTC process • Confidentiality of testing and results • The meaning of HIV test results • Services available in the case of either an HIV-negative or HIV-positive test result • Assurance of recommendations regarding disclosure of the HIV test results • An offer to answer any question the patient/client may have • Informed consent	
• HIV risk assessment • Preparation for testing and receiving results • Suicide assessment and coping skills • Development of a risk reduction plan	• Why PIHTC is recommended • Informing the patient of the right to decline the test and that testing will be performed unless the patient exercises that right • The fact that the test result will be treated confidentially and will not be shared with anyone other than health care providers directly involved in providing services to the patient • Reassurance that refusal to test will not result in the patient being denied care for their current health problem

Follow-up where a test is declined

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

Informed consent

Informed consent for the test should always be obtained individually, in private and in the presence of a health care provider. Consent can be obtained using the opt-in or opt-out approach. Refer to table 2.1 for more information.

With “opt-out” approach, individuals must specifically decline the HIV test after receiving pre-test information if they do not want the test to be performed; otherwise the provider goes ahead and performs the HIV test. The opt-out approach is used in all PIHTC settings. In most circumstances, the health care provider's recommendation will lead to the procedure being performed unless the patient declines. With “opt-in” approach, individuals must verbally explicitly agree to the test being performed after pre-test information has been received. The opt-in approach is used primarily in outreach and VCT settings.

Verbal informed consent is encouraged using opt-out approach. Under the opt-out approach, consent is 'assumed' unless the patient specifically declines the HIV test.

2.5 Types of HIV Testing

Two types of laboratory tests are used in Swaziland:

Antibody (serologic) tests	Rapid tests	***Determine™*** ***Uni-Gold™*** ***Clearview® (used as a rapid tie-breaker)***
	ELISA	As a tie-breaker at National Referral Lab*
Virologic tests	DNA PCR for early infant diagnosis	

*Use ELISA only if Clearview rapid tie-breaker is not available

While antibody testing provides a definitive diagnosis in adults and children over 18 months, virology testing is needed for definitive diagnosis in children younger than 18 months because the presence of maternal antibodies confounds the results of the antibody test.

Antibody Testing

Rapid tests detect antibodies to HIV and can be used to definitively diagnose adults and children 18 months of age or older. Three rapid tests are approved for use in both PIHTC and CIHTC settings; a sensitive test (Determine™ HIV 1/2), a specific test (Unigold™ HIV1/2) and a rapid tie-breaker test (Clearview ®HIV 1/2). In Swaziland, each rapid HIV test is done serially (see figure 2.1 for testing algorithm).

Virologic Testing

DNA PCR HIV testing using the Dried Blood Spot (DBS) technique is used to definitively diagnose children less than 18 months of age.

Window Period

The window period is the period from getting infected with HIV to the time of being able to detect HIV (antigen or antibody) in the serum/blood. The individual is highly infectious during the window period. The length of the window period varies from individual to individual, and also depends on the HIV test used (antibody, virologic). Retesting 8 weeks after the initial test rules out the window period.

Table 2.4: Summary of HIV Tests Performed

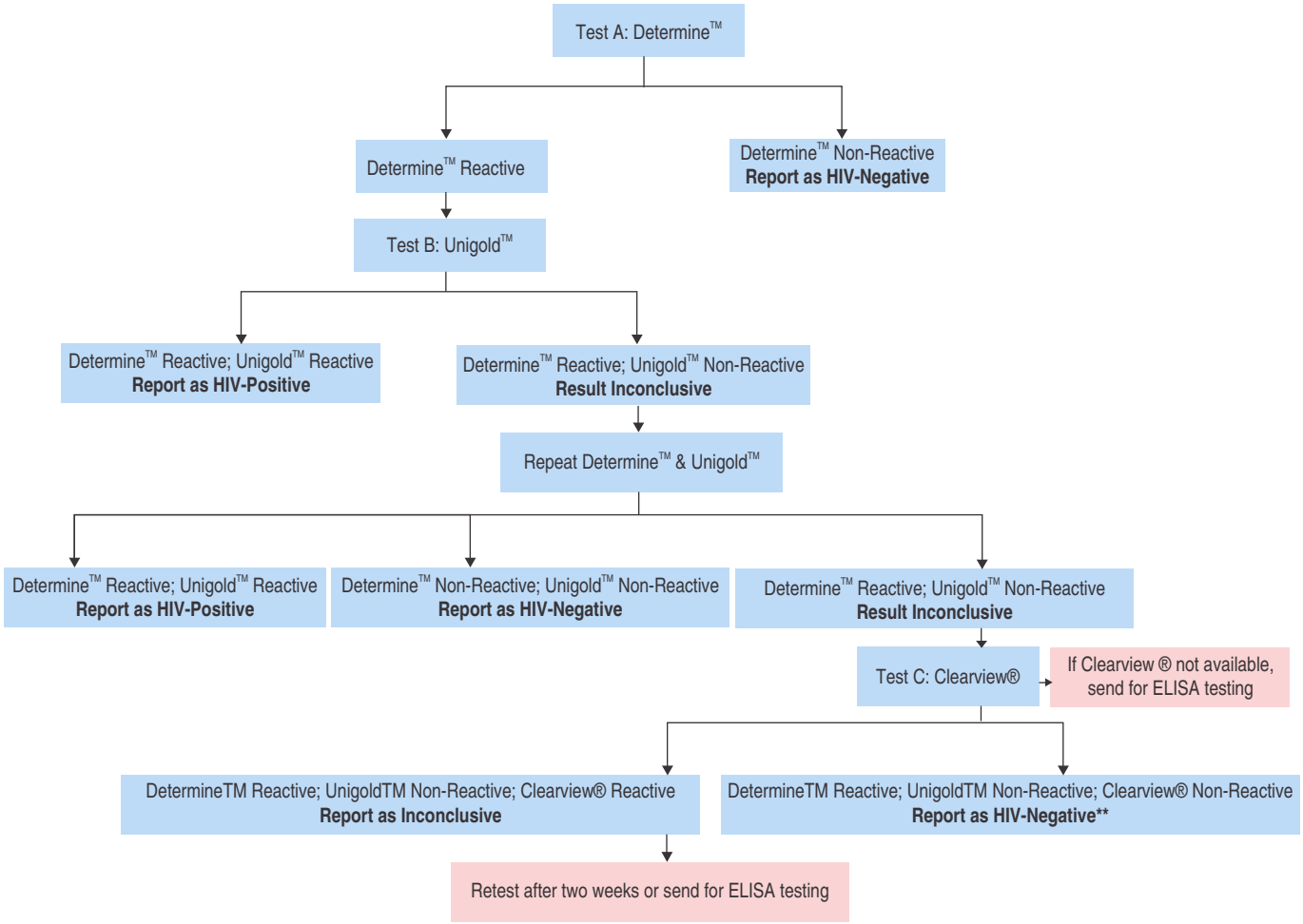
Test type	Antibody (serologic)		Virologic
Test name	**Rapid test** Determine™, Unigold™, Clearview®	**ELISA**	**DNA PCR**
Blood collection site	Finger*	Venipuncture	Heel/toe/finger, Venipuncture
Window period	8 weeks	8 weeks	2-6 weeks
Indication	Diagnosis 18 months or older	Tie-breaker for discordant rapid test results when Clearview not available	Diagnosis under 18 months and tie-breaker for pregant and lactating women
Turn-around-time	30 minutes	2-6 weeks	2-6 weeks

*In certain circumstances, venipuncture may need to be done instead of finger-prick (e.g., if other tests need to be run concurrently)

2.6 Testing Algorithm

An initial blood sample is taken and tested. If the result is negative the result is given to the client as HIV negative. If the result is positive a second test is done using a different rapid HIV test. If the second test is also positive, the result is given to the client as HIV positive. However, if the second test is negative the results are interpreted as discordant and a third rapid test should be used as a tie breaker, if available. If a rapid tie-breaker is unavailable at the time, a venous sample should be sent to the NRL for a tie breaker using Enzyme Linked Immunosorbent Assay (ELISA) testing. The results of the tie breaker are the ones to be given to the client.

Figure 2.1: Serial HIV Testing Algorithm - Rapid Testing in Adults and Children Over 18 Months



***For children who are still breastfeeding, retest after cessation of breastfeeding*

2.7 Post-test Counselling

2.7.1 General Population

Table 2.5: Summary of Post-Test Counselling

Post-test counselling for both positive and negative results should include:	
• Simple and clear communication of test result • Client understanding of the result • The opportunity for the client to ask questions • Review of risk reduction plan including condom and lubricant use skills building • Development of a coping strategy for the client • Assessment of referral needs for other services • Discussion of disclosure of test results • Discussion of partner and family referral for HIV testing where appropriate • Clarify misconceptions and myths about HIV transmission and risks	
Counselling for negative patients should also include:	**Counselling for positive patients should also include:**
• Explanation of window period and recommendation of when to re-test • Discussion of methods to prevent getting HIV such as VMMC, correct and consistent use of condoms, partner reduction etc. • Scheduling of on-going supportive counselling sessions • Referral for prevention services	• Supporting the emotions arising from test result • Discussion of any immediate concerns • Informing individual of available pre-ART and ART services • Information on preventing HIV transmission • Discussion of "positive living" • Scheduling a follow-up counselling session within two weeks to assess coping strategies • Referral to HIV care services and support group

2.7.2 Counselling for Couples

See also counselling points under 'General Population' section (Table 2.5)

Table 2.6: HTC counselling for couples

Topic	Counselling Points
When to test	• Encourage couples testing at all possible times, and when testing an individual, encourage that person to bring in their partner for couples testing. In particular, encourage couples testing during family planning, pregnancy, delivery and post-partum for PMTCT.
Pre- test information	In addition, provide information on the following key points: • Possibility of discordant results where one partner tests positive and the other tests negative • Importance of HIV-negative partner remaining HIV-negative, and the opportunities available for doing so, including treatment for the HIV-positive partner • Issues of support and disclosure • Risk of reinfection
Consent	• Each individual in the relationship must consent to participate in the couple testing
Testing	• In couple testing, the tests for the couple should be conducted simultaneously
Post-test counselling	Counsel on the following points: • Mutual disclosure • Condom use • Family planning • Partner support (discordant couples (stigma, discrimination), concordant positive, concordant negative) • Being faithful • Family testing

2.7.3 Counselling for Pregnant and Lactating Women

See also counselling points under 'General Population' section (Table 2.5)

Table 2.7: HTC counselling for pregnant and lactating women

Topic	Counselling Points
When to test	Provide counselling information and HIV testing at the initial ANC visit, as soon as the woman realizes she is pregnant, for all women with unknown HIV status and for those who have tested negative previously. Provide re-testing after 8 weeks and at every following ANC visit, making particular effort to ensure retesting during the third trimester (around 32-36 weeks)
Pre- test information	Provide information on the following key points: • The risks of transmitting HIV to the infant • Measures that can be taken to reduce MTCT, including ART and infant feeding counselling • The benefits to infants of early diagnosis of HIV • Importance of partner testing • The risk of HIV transmission from an HIV positive male partner to the previously negative woman and implications for MTCT
Consent	*See counselling points under 'General Population' section (Table 2.5)*
Testing	*See counselling points under 'General Population' section (Table 2.5)*
Post-test counselling	Counsel on the following points: • Child birth plans • Family planning • Partner testing • Adequate nutrition for the mother – including iron and folic acid supplements • Infant feeding options • For HIV-positive pregnant and lactating women, antiretroviral therapy for the mother's own health and for PMTCT should be promoted and the importance of HIV testing for the infant reviewed

2.7.4 Counselling for Key Populations

See also counselling points under 'General Population' section (Table 2.5)

Table 2.8: HTC counselling for key populations

Topic	Counselling Points
When to test	Offer testing at all contact points with the health care system, and encourage re-testing every 8 weeks, as these groups are at a particularly high risk for HIV infection
Pre- test information	Provide information on the following key points: • Counsel on harm reduction programs and services • Importance of reducing sexual partners • Importance of partners testing
Consent	*See counselling points under 'General Population' section (Table 2.5)*
Testing	*See counselling points under 'General Population' section (Table 2.5)*
Post-test counselling	***Counsel on the following points:*** ***HIV prevention*** • Remind the client on the modes of transmission of HIV and how they can prevent spread • Encourage client to reduce sexual partners where appropriate • Educate on condom (and lubricant) use, demonstrate and provide condoms • Educate on use of barrier protection such as condoms when having sex • Encourage use of new razors and needles • Encourage partner testing • Ensure understanding of available referral services for both positive as well as negative clients ***HIV transmission*** • HIV can be transmitted through anal sex • Advice on the use of water-based lubricants • High risk of HIV transmission associated with sharing needles and injection materials • Untreated STIs will increase risk of HIV infection ***Importance of reducing sexual partners*** • Multiple sexual partners increases risk of HIV (re)infection/ transmission

HTC and other health services should be made available to everyone, regardless of whether their activities are illegal or not

2.7.5 Counselling for Adolescents Over 12 Years

See also counselling points under 'General Population' section (Table 2.5)

Table 2.9: HTC counselling for adolescents over 12 years

Topic	Counselling Points
When to test	Children over 12 years and adolescents should be offered testing at all the same times as adults. Particular attention should be paid to adolescent women presenting for Family Planning, and to any children or adolescents presenting often at the health facility with illness. In the health system, adolescents are considered from ages 10 to 19, but for the purposes of HTC, adolescents over 12 years are considered here as they can consent themselves for services.
Pre- test information	*Provide information on the following key points:* • Prevention including abstinence, condom use, and VMMC for males • Importance of delay in sexual debut • Importance of reducing sexual partners • Risk of changing sexual partners
Consent The age of consent for HTC is 12 years	• Anyone 12 years or older may give informed consent. • Children under 12 years may provide informed consent for HIV testing if they are considered a premature adult (i.e. are pregnant, are being treated for a sexually transmitted infection, are accessing FP services, and/or are sexually active). • For most adolescents under 12, consent may be given by parents, guardians, caregivers, or health care workers or social workers. Although adolescents may not give informed consent for testing, their agreement should be sought via age-appropriate counselling.
Testing	*See counselling points under 'General Population' section (Table 2.5)*
Post-test counselling	Counsel on the following points: • HIV should be clearly explained in simple terms • Listen and address adolescent's concerns • Focus on risky behaviours and risk reduction plans • If test is positive, reassure that they can live a long healthy life • Clarify misconceptions and myths • Educate about the importance of good nutrition • Refer to appropriate prevention, care and treatment services

Assessment of maturity and mental capacity for children, and those with limited mental capacity: the person must show that he or she understands the benefits, risks and social implications of the HIV test

2.8 Infants and Children Under 12 years

2.8.1 When to test

Table 2.10: When to Test Infants and Children

Age of child	Who to test
6-8 weeks	Exposed infants
9 months	All infants
12 months	Exposed infants
18 months	All children
8 weeks after cessation of breastfeeding	Exposed infants and children
Any suspicion of infection	All infants and children

Encourage mothers to attend at all visits; if mother is present and not already identified as HIV-positive, test the mother to screen for infant exposure before proceeding to the child

2.8.2 Counselling for Infants and Children

See counselling points under 'General Population' section (*Table 2.5*)

Table 2.11: HTC counselling for infants and children under 12 years

Topic	Counselling Points
Pre-test information	• Counsellors providing services to adolescents and minors should receive additional training on the unique issues relating to HTC for these groups and ensure the availability of follow-up post-test support services • Briefly assess the child's knowledge and understanding of HIV / AIDS • Counsel according to their level of development and knowledge using age-appropriate language • Address both the child's and the guardian's questions • Ascertain the HIV exposure status of all infants with unknown or uncertain HIV exposure being seen in health care facilities at or around birth or at the first postnatal visit (usually 4–6 weeks), or other child health visit in line with EPI Schedule Continued Overleaf...

Table 2.11: HTC counselling for infants and children under 12 years (continued)

Topic	Infants and Children under 12 years
Consent	• The age of consent is 12 years. Children younger than 12 years should still be informed about the test through age-appropriate counselling and their agreement / assent sought for testing. • Premature adults – Children under the age of 12 years may consent for HIV testing if they are pregnant, being treated for a sexually transmitted infection, accessing family planning services, and/or are sexually active. • Parents should be informed of the infant testing algorithm early in the ANC process and consent obtained for testing the infant at 6-8 weeks of life. They should also be informed that if a primary caregiver does not attend with the child, that the health worker shall give consent to test and the parent/caregiver will be called in for results.
Parents, guardians, caregivers, or health workers (in consultation with the head of hospital/health facility)may give consent for infants and children under 12 years .	
Post-test counselling	• Younger children should be told their status incrementally to accommodate their cognitive skills and emotional maturity, in preparation for full disclosure

2.8.3 Testing - For all Infants

Provide HTC for all infants and children coming to any health facility through routine PIHTC, in addition to the regular ages outlined below:

Unknown infant exposure status:
If no previous testing information for mother or infant is available, perform a rapid test to determine exposure status and proceed per the algorithm.

- Conduct virological testing at 6-8 weeks of age or at the earliest opportunity thereafter for all HIV-exposed infants
- Start ART without delay and collect a second specimen to confirm the initial positive virological test result for infants with an initial positive virological test result.
- **Conduct routine HIV serological testing on all healthy exposed infants at 9, 12, and 18 months of age (or 8 weeks after cessation of breastfeeding).**
- Conduct virological testing on all infants who have reactive serological assays at 9 months to identify HIV-infected infants who need ART
- Perform HIV serological testing on children 18 months of age or older with suspected infection or exposure, according to the standard diagnostic HIV serological testing algorithm used in adults

A negative test for an exposed infant is incredibly important and should not be overlooked as an opportunity: treat all negative tests as opportunities to counsel the mother and ensure that the infant remains negative.

2.8.4 Infant Testing Algorithm

Test anytime if child is sick or HIV is suspected; all infants may be exposed to HIV until they are no longer breastfeeding

Figure 2.2: Infant and Young Child HIV Testing Algorithm

Age of Infant	Infants & Young Children Eligible for Testing	How to Test the Infant or Young Child
6-8 Weeks	***All Exposed infants*** *Offer test to mother and infant if exposure status unknown*	DNA PCR TEST → HIV Positive / HIV-Negative, Still Exposed • For infant: Give co-trimoxazole, stop NVP at 6 weeks • Encourage EBF for 6 months, then BF + complementary foods until at least 12 months and safe to stop BF • For mother: Ensure on ART, support adherence & family planning; encourage family testing
9 Months	***All infants*** *Offer test to mother and infant, regardless of exposure status, unless known to be HIV-positive*	RAPID TEST → Reactive → DNA PCR TEST → HIV Positive / HIV-Negative, Still Exposed RAPID TEST → Not Reactive
12 Months	***All Exposed infants*** *unless known to be HIV-positive*	RAPID TEST → Reactive → DNA PCR TEST → HIV Positive → *Encourage continued breast-feeding for best nutrition* DNA PCR TEST → HIV-Negative, Still Exposed → *If safe, encourage ending breast feeding over the course of one month to stop exposure* RAPID TEST → Not Reactive
18 to 24 Months	***All Children*** *Offer test to mother and child, regardless of exposure status, unless known to be HIV-positive*	*Follow adult testing algorithm:* RAPID TEST → Reactive: HIV-positive / Not Reactive: HIV Negative *Confirm all reactive results with second rapid test*
After Stopping Breastfeeding	***All Exposed Infants and Young Children*** *unless known to be HIV-positive*	<9 months: DNA PCR 6weeks post-BF 9-18 months: Rapid Test and confirm with DNA PCR 8 weeks post-BF >18 months: Rapid testing 8 weeks post-BF (adult algorithm)

Mothers / primary guardians should attend all clinic visits with infant and be offered a test if status is unknown or previously negative – this test will act as the screening test for the infant. If mother does not attend, conduct DNA/PCR test if known to be exposed or screen with rapid test if exposure status is unknown but have mother return with infant for results, regardless of whether positive or negative.

2.9 Ensuring Quality in HIV Testing and Counselling Services

2.9.1 Quality assurance

Quality assurance (QA) refers to administrative and procedural activities implemented in a quality system so that requirements and goals of a service will be fulfilled. HIV testing and counselling services must be accompanied by appropriate and high quality pre-test information and post-test counselling. Quality assurance mechanisms and supportive supervision and mentoring systems should be in place to ensure the provision of high-quality testing and counselling.

Table 2.12: Quality Assurance Procedures

QA for Testing		
HTC provider	**Supervisors**	**Laboratories/National HTC Program**
• Conduct a quality control every time a new batch is opened • Participate in all proficiency panel testing and document reports • Store test kits in a temperature controlled environment e.g. refrigerator • Ensure samples are stored and transported appropriately • Adhere to rapid HIV testing SOPs and national HIV testing algorithms	• Ensure facility has the ability for cold chain management • Ensure samples are stored and transported appropriately • Oversight of testing performed by HTC providers • Ensure adherence to rapid HIV testing SOPs and national HIV testing algorithms • Monitor stock management of HIV rapid test commodities	• Conduct regular on-site supportive supervision for laboratory and point of testing sites • Conduct rapid HIV testing trainings, DNA PCR refresher trainings, • Conduct regular proficiency panel testing and ensure facilities receive reports • Ensure documentation and dissemination of QA assessments reports • Review HIV testing registers • Ensure samples are stored and transported appropriately • Review HIV testing SOPs and national HIV testing algorithms • Disseminate information on HIV testing and monitoring compliance with recommended testing algorithm(s) • Evaluate the performance of new HIV rapid test kits at national level. Only approved kits may be used

Table 2.12: Quality Assurance Procedures (continued)

QA for Counselling		
HTC provider	**Supervisors**	**National HTC Program**
• Administer counsellor reflection forms • Administer client satisfaction measuring tools i.e. client exit forms • Document and disseminate QA assessments report	• Regular Site visits • Conduct regular sit-ins with HTC providers • Supportive supervision for counsellors • Counsellor care • Client intake record and review procedures • Documentation and dissemination of QA assessments report	• Oversight of HIV Counselling QA and control (e.g. accreditation of HTC training organs and the standardization of the HTC curricula) • Refresher trainings • Quality assurance tools

NB: All HTC facilities are required to participate in internal and external QA activities. Facilities with consistently unreliable QA tests will be followed through with additional technical supervision and support from NRL.

2.9.2 Quality improvement

HTC providers are encouraged to make appropriate quality improvements as gaps are identified. Sites must establish multi-disciplinary teams, performance standards and develop QI plans which should be monitored regular by facility supervisors.

2.9.3 Documentation

HIV testing and results should be documented in the patient's personal health record as well as in the HTC and other appropriate registers. Care must be taken to record the results in a clear but confidential manner. To ensure consistency of reporting, “R” = Reactive (positive) and “NR” = Non-Reactive (negative). Other results such as discordant are rare and should be documented in full with an explanation of the follow-up testing plan.

2.9.4 Safety in HTC

Standard Universal precautions and strict laboratory safety precautions must be followed. All testing facilities are required to have site-appropriate SOPs on laboratory safety precautions on hand. These should be displayed conspicuously (pasted on the walls) in corresponding key areas where the testing is performed.

2.10 Referrals and Linkages

It is the responsibility of the testing health care worker to ensure the referral is made, and that the receiving site is aware that a client is expected for follow up services.

It is the responsibility of the receiving site to appoint the expected referral (if not attending the same day) and follow up in the case of non-attendance to ensure linkage

HTC providers should refer for the following services as a high priority, among any others deemed necessary:

- HIV Care and Treatment
- On-going counselling
- HIV prevention (e.g. VMMC, family planning, PMTCT)
- Sexual and reproductive health, including family planning
- Support groups
- Medical and psychosocial care and support services

Written results should be provided to the client in all cases. The National Referral Form should be used, as it includes mechanisms for feedback between referring and receiving sites. Refer to the National Referrals and Linkages Framework for further details on linkage and retention.

The responsibilities of health care workers at the testing site with regard to linkage and referrals include:

- Providers of referral services should know and understand the service needs of their clients and be aware of available community resources to meet these needs.
- Staff members working in community-based and outreach settings should be trained to implement and manage referrals.
- Providers should establish appropriate collaborative relationships for referrals.
- Providers who offer HIV prevention counselling and testing but not a full range of medical and psychosocial support services should develop direct, clearly defined arrangements with other providers who can offer needed services.
- A referral directory or guide should be maintained to help staff members make appropriate referrals.

Table 2.13: Summary of Referral and Linkages

Referral and linkages for both positive and negative patients should include • Same day referral, if services offered on-site • Referral to another facility that is conducive to the care of the patient	
Referral and linkages for negative patients should also include: • Referral for re-test • Referral to other prevention services(condoms, VMMC, FP)	**Referral and linkages for positive patients should also include:** • Ensuring enrolment to care and treatment services • Ensuring effective referral PMTCT services • Referral to other supportive care services

Chapter 3:
Basic Care Package for **HIV-positive Individuals**

3.1 Beginning Chronic Care

HIV Testing and Counselling (HTC) is the gateway to HIV prevention, care and treatment services. Effective linkages to these services are crucial and need to be strengthened. The ART program recommends that all patients who test HIV-positive should be referred to and enrolled into chronic care and all facilities should strive to provide basic chronic care packages for all HIV positive individuals.

Steps in Chronic Care

Step 1: Register patient into chronic care register (Pre-ART Register) / and APMR electronic patient management system where applicable

Step 2: Completion of a chronic care patient file and appointment card

Step 3: Screening for TB, other opportunistic infections (OIs), and any other illnesses (NCDs)

Step 4: Blood drawn for baseline tests

Step 5: Management of OIs and any other illnesses (NCDs)

Step 6: Provision of CTX and INH prophylaxis

Step 7: Offer family planning services

Step 8: Offer ongoing psychosocial and adherence support

Step 9: Set up next appointment and document in the appointment register

Step 10: Follow-up with patients in the event of missed appointments or as needed

3.2 Monitoring for PLHIV not yet on ART (Pre-ART)

All PLHIV should have regular clinical check-ups based on their WHO clinical stage, immunological (CD4) and functional status.

3.2.1 Clinical Monitoring

Table 3.1: Clinical Check-up Schedule for Adults Not on ART

Clinical Stage	Follow-up Schedule	Components of Routine Evaluation
All PLHIV should undergo routine clinical staging at each health facility visit. This is particularly important where CD4 cell count is not readily available.		
Stage 1 or 2	• Book a clinical review at one month and every three months* • If the patient has an opportunistic infection or inter-current illness, book clinical visits as necessary	• Take appropriate history and perform physical examination • Clinical review of symptoms and signs, medication use, and side effects • Determine HIV clinical stage and functional status and document • Assess adherence and psychosocial status and provide ongoing counselling • Assess nutritional status • Screen for TB • Provide acute care, if necessary • Manage current illnesses and complaints • Manage chronic conditions • Resupply co-trimoxazole and INH • Offer family planning
Stage 3 or 4	• ART is a priority for these patients. If patient is not ready, book a monthly clinical review	

** Book additional visits for counselling and management of illness as needed*

3.2.2 Laboratory Monitoring

Table 3.2: CD4 and Other Laboratory Testing Schedule for Adults not on ART

Population	Lab test	Frequency
All adults	• CD4 count • Scheduling of any other tests should be based on clinical indication	• At initial HIV diagnosis. • If CD4 count <500 cells/mm^3: • Initiate or refer for ART initiation. (Refer to page xxx in chapter xxx for CD4 monitoring in patients on ART) • If CD4 count >500 cells/mm^3: • Every 6 months
Females	VIA or Pap smear	Annually

3.3 Prophylaxis

Prophylaxis is medication that is taken to prevent life threatening opportunistic infections in PLHIV.

3.3.1 Co-trimoxazole Preventative Therapy (CPT)

Indications

Adults, adolescents and children

All patients with HIV infection, including those on ART should receive co-trimoxazole prophylaxis.

Pregnant women

It is safe to give co-trimoxazole to pregnant and breastfeeding women even in the first trimester of pregnancy.

Dosing for Adults, Adolescents and Children

When initiating, dispense a one month's supply and schedule a follow-up visit for two days before the supply is due to run out.

Patients with a history of severe allergy to sulphur should not be given co-trimoxazole. In such cases, dapsone is a safer alternative.

Dosing for co-trimoxazole for adults, adolescents and children

Age	Weight	Suspension (200 mg SMZ + 40mg TMP) / 5ml Once daily	Paediatric Tablet 100mg SMZ + 20mg TMP Once daily	Single-Strength Adult Tablet 400mg SMZ + 80mg TMP Once daily	Double-Strength Adult Tablet 800mg SMZ + 160 mg TMP Once daily
6wks-<6mths	<5 kg	2.5mL	1	¼	—
6mths – 5yrs	5–15 kg	5mL	2	½	—
⩾6yrs – 14 yrs	15-30 kg	10mL	4	1	—
>14 yrs	>30 kg	—	—	2	1

All doses should be taken with food and plenty of fluids to reduce stomach upset

Adverse Events

Table 3.3: Co-trimoxazole Toxicity Grading Scale for Adults and Adolescents

Toxicity level	Clinical Description	Recommendation
Grade 1	Erythema	Continue prophylaxis with careful and repeated observation and follow-up. Provide symptomatic treatment, such as antihistamines.
Grade 2	Diffuse maculopapular rash, dry desquamation	
Grade 3	Vesiculation, mucosal ulceration	Discontinue co-trimoxazole. Desensitisation can be considered where medical doctor is available (see Section on co-trimoxazole desensitization on page 54
Grade 4	Exfoliative dermatitis, Stevens-Johnson syndrome or erythema multiforme, moist desquamation	Permanently discontinue. Refer patient for hospital care.

Document any allergic reactions clearly in the patient's file and appointment card.

Discontinuation of Co-trimoxazole Preventative Therapy

All patients

Patients should continue co-trimoxazole prophylaxis for life, unless the following apply:

The doctor finds a medical reason to stop co-trimoxazole

- Severe (Grade 3 or 4) adverse reaction to co-trimoxazole or any other sulphur-containing medication
- Severe kidney disease (creatinine clearance < 50ml/min) and/or liver disease (liver function tests > 5 times upper limit of normal)

Cases where adherence is an issue and pill burden is a factor

- High pill burden and there is evidence of immune recovery (CD4 count >350 cells/mm^3 for at least 6 months), AND
- There is no history of PCP or toxoplasmosis

The reason for stopping co-trimoxazole should be documented in the patient's file and patient's appointment card.
Every effort should be made to continue with the prophylaxis unless there is an absolute contra-indication.
If co-trimoxazole must be permanently discontinued, dapsone is an acceptable alternative.

Adults and Adolescents: Dapsone 100mg once daily (with food)
Children: Dapsone 2mg/kg once daily (with food)

Co-trimoxazole Desensitisation in Adults and Adolescents

In instances of Grade 3 reactions to co-trimoxazole, consider desensitisation as described below.

Desensitisation should only be performed under the supervision of a medical doctor

An antihistamine regimen should be started one day before the desensitisation regimen begins, and continued daily until the dose escalation is complete. If a severe reaction occurs, terminate the desensitisation regimen. For a minor reaction, repeat the same step for an additional day. If reaction subsides, advance to the next step; if reaction worsens, terminate the desensitisation regimen.

In patients with a Grade 4 reaction, do not attempt desensitisation, immediately refer to a hospital for further management.

Table 3.4: Co-trimoxazole Desensitisation for Adults and Adolescents

Step	Dose	Suspension*	Tablet
Day 1	80 mg SMZ + 16 mg TMP	2 mls of oral suspension	———
Day 2	160 mg SMZ + 32 mg TMP	4 mls of oral suspension	———
Day 3	240 mg SMZ + 48 mg TMP	6 mls of oral suspension	———
Day 4	320 mg SMZ + 64 mg TMP	8 mls of oral suspension	———
Day 5	400 mg SMZ + 80 mg TMP	———	One single-strength SMZ–TMP tablet
Day 6 onward	800 mg SMZ + 160 mg TMP	———	Two single-strength SMZ–TMP tablets or one double strength tablet

Co-trimoxazole oral suspension ***(200 mg SMZ + 40mg TMZ)/ 5ml***

3.3.2 Isoniazid Preventative Therapy (IPT)

Indications

- All PLHIV who DO NOT have active TB (screened negative using the TB symptom screening tool) qualify for IPT for 6 months
- All HIV-positive children in whom active TB has been ruled out:
  - Children ≤12 months should be given IPT with history of TB contact
  - Children >12 months should be given IPT routinely

Contraindications

- Acute and chronic liver disease
- History of poor adherence
- Excessive consumption of alcohol

Adherence must be monitored closely, so this treatment is appropriate only when such monitoring is possible.

Dosing

⩾5	½ tablet	50
5.1–9.9	1 tablet	100
10–13.9	1½ tablets	150
14–19.9	2 tablets	200
20–24.9	2½ tablets	250
⩾25 to Adult	3 tablets or 1 adult tablet	300

Pyridoxine 1-2 mg/kg daily (25-100mg for adults) with each dose of isoniazid is recommended to reduce the risk of peripheral neuropathy.

Isoniazid is taken once daily for 6 months. Best absorbed when taken on an empty stomach (1 hour before or 2 hours after a meal).

Monitoring

Align IPT visits with scheduled HIV care visits. At each visit, assess for:

- TB symptoms (cough, fever, night sweats, and weight loss)
- Toxicity (hepatitis, neuropathy, and rash)
- Adherence
- Blood draw performed one month after initiation of IPT
- If a person on IPT develops TB symptoms, discontinue IPT and promptly evaluate for TB
- Hold INH if:
  - Symptoms of acute hepatitis and elevation of ALT three times ULN
  - When ALT increases or 5 times the ULN

Defaulting IPT

- Patients who miss up to one month of therapy (30 days) should have length of IPT extended to accommodate the missed doses
- Patients missing doses frequently e.g. 2 -3 times per week should have the IPT stopped and be counselled on medication adherence. Re-initiate the IPT only if patient is agreeable to medication schedule and dosing. The number of doses missed should be added to the length of treatment already received but should not last longer than 9 months (270 days)
- Patients who miss medication doses for up to 60 consecutive days should have IPT stopped, and counselled on medication adherence. If patient is to re-initiate IPT, they will be registered as a new patient and given a new course of IPT

Patient education and counselling

Symptom awareness

All PLHIV should be educated on the importance of seeking medical care promptly if they—or any person they live with—develops symptoms suggestive of TB (e.g. cough with sputum and blood at times, chest pains, weakness, weight loss, fever and night sweats) or develop recognised side effects of Isoniazid such as yellowing of eyes, itchy skin rash, and abdominal pain with vomiting.

Patient's Household Members

Household contacts of the person with TB should be evaluated for TB and offered HIV testing and counselling. IPT should be offered to all household contacts who are HIV-positive or are children under 5, and do not have symptoms and signs of TB.

For further information on IPT, refer to the Swaziland IPT guidelines.

3.3.3 Fluconazole Prophylaxis

Indications

Currently fluconazole is only provided as secondary prophylaxis after a patient has been successfully treated for cryptococcal disease (most commonly cryptococcal meningitis).

Contraindications

- History of hypersensitivity to fluconazole or other azole medicines
- Patients taking terfenadine multiple doses of 400 mg per day or higher
- CYP3A4 substrates which may lead to QT prolongation (astemizole, quinidine, cisapride)
- Pregnancy

Dosing

When to Start
Fluconazole should be started soon after the consolidation phase of cryptococcal meningitis treatment.

When to Stop
Fluconazole secondary prophylaxis can safely be stopped in patients on ART who return two consecutive CD4 cell count results above 200 cells/mm^3 6 months apart. Consider re-starting fluconazole in patients who have a history of cryptococcal disease and whose CD4 cell count has dropped below 200 cells/mm^3

Adult dose: 200mg fluconazole once daily

Paediatric dose: 12.5mg/kg/day

3.4 OI Screening and Treatment

For opportunistic infections (OIs) not covered in these guidelines, refer to the Swaziland Standard Treatment Guidelines (STG).

3.4.1 Important OIs

Important OIs affecting patients in Swaziland include tuberculosis (TB), cryptococcal meningitis, pneumocystis pneumonia, Kaposi's sarcoma, cervical cancer, recurrent bacterial pneumonia, recurrent oral candidiasis, oesophageal candidiasis, herpes zoster and toxoplasmosis. For detailed management of these conditions, please refer to the Swaziland Standard Treatment Guidelines (STG).

3.4.2 Tuberculosis

Prevention of Tuberculosis among PLHIV

All PLHIV should be regularly screened for TB at the time of initial presentation for HIV care and at every visit to a health facility or contact with a health care worker afterwards. Efforts to reduce the risk of TB transmission within the home and in health facilities should be included in the care of PLHIV.

The following activities should be implemented at all entry points providing HIV and TB care:

1. Three I's (Prevention and treatment of TB among PLHIV)
   a. ICF: Intensified TB case-finding (ICF) and treatment of all identified TB cases
   b. IPT: Use IPT to prevent TB (see IPT section on page 55)
   c. IPC: Infection prevention and control of TB (IPC); refer patients with active TB to TB clinic if available, separate people in facility waiting areas, ensure air flow.

2. Prevention and treatment of HIV infection in patients with active tuberculosis
   a. Provide HTC to patients with presumptive and diagnosed TB
   b. Provide co-trimoxazole preventive therapy for TB patients living with HIV (see CPT section page 50)
   c. Ensure HIV prevention interventions for HIV-negative TB patients and early ART initiation for TB patients living with HIV
   d. Provide IPT for TB/HIV co-infected patients who have successfully completed their TB treatment.

For more information, please refer to the National 3 Is guidelines

Pulmonary Tuberculosis Diagnosis in Adults and Adolescents

For more information on the diagnosis and management of Tuberculosis see National Tuberculosis Guidelines.

Evaluation for Other Diagnoses

- When treating empirically for a lower respiratory tract infection use antibiotics that cover both typical and atypical pneumonias (except fluoroquinolones)
- Further investigations should be done at the same time so as to decrease the number of visits and speed up the diagnosis
- Advise the patient to return for reassessment if symptoms recur

3.4.3 Cryptococcal Meningitis

Cryptococcal meningitis is caused by the fungus, cryptococcus neoformans. Patients with cryptococcal meningitis should be referred to a doctor for further management as soon as the condition is suspected.

When to Suspect

Symptoms include fever, fatigue, headache, blurred vision and confusion. Symptom onset is often sub-acute and progressively worsens over several weeks.

Diagnosis

Gold standard is culture of CSF for Cryptococcus neoformans. Other tests include:

- Positive Cryptococcal antigen (CrAg) (CSF CrAg is more specific)
- CSF India ink

Management

If cryptococcal meningitis is suspected in the primary health care setting, that patient should be urgently referred to a hospital for further management.

Treatment

Amphotericin B is the drug that is readily available in Swaziland and forms the mainstay of cryptococcal meningitis treatment.

Induction: Intravenous Amphotericin B (0.7-1.0 mg/kg/day) combined with oral flucytosine (5FC) 100mg/kg/day (in 4 divided doses) is the recommended treatment. If 5FC is not available, fluconazole 400-800mg/day should be used with Amphotericin B.

Therapeutic CSF tapping: Is recommended if the opening pressure is >250mm H_2O, persistent headache, recurrent vomiting or altered mental state

Consolidation: Fluconazole 400 mg/day for 8 -10 weeks

Secondary prophylaxis: Fluconazole 200 mg/day until two consecutive CD4 cell counts with results >200 cells/mm^3 6 months apart.

*lipid formulations of Amphotericin B are superior but also cost more. Dosage: 4-6mg/kg/Day.

Delay ART initiation for 4 - 8 weeks depending on the patient's condition. Aim to initiate at 4 weeks post diagnosis

3.4.4 Kaposi's Sarcoma

Kaposi's sarcoma (KS) is a condition caused by Human Herpes Virus-8 (HHV-8). Patients with KS should start ART regardless of CD4 cell count.

Protocol for Management of KS

- Chemotherapy for KS is available in all four regional hospitals.
- ART is the first line treatment for KS.
- Patients with advanced KS (Poor Risk) should be referred for chemotherapy.

For risk categories, see page 62.

Good Risk: First line treatment is ART. For single lesions; Intra-lesional vincristine or vinblastine can be used in addition to ART.

Adriamycin* (Doxorubicin) 40 -60 mg/m^2 over 3-5 minutes X1 every 21 days
+
Bleomycin** 10 - 20 units/m^2
+
Vincristine 1.4 – 1.5 mg/m^2; Maximum of 2 mg/dose
OR
Vinblastine 3.7 – 18.5mg/m^2

**Adriamycin: Recommended life time dose is 550 mg*
***Bleomycin: Recommended life time dose is 400 units*

AIDS Clinical Trial Group (ACTG) Staging System

T (Tumour) Status

T0 (Good Risk): Localized tumour

- Lesions are limited to the skin and/or the lymph nodes and/or there is only a small amount of disease on the palate. Lesions in the mouth are flat.

T1 (Poor Risk): Lesions are wide spread

- One or more of the following: Oedema or ulceration; extensive oral KS; nodular lesions and/ or lesions in other areas of the mouth besides the palate; lesions in other organs other than lymph nodes (such as lungs, intestines, liver etc.)

I (immune System) Status
I0 (Good Risk): CD4 cell count is $\geqslant$150 cells/mm^3

I1 (Poor Risk): CD4 cell count is < 150 cells/mm^3

S (Systemic Illness) Status
S0 (**Good Risk**): No systemic illness present
- Karnofsky performance status (KPS) score $\geqslant$ 70

S1 (**Poor Risk**): Systemic illness present
One or more of the following is true:
- History of opportunistic infections
- One or more B symptoms. These include: unexplained fever, night sweats, weight loss, diarrhoea, anaemia
- A KPS score < 70

Once these features have been assessed, patients are assigned an overall risk group (either Good Risk or Poor Risk)

Good Risk: T0 S0, T1 S0, or T0 S1
Poor Risk: T1 S1

3.4.5 Cervical Cancer

When to suspect

Unfortunately, there are no early signs and symptoms of cervical cancer. Most often, the cancer is diagnosed at an advanced stage. Symptoms may include:

- Unusual vaginal discharge, sometimes foul smelling
- Irregular vaginal bleeding in women of reproductive age
- Postmenopausal spotting or bleeding
- Post coital spotting or bleeding in women of any age, even in young women
- Lower abdominal pain

Diagnosis

The definitive diagnosis of cancer is confirmed by histopathological examination of tissue specimens taken from the lesion.

Cervical Cancer Screening

Since all women are at risk of cervical cancer, it is recommended that women that have initiated sexual activity should go for screening every 2 years and those who are HIV-positive should be screened every year at least. The available screening tests include;

- Cytology: conventional (Pap smear)
- Visual inspection with acetic acid (VIA) - VIA is the method widely used in Swaziland

Management Options of Pre-Cancer Lesions

Biopsy performed with the aid of colposcopy (colposcopy and biopsy) is the standard method for diagnosis of cervical pre-cancer lesions and pre-clinical invasive cancer.

Treatment is:

- Cryotherapy
- LEEP
- Cold knife conization

"Screen-and-treat" approach

In this approach, treatment decisions are based on the results of the VIA screening test, without a prior diagnostic test. Women that screen-positive can be treated with cryotherapy at the primary health care level.

Colposcopy-based "see-and-treat" approach/ digital cervicography

Patients with a positive screen (on Pap smear, VIA, or HPV) can be examined with colposcopy. If a pre-cancerous lesion is detected, it can be treated immediately with cryotherapy if applicable. Colposcopy directed biopsies can be taken before cryotherapy to confirm the diagnosis. If LEEP is used, a biopsy specimen will be available as a result of the procedure. This approach is dependent on the availability of equipment and experienced providers.

Management of invasive cancer

In order to manage a cervical cancer patient properly, it is essential to understand the extent or "stage" of her disease at the time of diagnosis. Although staging systems are to some extent artificial, they guide the clinician in both tailoring treatment and assessing prognosis.

Cervical cancer staging system

The classification of the International Federation of Gynaecology and Obstetrics (FIGO), which is based on tumour size and the extent of spread of disease in the pelvis and distant organs, is recommended for staging invasive cervical cancer.

Stages of Cervical Cancer

Stage 0: Cancer cells found only on the surface (epithelium) of the cervix

More invasive cancers are separated into four stages:

Stage I: Cancer has not spread beyond the cervix

Stage II: Tumour has spread to the upper part of the vagina or the parametrium

Stage III: Tumour extends to the lower part of the vagina or the pelvic wall and may block urine flow

Stage IV: The tumour has reached the bladder or rectum, or cancer cells have spread to other parts of the body

Treatment Options: Invasive Cervical Cancer

Radiotherapy

Radiotherapy is used with or without surgery. External radiation therapy uses high-energy X-rays to kill cancer cells in the targeted areas and can also be used after surgery. Other forms include internal radiation or brachytherapy. It is usually indicated for larger tumours (from stage IB), in patients who are unable to tolerate general anaesthesia, with extensive involvement of the lymph nodes in the groin or to alleviate symptoms, especially bone pain and vaginal bleeding.

Chemotherapy

Chemotherapy is not used for primary therapy, but may be given with radiotherapy, or used before or after surgery.

Surgery

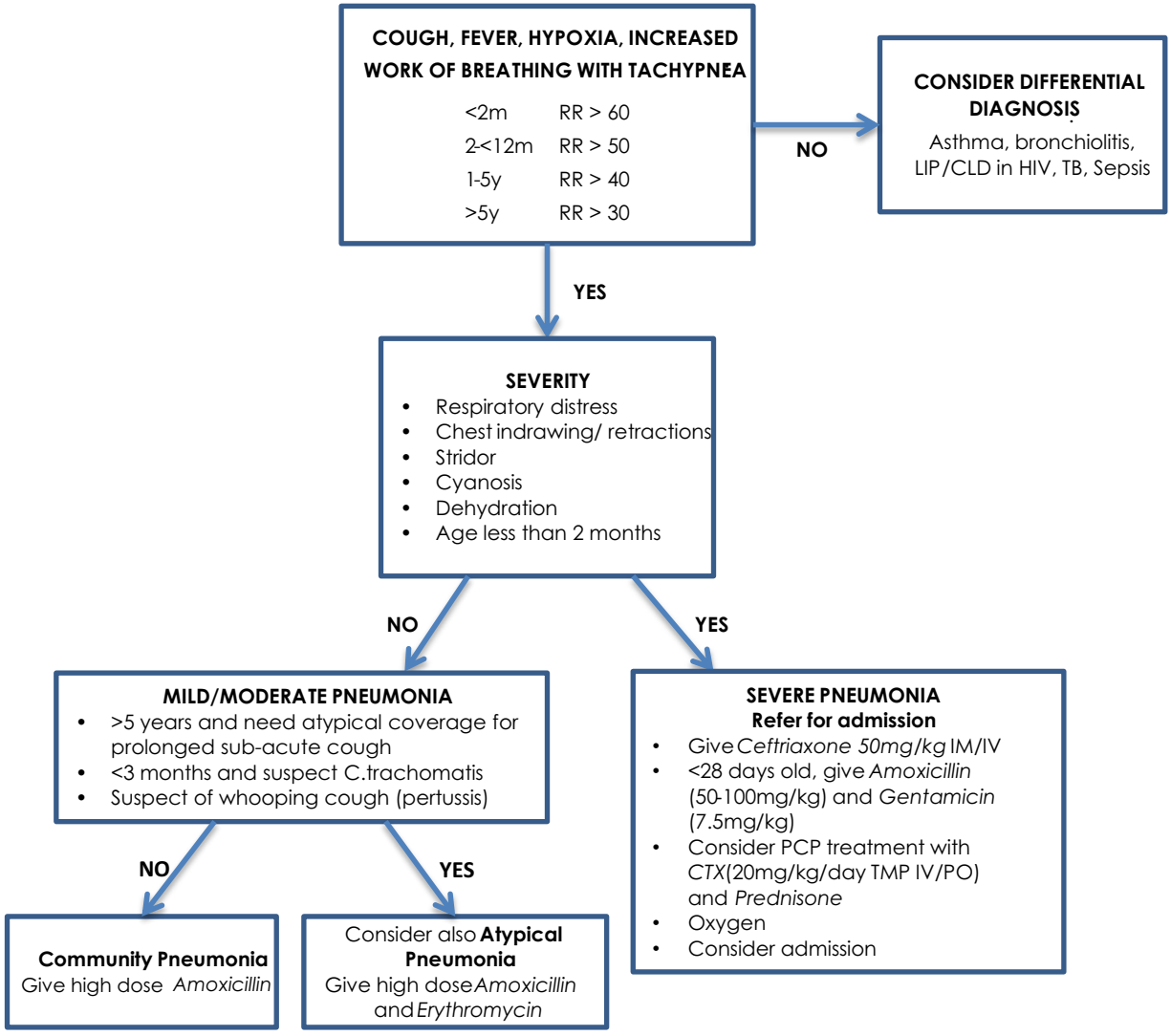
Curative surgery in cervical cancer aims to remove the primary tumour, with all extensions, in a single operation. If the cancer has not progressed beyond Stage II, hysterectomy is usually recommended and this involves the removal of the cervix and uterus as well as some surrounding tissue.

Palliative care

Palliative care is offered to clients and their families in the last stages of cervical cancer where surgery, radiotherapy, or chemotherapy is no longer curative.

3.4.6 Special Considerations: OIs in Children

Respiratory Conditions



If symptoms do not subside after treatment, reasses and / or refer as necessary

Table 3.5: Pneumonia Treatment for HIV-Positive Paediatric Patients

	AMOXICILLIN High Dose (80-100mg/kg/day) Give BD for 5 days		ERYTHROMYCIN (30-50mg/kg/day) Give TDS for 5 days	
Weight (kg)	**Tablet** (250mg)	**Syrup** (125mg/5ml)	**Tablet** (250mg)	**Syrup** (125mg/5ml)
< 4	½	5 ml	¼	2.5 ml
4 - < 6	1	10 ml	¼	2.5 ml
6 - < 10	1.5	15 ml	½	5 ml
10 - < 15	2	20 ml	½	10 ml
15 - < 25	3	30 ml	1	10 ml
Adult(⩾ 25 kg)	4	—	2	—

Follow up in 2 days. If not improving on Amoxicillin +/- Erythromycin, consider TB, LIP or asthma.

Chapter 4:
Antiretroviral Therapy

4.1 When to Start

Identify and treat OIs BEFORE initiating ART

All HIV infected adults and adolescents with CD4 ⩽500 cells/mm^3 should be started on ART

- Special attention should be given to **patients with advanced disease (CD4 ⩽350 cells/mm^3 OR WHO stage III or IV) and those above 50 years of age.** They should be initiated on ART as a matter of urgency

Special Populations listed below should be started on ART regardless of CD4 cell count or WHO clinical stage:

- The HIV positive partner in a sero-discordant relationship*
- Pregnant women
- Patients with tuberculosis
- Patients with HBV co-infection**
- Patients with HIV Associated Nephropathy (HIVAN)
- Children under 5 years of age

**Relationship refers to when the individuals identify themselves as partners*
*** If the laboratory test for HBV surface antigen is positive*

4.2 Preparation of Patients for ART

Patients and caregivers must be well-prepared for ART to avoid treatment failure

Patients should be initiated on ART as soon as possible, preferably on day of HIV diagnosis while adherence counselling is ongoing

Patient Readiness

Patient readiness is determined by:

- Willingness to take ART
- Eligibility based on clinical, immunological or special population criteria
- A favourable psychosocial assessment
- Ongoing adherence counselling

Provider Readiness

Provider readiness is determined by:

- Complete patient documentation, including patient file, registration in appropriate registers and patient booklet
- Comprehensive patient assessment:
  - o Complete physical assessment
  - o Complete laboratory assessment (unavailability of laboratory tests should not hinder ART initiation) see Table 4.1
  - o Complete psychosocial assessment

Encourage early ART initiation for eligible patients

4.2.1 Baseline Laboratory Tests

Baseline laboratory investigations are an essential component of preparations for ART initiation. **However unavailability of tests should not delay ART initiation.**

Table 4.1: Recommended Baseline Laboratory Investigations

Test	Comments
CD4	Is required to determine ART eligibility if the patient does not qualify by other criteria
FBC	Is essential for patients being initiated on AZT. If not available, perform point of care Hb using Hemacue
AST/ALT	If not available, look for signs of liver disease prior to initiation
Creatinine	Is essential for patients being initiated on TDF. If not available rule out renal dysfunction clinically prior to initiation
Hep B surface antigen	If positive, initiate patient on ART regardless of CD4 cell count

Unavailability of baseline results (including creatinine unless the patient has risk factor/s for renal dysfunction) should not delay the initiation of patients on ART or deny them the opportunity to be initiated on the preferred first line of TDF+3TC+EFV. Collect a blood sample as soon as available to serve as the baseline.

4.2.2 Pre-ART Adherence Counselling

- It is recommended that all adult patients should participate in one group counselling session and at least one individual counselling session.
- Treatment supporters should be encouraged to attend counselling sessions
- These two counselling sessions can happen on the same day as HIV diagnosis

Adherence counselling and support should be provided during all patient encounters and key messages repeated regularly

General Guidance on Adherence Counselling*:

- Adopt a "no blame" approach to facilitate open and honest discussion
- Actively involve the patient in the decision making of their care and treatment
- Interventions to support adherence should be individualised to address specific barriers:
  - Identify and address any concerns about personal need for ART
  - Identify and address specific concerns about taking ART
  - Identify and address practical barriers to adherence (limitations in capacity and resources)
- Only use interventions to overcome practical problems if there is a specific need. These interventions might include:
  - Patients recording their medicine taking (ticking)
  - Simplify the dosing regimen
  - Use adherence aides like pill boxes and phone alarm reminders
  - If side effects are a problem:
    - *Discuss benefits and long term effects and options for dealing with side effects*
    - *Consider adjusting the dosage, substitution or other strategies such as changing dose timing or formulation*
- Patients' experience of taking ART and their needs for adherence support may change over time
  - Patients' knowledge, understanding and concerns about medicines and the benefits they perceive should be reviewed regularly

Adopted from the British HIV Association guidelines for treatment of HIV-1-positive adults with antiretroviral therapy 2012

Group Education Sessions

Key Messages:

- Basic facts about HIV (including transmission and prevention of transmission)
- Eligibility criteria
- Chronic care in HIV
- Importance of adherence (viral suppression, reduce transmission, prevent OIs, prevent drug resistance)
- Positive health, dignity and prevention (PHDP)
  - Risk reduction counselling
  - Disclosure
  - Partner testing
  - Adherence counselling
  - Condoms and family planning
  - STI diagnosis and management

Individuals Sessions

Key Messages:

- Understanding of patients results and need for ART
- Understanding ART and its benefits
- Discuss the patient's regimen and side effects related to the patient's regimen
- Importance of disclosure
- Importance of adherence
- Importance of a treatment supporter
- What to do when dose is missed

Pregnant Women

Key Messages:

- Basic facts on ARVs(as covered in non-pregnant populations)
- Importance of ART for PMTCT and for the woman's own health
- Importance of adherence to ART for PMTCT and for the woman's own health
  - Development of an adherence plan
  - Joining a support group
- ART side effects and what to do
- What to do when a dose is missed
- Importance of keeping appointments and routine ANC visits schedules
- Importance of delivering at a health facility
- Ensure child is breastfed and tested accordingly

4.3 What to Start: First-Line ART

See Annex 7.3 Overview of ARV Drugs

Basic Principles of ARV Therapy

- ART regime for treatment naïve patients should contain 2 NRTIs and 1 NNRTI preferably.
- Regimen selection should take into consideration factors such as co-morbid conditions (e.g. tuberculosis, hepatic dysfunction, renal dysfunction) and potential interactions with other medications. (See Annex 7.5)

4.3.1 New Guidance

- EFV can be used in women of child-bearing age and pregnant women in the first trimester. If a woman becomes pregnant while on EFV, continue this therapy
- TDF can be used in women of child-bearing age and in pregnant women
- d4T and ddI are **not recommended** as components of a standard first line regimen

4.3.2 First-Line ART for Adults and Adolescents

Recommended first-line regimen: TDF (Tenofovir) + 3TC (Lamivudine) + EFV (Efavirenz)

4.3.3 Alternative First-Line Regimens

Table 4.2: Alternative First-Line Regimens

Scenario	Alternative Regimen
When EFV cannot be used: • Grade 3 or 4 EFV-induced skin reaction. • Severe mental illness (e.g depression, psychosis) • Bilateral gynaecomastia in males	**TDF + 3TC + NVP** OR **AZT + 3TC +NVP**
When TDF cannot be used: • Confirmed and/or suspected severe renal dysfunction(CrCl<50ml/min) • Presence of nephrotoxic drugs	**ABC[a] +3TC[b] + EFV** OR **AZT + 3TC[b] + EFV**
When AZT cannot be used: • Anaemia(Hb<10)	**ABC[a] +3TC[b] + EFV** OR **d4T + 3TC + EFV**

All adults, adolescents, pregnant women, sero-discordant couples, TB/HIV and HBV Co-infection receive the same first-line

[a] For patients who have a baseline viral load >100,000 copies/ml, use ABC with caution

[b] See table below for 3TC dose reduction in renal dysfunction patients

4.3.4 TB/HIV Co-infection

People Diagnosed with TB and HIV at the Same Time

Initiate TB treatment as a first priority (see TB guidelines), then initiate ART (in all TB patients, regardless of CD4 count) when TB treatment is tolerated - preferably within 2 weeks of starting TB treatment.

Recommended first-line regimen:

TDF (Tenofovir) + 3TC (Lamivudine) + EFV (Efavirenz)

ART should be started as soon as TB treatment is tolerated, preferably within 2 weeks of TB treatment initiation

People Who Develop TB While on ART

Continue ART with changes to the regimen as necessary and move patient to TB clinic from ART clinic for duration of TB treatment. Client should return to ART clinic after finishing TB treatment.

TB Treatment Drug Interactions

Table 4.3: TB Drug Interactions

Drug Combination	Recommendation
Rifampicin and Nevirapine	• If NVP is co-administered with rifampicin ∘ Closely monitor for HIV treatment failure and hepatotoxicity ∘ Start the full dose of NVP
Rifampicin and LPV/r	• LPV/r can be used with rifampicin ∘ Boost 1:1 lopinavir and ritonavir ∘ Closely monitor for toxicity and also virologic failure
Rifampicin and oral contraceptive pills	• Oral contraceptive pills may not be effective when administered with rifampicin • Women of childbearing age should either receive a contraceptive pill containing a higher dose of oestrogen (50mcg) or use another form of contraception • Emphasize condom use during this period

MDR TB and ART

- Treatment with tenofovir (TDF) and other nephrotoxic drugs can increase the risk of renal impairment. Many second-line TB drugs are nephrotoxic (amikacin, capreomycin, cycloserine, imipenem, kanamycin, para-aminosalicylic acid), thus the combinations should be used with caution and renal function closely monitored
- Liver function should be monitored for hepatotoxicity when using ethionamide and prothionamide with hepatotoxic ARVs
- Consider the increased potential for psychiatric side effects in patients taking efavirenz with terizidone

TB Treatment in Pregnant and Breastfeeding Women

Pregnancy: TB Treatment can be given during pregnancy; however streptomycin should not be given due to toxicity to the foetus.

Breastfeeding Mothers:

- All first-line TB drugs can be safely used by breastfeeding women
- Women should be encouraged to continue breastfeeding
- Breastfeeding mothers must be provided with surgical masks

For more information on pregnancy and MDR-TB drugs, refer to the MDR-TB Guidelines.

All pregnant women should be screened for TB.
Chest X-Rays are not recommended during pregnancy.

For more information on TB diagnosis and treatment see National Tuberculosis Control Guidelines.

4.3.5 Hep B Co-infection

Ideally, laboratory tests to assess the severity of HBV infection should be performed before starting ART; however these tests are not readily available in Swaziland and thus all HIV-positive individuals who are Hepatitus B surface Antigen positive should be started on ART regardless of their CD4 count or WHO clinical stage.

The recommended first-line regimen for patients with Hep B co-infection is:

TDF (Tenofovir) + 3TC (Lamivudine) + EFV (Efavirenz)

4.3.6 Patients with Renal Dysfunction

Patients at risk of renal disease include those listed below and creatinine clearance should be calculated every time a serum creatinine result is reviewed:

- Known underlying renal disease
- Age > 50 years
- Low BMI <18.5
- Diabetes Mellitus
- Hypertension
- Receiving nephrotoxic drugs

Creatinine Clearance (Cockcroft-Gault Formulae):

$$\frac{(140 - \text{Age}) \times \text{weight in kg} \times 1.23}{\text{Serum creatinine (in µmol/L)}}$$

$$\frac{(140 - \text{Age}) \times \text{weight in kg} \times 1.04}{\text{Serum creatinine (in µmol/L)}}$$

If nephropathy has been confirmed:

- Fixed-dose combinations should not be used
- Individual ARV doses should be adjusted to creatinine clearance, with special attention paid to 3TC (consult doctor)
- TDF should be avoided in patients with creatinine clearance of <50 ml/min

If there are no alternative NRTIs, the TDF dose can be adjusted according to the creatinine clearance, similarly to 3TC as depicted in the following table:

Table 4.4: TDF and 3TC dose reduction in renal impairment

Creatinine Clearance (ml/min)	Tenofovir (TDF) Dose	Lamivudine (3TC) Dose*
≥50	300 mg OD	150mg BD or 300mg OD
30-49	300 mg every 48 hrs	150mg OD
15-29	Avoid, unless receiving haemodialysis then give 300mg every 7 days	100mg (10ml) OD
5-14	Avoid, unless receiving haemodialysis then give 300mg every 7 days	50mg (5ml) OD
<5	Avoid, unless receiving haemodialysis then give 300mg every 7 days	25mg (2.5ml) OD
*Daily 3TC doses apply to both renal dysfunction patients and haemodialysis patients.		

4.3.7 Sero-discordant Couples

A couple for the purposes of these guidelines is defined as people who present together as a couple in a sexual relationship.

A sero-discordant couple is a couple in which one is HIV-positive and the other is HIV-negative. There is strong evidence to show that the rate of transmission is reduced when the positive partner is taking ART.

Recommended first-line ART regimen

TDF (Tenofovir) + 3TC (Lamivudine) + EFV (Efavirenz)

4.4 Patient Follow-up and Monitoring

4.4.1 Clinical Monitoring

During the first six months of treatment, patients should be reviewed monthly. The following should be done at every visit:

- **Adherence counselling and support:** At every visit, include an assessment of adherence (e.g. pill count, assessment of barriers etc.).
- **Clinical monitoring:**
  - Clinical review of symptoms, signs, medication use and side effects
  - Check for immune reconstitution inflammatory syndrome (IRIS)
  - Physical examination including determination of HIV clinical stage and functional status
  - TB Screening, OI screening
  - Acute care, if necessary
  - Management of symptoms
  - Management of chronic problems, e.g. diabetes, hypertension
  - Resupply CTX, ART and IPT if indicated

Immune Reconstitution Inflammatory Syndrome (IRIS)

Any OI occurring during the first six months after ART initiation might have two causes:

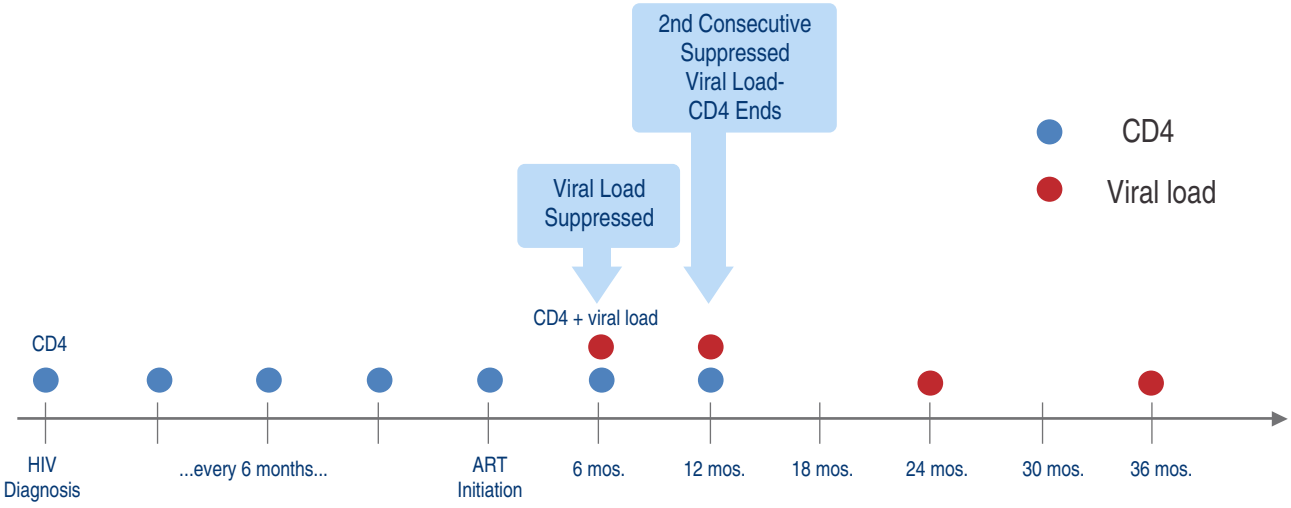
1. The immune system is not yet fully functional (the least likely scenario)
2. IRIS has occurred. Typically seen when a patient's impaired immune function is restored, IRIS is characterized by the paradoxical clinical worsening of a known condition or the appearance of a new condition. Infectious pathogens most frequently implicated in the syndrome include mycobacteria, varicella zoster, herpes viruses, and cytomegalovirus. At clinic level, health care workers should refer patients with suspected IRIS to the doctor or to the hospital.

4.4.2 Laboratory Monitoring

Laboratory monitoring will be done at predetermined intervals.

- *CD4 cell counts:* should be done at 6 month intervals after ART initiation. Once patient has 2 consecutive CD4s > 350cells/mm^3 and is virologically suppressed (see below), CD4 monitoring can be stopped. If treatment failure is suspected, resume CD4 monitoring until patient is virologically suppressed and has 2 consecutive CD4s > 350 cells/mm^3.
- *Viral load:* should be measured 6 months after ART initiation to confirm virological response to ART. After 2 consecutive suppressed viral load results 6 months apart, viral load monitoring can be done annually.
- *Pregnant women:* All women already on ART should have a viral load test at their first ANC visit, all women starting ART after the first ANC visit should have a viral load test at 6 months (see Figure 5.1).

Figure 4.1: Timing of Viral Load and CD4 Monitoring of Stable Patients



Only move to annual viral load monitoring testing if patient has had 2 consecutive suppressed viral loads 6 months apart

4.4.3 Recommended clinical and laboratory monitoring for adult patients

Table 4.5: Clinical and Laboratory monitoring schedule

An 'X' in the table below indicates that the activity or test should be performed

Clinical Monitoring	Baseline	2 weeks	1 month	3 months	6 months	7 months	9 months	12 months	Thereafter
Clinical and Adherence Monitoring	X	X	Perform all clinical evaluations and adherence monitoring at every monthly visit 1-7 after initiation				X	X	Refills: every 3 months Clinical Review: every 3 months
Laboratory Monitoring	**Baseline**	**2 weeks**	**1 month**	**3 months**	**6 months**	**7 months**	**9 months**	**12 months**	**Thereafter**
CD4 count or %	X				X			X	Every 6 months(stop when 2 consecutive CD4>350 and VL suppressed)
Viral Load					X	1st VL results given to patient		X	Every 12 months (if VL >1000, see VL algorithm below)
CBC/FBC	X								Repeat according to clinical requirements
Haemoglobin			X(if regimen includes AZT)	X(if regimen includes AZT)				X	Every 12 months (if regimen includes AZT)
Urea and Creatinine	X		X (pregnant women)		X (if regimen includes TDF)			X (if regimen includes TDF)	Every 6 months (if on TDF) All visits (if known renal dysfunction)
AST/ALT	X	X (if regimen includes NVP)		X (if regimen includes NVP or previous abnormal liver function)					If stable repeat every 12 months (as needed if clinically indicated)
Females	Pregnancy test								Pap smear every 12 months

Table 4.6: First Viral Load Test Results

1st viral load test result	Most likely reasoning	Timing of test
⩽1000 copies/ml	Viral suppression	6 months after ART initiation, or at routine annual testing
>1000 copies/ml	Virological failure	2 consecutive results 3-4 months apart (when tested more than 6 months after initiation)

- Patients with viral load > 1000 copies/ml should have a repeat viral load test done 3 months after receiving the result. A stepped-up adherence form should be opened for the patient, and *stepped-up adherence* counselling and support should be provided
- In the case of virological failure, it is important that the patient only receives a 1 month supply of ARVs, to ensure that they attend the next appointment for ongoing adherence monitoring – both counselling and follow up viral load testing
- Patients with virological suppression (viral load ⩽ 1000 copies/ml) should undergo repeat viral load testing annually

Table 4.7: Repeat Viral Load Test Results after initial non-suppression

Repeat Viral Load test result	Most likely reasoning	What to do
⩽1000 copies/ml	Patient was poorly adherent	Adherence should be reinforced, and the viral load should be rechecked after 6 months and annually thereafter if viral load ⩽1000 copies/ml
>1000 copies/ml	Diagnosis is virological treatment failure most likely due to resistant virus	These patients should be referred to the Dr and MDT for consideration of switching to second- line therapy

Figure 4.2: Viral Load Algorithm for Management of Treatment Failure (Adults)

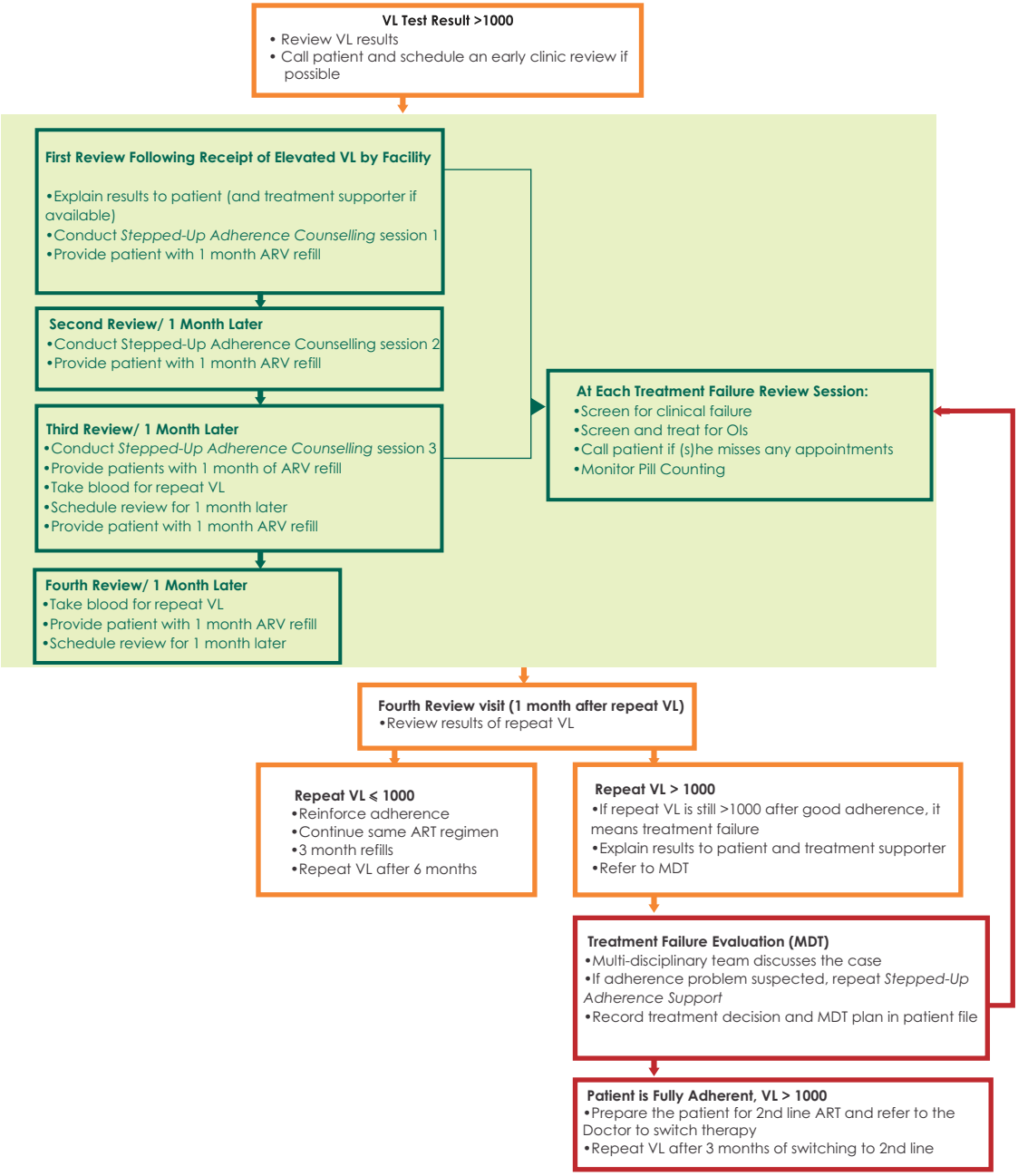


Table 4.8: Stepped-Up Adherence Counselling, Support Package for Adults on ART

Psychosocial: how to **address** patients	• Have a **positive, caring and engaging attitud**e towards the patients and their supporters. • **Address understanding** of the chronic care issues by the patients and their supporters. • Use **job aids** for counselling on difficult topics: pictures, photos or any other tool that the client relates to. • **Engage the family and other treatment supporters** in the care of the client. Invite and counsel any new treatment supporter. Arrange family meetings if situation allows. • **Empowerment:** encourage questions/discussion. Listen to the person's own story. Focus on positive things, encourage a positive attitude to living with HIV. Address myths, misperceptions and spread knowledge. • **Involve the client** in important decisions to better understand why certain decisions are made. Make short term plans, set up goals with the patient and/or caregiver and follow up how goals were achieved.
Other Psychosocial aspects of care	• On a regular basis follow up what **time** medicines are taken and **adjust** the time if necessary. • Encourage participation in **support groups,** map the closest ones and **facilitate referrals.** Start/support peer support counselling groups at your facility. • For clients that may benefit of it, conduct a series of biweekly/monthly sessions facilitated by committed psychosocial support staff who **know the patients well.** • If possible conduct **home visits** to help understand the social environment and offer relevant support, engage community health care workers in support. • Screen for mental condition: depression, alcohol or drug use, home based violence, sexual violence, peer bulling, etc. • Screen for other possible barriers to care or barriers for adherence: transport costs, stigma, misconceptions, side effects and address them.
Clinical/follow up	• Make sure to regularly update **contact details** for clients; phone numbers and address. If possible confirm them. • Actively rule out **opportunistic infections** or other medical conditions. • Provide adherence counselling and follow up issues at every visit. Encourage use of an alarm, cell phone, watch etc., as **reminders for medication doses.** Encourage **use of a pillbox** and monitor use and maintenance if patient benefits of it. Encourage keeping the medication stored safely. • Address potential medication **side-effects.** Make sure the patient has adequate lab monitoring including **CD4 and viral load as per guidelines.** Only repeat **viral load** after at least 3 months of **recorded good adherence** according to the guidelines. Call the patient back if labs are found to be abnormal and require immediate action. • Encourage to still take meds even if late or on an empty stomach rather than skipping pills. Repeat doses that were spit out or vomited within 30 minutes. • Set up and use a system at your facility to **avoid patients being lost to follow up,** both pre-ART and for clients who defaulted ART and to call back clients who missed

4.5 Managing Treatment Failure

4.5.1 Identifying Treatment Failure

- A single viral load between 50-1000 copies/ml, preceded and followed by an undetectable viral load should not be a cause for clinical concern
- A single viral load >1000 copies/ml should be investigated further. Stepped-up adherence counselling should be given for at least **3 months**, and viral load should then be repeated. Treatment failure is defined as 2 viral loads > 1000 copies/ml, at least 3 months apart, irrespective of clinical and immunological findings, despite stepped-up adherence counselling in the interim

Table 4.9: Parameters of Treatment Failure

Failure	Definition	Comments
Clinical failure	**Adults:** New or recurrent clinical event indicating severe immunodeficiency (WHO clinical stage 4 condition) after 6 months of effective treatment	• The condition must be differentiated from immune reconstitution inflammatory syndrome (IRIS), occurring after initiating ART • For adults, certain WHO clinical stage 3 conditions (pulmonary TB and severe bacterial infections) may also indicate treatment failure
Immunological failure	**Adults:** CD4 count falls to the baseline (or below) Or Persistent CD4 levels below 100 cells/mm^3	• Without concomitant or recent infection to cause a transient decline in the CD4 cell count, a systematic review found that current WHO clinical and immunological criteria have low sensitivity and positive predictive value for identifying individuals with virological failure. The predicted value would be expected to be even lower with earlier ART initiation and treatment failure at higher CD4 cell counts. There is currently no proposed alternative definition of treatment failure and no validated alternative definition of immunological failure
Virological failure	Plasma viral load (VL) above 1000 copies/ml based on two consecutive viral load measurements at least 3 months apart, with stepped-up adherence support in the interim	• An individual must be taking ART for at least 6 months before it can be determined that a regimen has failed

4.5.2 Treatment of Virological Failure

Virologically confirmed treatment failure should be referred to a doctor for management. Patients failing treatment should be managed by a multi-disciplinary team (MDT). It is recommended the treating doctor discuss with at least two other doctors prior to switching.

Potential causes of treatment failure should be assessed. These include:

- Patient factors
  - o Poor adherence
  - o Inter-current illness
  - o Co-morbidities
  - o Substance abuse
  - o Extreme age
  - o Advanced disease
  - o Transmitted resistance
  - o Social and economic factors
  - o Toxicity
  - o Malabsorption
- Health system factors
  - o Drug stock outs
  - o Incorrect regimen and drug doses
  - o Accessibility to services
  - o Drug-drug interactions

Patient may be switched to second line therapy after a thorough assessment and continues to fail virologically

Before Switching Regimens

- Take a thorough ARV history to help determine the appropriate second-line regimen
- Optimize adherence
- Treat all inter-current OIs until they have resolved
- Treat and control all co-morbidities when possible

4.5.3 Preventing Treatment Failure

- Ensure patients have had adequate preparation prior to ART initiation; adherence, psychosocial assessments and patients willingness to initiate. See section 4.2 on preparation for ART
- Conduct a viral load test at 6 months as a measure of early adherence and monitor CD4 count every six months until CD4 count is >350 cells/mm^3 on 2 consecutive occasions
- Provide on-going adherence and psychosocial support. See Table 4.8

4.6 What to Switch: Second and Third-Line ART

4.6.1 Second-line ART for Adults and Adolescents

Second-line ART for adults and adolescents should consist of two nucleoside reverse-transcriptase inhibitors (NRTIs) + a ritonavir-boosted protease inhibitor (PI). The following sequence of second-line NRTI options is recommended:

First-Line Regimen	Second-Line Regimen
TDF + 3TC + EFV TDF + 3TC + NVP	AZT + 3TC + LPV/r or ATV/r*
AZT + 3TC + EFV AZT + 3TC + NVP	TDF + 3TC + LPV/r or ATV/r*

** Preferred when available*

4.6.2 Treatment-Experienced Patients

Treatment-experienced patients are defined as those with loss or lack of virologic response to at least two ARV regimens, including at least one member of each of three drug classes (nucleoside reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), and protease inhibitor (PI)).

The goal of treatment for these patients is to re-establish virologic suppression to <50 copies/ml. Assessing and managing a treatment-experienced patient is complex and as a rule should be managed by a MDT. Patients who were previously treated with regimens other than the standard first-line must be individually evaluated before switching to a second-line regimen

4.6.3 Third-Line ART for Adults

Third-line regimens should include new drugs with minimal risk of cross-resistance to previously used regimens, such as integrase inhibitors and second-generation NNRTIs and PIs. However, patients on a failing second-line regimen with no new ARV options should be put on a holding regimen.

Before Switching to Third-Line

- Review and document a full medical, laboratory and ARV drug history. A full physical exam is advisable to exclude any OIs or co-morbidities
- Arrange for in-depth stepped-up adherence counselling for the patient
- Order baseline laboratory test (Hb, ALT, Bilirubin, Fasting Blood Sugar)
- Order resistance testing (genotypic or phenotypic) while the patient is still on failing second-line regimen or no later than four weeks after discontinuing failing regimen

Switching to Third-Line

- Initiate third-line regimen treatment after reviewing results to resistance tests and after satisfactory stepped-up adherence counselling
- Arrange for repeat viral loads and follow up metabolic tests (Fasting Blood Sugar, cholesterol and triglycerides) at 3 and 6 months

Recommended Combination for Third-Line Regimen

Darunavir/ritonavir (DRV/r) 600mg/100mg 12 hourly
+
Etravirine (ETV) 200mg 12 hourly
+
Raltegravir (RAL) 400mg 12 hourly

4.7 Adherence

4.7.1 Adherence Defined

Adherence is defined as the "extent to which a client's behaviour coincides with the prescribed health care regimen as agreed through a shared decision-making process between the client and the health care provider".

- This definition implies that the patient's active participation to establish treatment goals and the medical regimen is critical
- For ART services, adherence to the medical regimen includes the client taking the correct number of pills (correct dosing) at the correct frequency
- Adherence of >95% - 105% is accepted as optimal adherence. Levels of adherence <95% or >105% are considered to be sub-optimal

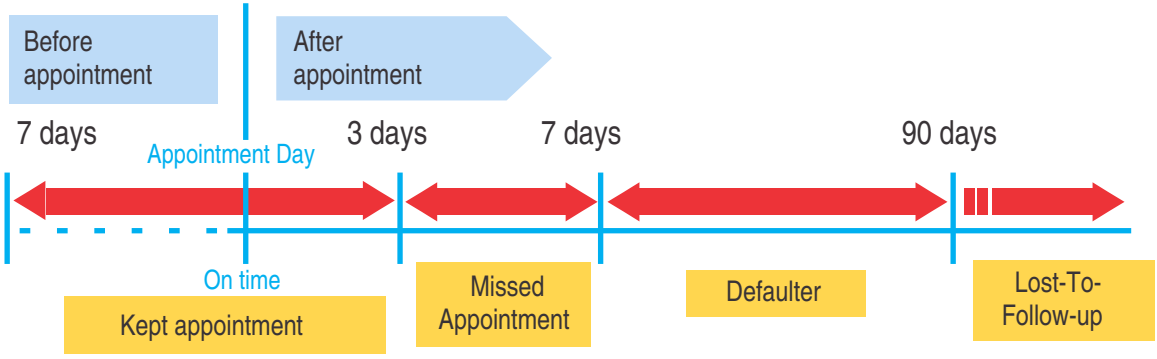
4.7.2 Importance of Adherence

Adherence is a concern to clinicians, healthcare systems and other stakeholders (e.g. taxpayers) because of evidence that non-adherence is prevalent and is associated with adverse outcomes and higher costs of care.

4.7.3 Recommendations for Adherence

- Provide comprehensive adherence counselling prior to ART initiation
- Reinforce adherence messages, consistently and regularly during patient follow up
- Provide intensified (Stepped-Up) adherence counselling for patients missing appointments/ doses and those failing therapy

4.7.4 Appointment Attendance Definitions



4.7.5 Key Adherence Messages

See section on preparation of patients for ART.

Prior to Initiation and ongoing care

Key Messages on adherence prior to initiation[1,2]

- Medication adherence
  - Use open-ended questions to encourage the client to open up
  - Perform a subjective assessment of adherence (patient self-reporting)
  - Perform an objective assessment of adherence to ARVs and OI prophylaxis
  - Discuss side effects
  - Work with client to use appropriate reminders (e.g. alarm on cellphone)
- Discuss the importance of keeping scheduled clinical and laboratory appointments
- Practice confidentiality and reassure clients that their HIV status or anything discussed in the sessions will not be disclosed without their consent
- Use an appointment system to track which clients are supposed to come to the clinic each day, and for which services
- Develop tracing systems to follow up with clients who miss appointments
- For clients who have missed appointments: Conduct home visits or link to Rural Health Motivators or other community health workers, provided the client has consented in advance to be contacted

[1]Delamater AM. Improving patient adherence. Clinical diabetes. 2006
[2]Osterburg L, Blashchke T. Adherence to medication. NEJM. 2005

A Patient Returning to Care After Defaulting/ Loss to Follow Up

Consider all points listed above under 'ongoing care' in addition to:

- Discuss barriers to adherence and challenges the patient faced
- Recognize and acknowledge the difficulty of adherence
- Reinforce education on HIV and ART adherence
- Take a full history and examination
- Work with the patient to identify strategies to improve adherence
- Provide support and encouragement

4.7.5 Key Adherence Messages (continued)

Patient Failing First or Second-Line (Stepped-Up Adherence)

Consider all points listed above under 'ongoing care' in addition to:

- Determine barriers to medication adherence; logistical (travel away from home, travel to facility), psychosocial (stigma, lack of disclosure) medication-specific (related to side effects, number of pills)
- Discuss the use of adherence reminders (dosing diary / calendars, pill boxes, setting an alarm (e.g. using a mobile phone), asking a friend / family member to remind you).
- Lifestyle changes since starting treatment making it more difficult to remain adherent (would the patient benefit from mandatory support group attendance or a stepped-up schedule of counsellor visits)
- Identify any psychological health issues, such as depression; or risky behaviours such as excessive alcohol use or drug use

Clients Who Repeatedly Face Adherence Challenges

Consider all points listed above under 'ongoing care' in addition to:

- Provide one-on-one counselling to try and understand what is happening in the person's life and the reasons behind the poor adherence
    - If transportation costs or distances are barriers, try to locate a clinic offering needed services closer to the person's home, then conduct a formal transfer
    - If alcohol and substance abuse may be the cause of non-adherence, screen for them and provide referrals for counselling and treatment if necessary
- Encourage the client to use a treatment supporter – an individual to directly observe him/her taking their medicine until adherence barriers are overcome-and encourage that they join a support group.
- Health care facilities should routinely document and trace patients who fail to return for clinic appointments (through the use of a telephone, home visit or via a community based health worker)

4.7.5 Key Adherence Messages (continued)

Patients with Co-Morbidities (including TB)

Consider all points listed above under 'ongoing care' in addition to:

- Medication adherence discussion must cover both ARVs and other medications; compliance with all therapy is vital
- Consider drug interactions leading to worsened side effects or treatment failure (see Table 4.3 and Annex 7.5 for interactions)
- In patients co-infected with TB:
  - Choose the most appropriate time and place for DOTS
  - Facilitate access to treatment through provision of HIV services at all TB facilities
  - Combine TB and ART reviews
- Defaulter tracing: Encourage treatment supporters to immediately notify the TB facility when the patients has defaulted or missed appointments, so tracing of the patient via a phone call or home visit from the RHM can be initiated. A defaulter card should be completed and the regional TB coordinator informed.

4.8 Defaulter Tracing

Facilities should set up defaulter tracing committees with representation from the entire Multidisciplinary Team (MDT). The objective of the committee is to oversee and ensure timely follow up of patients who have not kept their appointments and develop a patient tracing plan.

4.8.1 Defaulter Tracing Methodology

With patient consent, SMS reminders, telephone calls and home visits can be utilised to improve patient appointment compliance.

The Linkage and Retention to HIV Care and Treatment SOP should be referenced for implementation steps.

Chapter 5:
Prevention of Mother-to-Child Transmission (PMTCT)

5.1 PMTCT Approach

Strategically, PMTCT is implemented through a four pronged approach as shown in Table 5.1 below.

Table 5.1: PMTCT Prongs

Prong	Description	Interventions
Prong 1	Primary prevention of HIV infection among women of child bearing age	• Counsel couples on HIV prevention, safe sex, treatment as prevention, behaviour change • Promote couples testing, mutual disclosure and support for discordance; repeat testing of negative mothers during pregnancy • Conduct STI screening and manage accordingly • Encourage women to support their partners to undergo VMMC • Provide support for individuals who suffer from gender-based violence eg. post rape care
Prong 2	Prevention of unintended pregnancies among HIV-positive women	• Family planning counselling - assist women to identify reproductive goals; discuss full range of contraceptive options including short acting, long acting, reversible and permanent options • Promote family planning with **dual protection**
Prong 3	Prevention of mother to child transmission of HIV (PMTCT) among HIV- positive pregnant women	• Routine offer of HTC to all pregnant women with unknown HIV status • Lifelong ART for pregnant and lactating women • Good obstetric practices • Infant prophylaxis • Reinforce safer infant feeding practices
Prong 4	Care, support and treatment for HIV-positive women and their families	• Integrated HIV treatment and support for the mother, infant and family • Strengthen patient follow-up, linkage to care and treatment • Promote community approaches for patient tracking and adherence support

5.2 Services for Non-Pregnant Women Within MNCH

Primary Prevention of HIV among Women of Child Bearing Age (Prong 1)

Table 5.2: HIV Prevention Services for Non-Pregnant Women

Service	Description
HTC	Provide routine HIV testing and counselling services for all women of child bearing age visiting the health facility and their male partners and referral for prevention, care and treatment services *See HTC Chapter 2*
HIV Prevention Counselling	Provide information and counselling on HIV prevention and how to reduce the risk of sexual HIV transmission *See HTC Chapter 2*
Counsel on family planning and safer sex, promoting dual protection **and offer condoms (both female and male) and build skills for condom negotiation and use**	• **Support woman/couple to identify reproductive goals, and select a contraceptive option per goals (cover short acting, long term reversible and permanent methods)** • **Counsel on dual protection** • Promote correct and consistent use of female and male condoms for the woman and her partner emphasizing the benefits of dual protection during pre-conception, pregnancy, postpartum, and infant feeding • Give reasons and benefits for using condoms • Dispel myths and misconceptions about condoms • Demonstrate condom use • Teach condom negotiation skills • Promote/teach mutual assistance in using – both partners' involvement • Provide condoms (both male and female)
Provide STI screening and management	See STI guidelines
Provide gender-based violence prevention and impact mitigation services	• Identify gender related risks that can expose women to HIV (gender based violence, poverty, unemployment) • Provide information to empower women on gender equality and equity – SRH rights • Provide counselling, psychosocial support, emergency contraception, HIV/STI PEP • Encourage joint decision making with partner on visit to health facility for care on condom usage; parental consenting on EIMC etc. • Provide information on services and organizations specialized on gender based violence • Refer people who have experienced or are experiencing gender-based violence to appropriate services, including legal and psychological support services e.g. to SWAAGA centres

Table 5.2: HIV Prevention Services for Non-Pregnant Women (continued)

Service	Description
Provide men's minimum healthcare package to any partner of the women visiting the health facility	Process of consultation • The Health Care Worker should explain the process of consultation to the client (man)– *examination, screening and testing; discussing the role of the man in HIV prevention (for himself, partner and child); including mention of gender-based violence, cultural norms and practices; discuss importance of communication with partner etc.* Provide health education on men's health • HCWs should educate/counsel and/or refer the male client on health issues – SRH (based on history, physical examination and investigation e.g. diabetes, cancer (prostate/breast) screening, BP, BMI, urinalysis,and syphilis, erection dysfunctions; etc.) • Advise on a healthy lifestyle – diet and exercise, alcohol & substance use Provide prevention measures • Offer HIV testing and counselling services • Demonstrate correct use of male and female condom • Provide treatment of STI's, TB and other infections if needed • Promote VMMC for HIV-negative men emphasizing the dual protection with condom use; and assist in referring and linking men to VMMC services • Advise on available services for Early Infant Medical Circumcision (EIMC) for male new-borns and male siblings

5.3 Prevention of Unintended Pregnancies in Women Living with HIV (Prong 2)

Table 5.3 below describes services to be provided to non-pregnant women to prevent unintended pregnancies. See also National Family Planning Guidelines.

Table 5.3: Services to Prevent Unintended Pregnancies

Service	Description
1. Provide information and counselling to support reproductive rights, including preventing unintended pregnancies	• Provide health education to women, men, families and community • Support woman/couple to identify reproductive goals – whether pregnancy is desired and when • Provide counselling on contraceptive options in relation to reproductive goals and maternal and perinatal health • Provide counselling about the full range of contraceptive methods including short and long acting reversible methods, surgical options and emergency contraception • Provide counselling on the safety of and eligibility to use a wide selection of contraceptives and family planning methods in the context of HIV • Provide adolescent friendly Family Planning counselling (see Paediatric section)
2. HCWs should offer HTC to all FP clients, and all PLHIV should be offered FP services as per National guidelines on integration of FP in HIV services	See also *National Family Planning Guidelines.*
3. Provide rights-based family planning counselling and services	• Provide family planning services to women living with HIV using a human rights-based approach, especially pertaining to reproductive health, gender-based violence, informed consent, confidentiality, disclosure, and freedom from coercion or force in the context of HIV care, etc. • Provide the full range of contraceptive methods including emergency contraception as part of a range of SRH services according to need; or refer accordingly

Advice for Couples considering having a Child: Both are HIV-Positive

- Before making recommendations assess the couple clinically, immunologically and virologically
- If woman not on ART, she should be started on ART as soon as possible
- If man not on ART assess eligibility and advise accordingly
- If they are already on ART ensure viral suppression
- If virologically suppressed,
  - Advise on fertility days and timed ovulatory intercourse (condom use at all other times)
- Provide adequate counselling around risks of reinfection and risks of MTCT
- Prevent/treat STI
- **The final decision to conceive depends on the couple. Health care workers should provide accurate and unbiased information necessary to support their decision making.**

Advice for Couples considering having a Child: Discordant Couple with the Woman HIV-Positive

- Provide ART to the HIV-positive partner as soon as possible if not already on ART.
- If HIV-positive partner is already on ART, ensure he/she is virologically suppressed
- If virologically suppressed,
  - Advise on fertility days and timed ovulatory intercourse (condom use at all other times)
- Provide adequate counselling around risks of infection of the negative partner and risks of MTCT
- **The final decision to conceive depends on the couple. Health care workers should provide accurate and unbiased information necessary to support their decision making.**

5.4 Services for Pregnant Women in Antenatal Care

The MOH recommends that the first ANC visit should take place as soon as the woman realizes she is pregnant, preferably within the first trimester (before 14 weeks of gestation). For women who present late in pregnancy and have missed some of the scheduled visits, all services should be provided during the current visit.

Main Changes for Pregnant Women

- All HIV-negative pregnant women need to retest 8 weeks after the initial negative result and at every ANC visit (aligned to the four focused ANC visits schedule recommended by WHO) including an exit test during the last trimester (around 32-36 weeks)
- All pregnant HIV-positive women should be initiated on lifelong ART regardless of CD4 and/ or WHO clinical stage, preferably at the first ANC visit, while maintaining ongoing counselling
- ART should be initiated at any gestational age (while waiting for the CD4 result and other baselines)
- ART services for pregnant women should be provided within ANC settings
- ART follow up in pregnant and lactating women includes routine monitoring of viral load 6 months after ART initiaion for women newly initiating ART OR at baseline for women already on ART with no documented viral load in the past 6 months

5.4.1 Summary of Services for Pregnant Women in Antenatal Care

Table 5.4: ANC Services for Pregnant Women

Service	Description
1. Comprehensive history taking	• Take medical history (including symptoms of opportunistic infections), obstetric, family and psychosocial history • Determine the HIV status of the woman and her partner • If HIV-positive, enroll for pre-ART and ART care (if not yet enrolled) • Enquire about partner and family support as well as status of the partner and other children, where applicable • Ask about history of medications, including use of ARVs (including for PMTCT purposes), known allergies, use of traditional medicines or herbal products, and alcohol use • Assess GBV status and refer as appropriate (see table 5.2)
2. Comprehensive physical examination and vital signs	• Conduct a general clinical assessment, obstetric assessment, pregnancy risk assessment, assess current signs of illness, common symptoms of TB, sexually transmitted infections (STIs) • For HIV-positive women, perform staging of clinical disease (see Annex 7.1 to determine the baseline clinical staging for clinical monitoring
3. Tuberculosis screening	• Screen all women (regardless of HIV status) for TB using the National TB screening tool • Refer or provide diagnostic and follow-up services according to National TB Management Guidelines
4. Nutritional assessment and counselling	• Assess nutritional status using MUAC. If MUAC is less than 23 cm, enrol on food by prescription • Provide iron, folic acid, and multivitamin in the first trimester as per MNCH national guidelines • Counsel on proper diet based on locally available foods

Table 5.4: ANC Services for Pregnant Women (continued)

Service	Description
5. HIV testing and counselling for the pregnant woman and her partner	• See HTC chapter for details • Every woman in ANC should be offered HTC at the first visit unless already known to be HIV-positive o Use opt-out approach o Extend the HTC to the partner and children using a family approach o Encourage couple testing and mutual disclosure • Ensure all clients get their HIV test results o For women who refuse HIV testing, continue counselling at every encounter • All HIV-negative pregnant women need to re-test 8 weeks after the initial negative result and at every ANC visit (aligned to the four focused ANC visits schedule recommended by WHO) including an exit test during the last trimester (around 32-36 weeks)
6. Basic laboratory investigations	• Screen for syphilis (RPR or VDRL) and provide treatment if reactive • Check haemoglobin level to screen for anaemia. If haemoglobin not available, check for clinical pallor • If test is available, check blood group and Rh factor • Urine tests to detect urinary tract infection, glucose and proteins • For HIV infected pregnant women, where possible take blood samples for: o CD4 cell count, LFTs, and renal function tests o Calculate creatinine clearance for ALL patients (refer to NARTIS job aid) • Screen for Hepatitis B infection and Hepatitis C serology, if available
7. Immunization	• Give tetanus toxoid and other immunisations according to National guidelines

Table 5.4: ANC Services for Pregnant Women (continued)

Service	Description
8. Counselling and education	• HIV prevention counselling for HIV-negative women o Provide HIV prevention counselling and services as outlined above o Provide referral to VMMC for the male partner if not already circumcised o Counsel the couple to consider neonatal male circumcision • Family Planning o Pregnant women should be educated on family planning including long-term methods to be able to make informed decision before delivery on what contraceptive method to use post-delivery o Recommend a dual (condom and other preferred) contraceptive method to use post-delivery • Pregnancy and delivery counselling and education topics o Danger signs: advise client to seek health care immediately if the following danger signs are present: Bleeding; fever >38°C; swelling of hands and face; severe headaches and blurred vision; severe pallor; and abdominal pain o STI signs and symptoms: if vaginal discharges or sores, she should seek health care o Birth preparedness planning: identification of signs of labour, preparation of baby layette, identification of transport, where to deliver, labour and delivery process, skin to skin contact post-delivery o Importance of delivering under the assistance of a skilled health worker, preferably in a safe environment like a health facility o Effects of alcohol and drug use on the growth and development of the foetus o Compliance with follow up visits, defaulter tracing o If patient presents with partner, see Table 5.2 for men's minimum health care package. Ensure he understands links between his own health and outcomes for mother and baby • Infant feeding (see page 126) o For all women, irrespective of their HIV status, promote and support exclusive breastfeeding for six months, and thereafter add complementary foods o Educate the woman on the known benefits of breastfeeding o All mothers need the same advice for first year, but HIV-positive mothers should understand that mixed feeding before 6 months increases risk of HIV transmission o Educate the mother on the need for HIV testing after cessation of breastfeeding and importance of final diagnosis

Table 5.4: ANC Services for Pregnant Women (continued)

Service	Description
9. Provision of psychosocial support services	• All women, especially HIV-positive should be referred for psychosocial support services and further counselling as needed. Mentor mothers and expert clients at health facilities provide these services to women
10. Refer high risk pregnancies	• Women with high risk pregnancies: pregnancy induced hypertension; diabetes; previous caesarean sections or pregnancy complications; multiple pregnancies; multiple abortions; heart diseases; etc. should be referred for care to higher level institutions
11. Provision of HIV care and ARVs for PMTCT for HIV-positive women	• See section 5.5

5.5 Provision of HIV Care and ARVs for HIV-Positive Pregnant Women

All HIV-positive pregnant women should be initiated on lifelong ART regardless of CD4 and WHO clinical stage, preferably on the day of HIV diagnosis

Table 5.5: HIV Care and Treatment Services for HIV-Positive Pregnant Women

Status of Woman	Action from HCW
Already on ART	• Check Viral Load if not done in the last six months (If VL not available, check CD4) • Conduct clinical treatment staging (T-staging) • Continue current ART regimen, if there is no evidence of treatment failure. If there is treatment failure (unsuppressed viral load) refer to a doctor • Give one 25 ml bottle of NVP with a syringe and instructions for the mother to give the baby 1.5 ml daily if she delivers at home • Ensure woman is receiving CTX 960mg OD
Newly HIV-Positive **Or** **HIV-Positive Not on ART**	• Take a comprehensive history and thoroughly examine the pregnant woman to rule out any opportunistic infections • Check for prior ARV exposure - prophylaxis or treatment • Check CD4 and conduct WHO clinical staging • Take blood for baseline tests (LFTs, kidney function tests) • Conduct ART education and adherence counselling • Initiate ART as soon as possible at any gestational age, preferably on the same day and in ANC (without waiting for the CD4 result and other baselines), ensuring mother understands the significance of not stopping once initiated • **First-line regimen for women is TDF + 3TC + EFV** • Initiate CTX 960mg OD if not already taking it (even for women in the first trimester) • Give one 25 ml bottle of NVP with a syringe and instructions for the mother to give the baby 1.5 ml daily if she delivers at home • Appoint woman for review visit in 2 weeks to review baseline tests and make any necessary ARV changes if needed (see special considerations in table 5.6)

Table 5.5: HIV Care and Treatment Services for HIV-Positive Pregnant Women (continued)

Status of Woman	Action from HCW
Currently on AZT	• Conduct CD4 if not done in the last 3 months • Conduct WHO clinical staging • Conduct ART education and adherence counselling • Switch to full ART: **TDF + 3TC + EFV** as soon as possible • Ensure woman has received one 25 ml bottle of NVP with a syringe and instructions for the mother to give to the baby 1.5 ml daily if she delivers at home. • Ensure woman is on CTX 960mg OD
Not ready for ART	• Counsel woman about importance of ART for her own health and for PMTCT • Address any fear and/or barriers for woman not being ready to initiate ART, including partner support • Review woman in 2 weeks and initiate ART if now ready • If woman is still not ready for ART, continue counselling at every visit • Ensure woman is on CTX 960mg OD • Give one 25 ml bottle of NVP with a syringe and instructions for the mother to give the baby 1.5 ml daily if she delivers at home

Counselling Points: Starting ART for life in Pregnant Women

- Counsel woman about importance of ART for her own health and for PMTCT therefore all pregnant women should be started on ART as soon as they are pregnant and adhere to treatment for life
- ART is recommended for life due to the positive impact on the mother's health, reduced risk of transmission during future pregnancies and prevention of partner transmission if in a sero-discordant relationship
- The ART combination recommended for first-line treatment is safe and easy to use during pregnancy and breastfeeding
- During pregnancy and breastfeeding condoms should still be used consistently and STIs should be checked and treated promptly
- Explain that after birth, the mothers ART refill visits will be integrated with PNC visits. The infant will be tested as part of PNC; therefore attendance at PNC is very important

All women initiated on ART should be seen for review after two weeks and every month thereafter for provision of routine ANC services and ART refills

Table 5.6: Special Considerations for ART Regimens in Pregnant Women

Condition	Recommended Regimen	Comments
TB	TDF + 3TC + EFV	HIV-positive pregnant women with TB co-infection should begin TB treatment as soon as possible and keep a routine follow up schedule. Refer if necessary. Refer to Chapter 4 for further detail.
Moderate - Severe Anaemia	TDF + 3TC + EFV	Treat anaemia according to the guidelines, screen for active TB disease and refer if necessary. Prioritize management of severe anaemia before ART initiation.
Poor renal function (CrCl< 50ml/min)	If Hb> 10	Initiate AZT* + 3TC + EFV and monitor accordingly. Refer if necessary
Refer to Adult ART Section (Chapter 4) for further details		

** AZT is preferred to ABC in pregnancy*

Table 5.7: Recommendations for ART Initiation in Women Exposed to NVP for PMTCT Purposes

Previous ARV Exposure to PMTCT	What to Initiate
Exposure to sdNVP (+/- antepartum AZT) with no tail in the last 12 months	Initiate a non-NNRTI regimen, TDF + 3TC + LPV/r or TDF + 3TC + ABC (temporarily, substitute ABC after 12 months from the last exposure). PI based regimen preferred over 3 NRTIs regimen.
Exposure to sdNVP (+/- antepartum AZT) with an AZT + 3TC tail in the last 12 months	Initiate a regimen with an NNRTI, TDF + 3TC + EFV unless there are any contraindications. Monitor the patient.
Exposure to sdNVP (+/- antepartum AZT) with or without a AZT + 3TC tail over 12 months ago	Initiate a regimen with an NNRTI, TDF + 3TC + EFV unless there are any contraindications. Monitor the patient.

5.6 Monitoring of HIV-Positive Pregnant Women

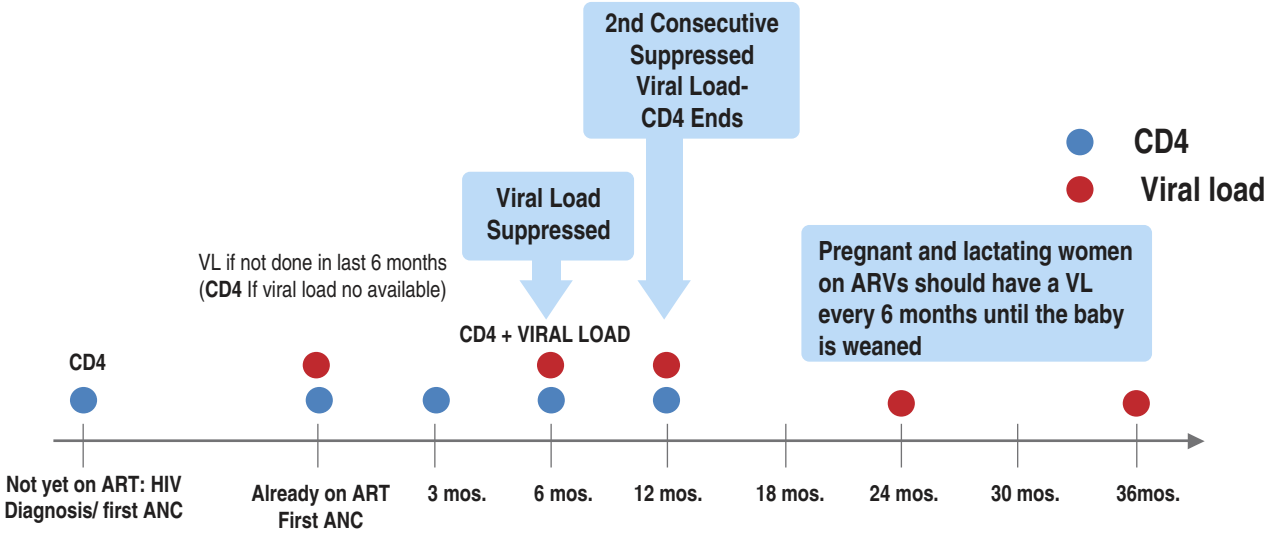
Monitoring visits should be for both HIV care and for routine ANC services:

ART Care: Adherence counselling (and pill counting), psychosocial support, side effect monitoring, clinical assessment and laboratory assessment.

ANC care: Comprehensive history taking, comprehensive physical examination, screening for TB, nutritional assessment and management, provision of immunization as needed, counselling and education (on risk of HIV reinfection, Family Planning, pregnancy and delivery, infant feeding, MTCT), and referral of high risk pregnancies

Adverse drug reaction reporting to CMS pharmacovigilence unit should extend to adverse drug reactions and toxicities noticed in pregnant women or their babies upon delivery

Figure 5.1: Timing of Viral Load and CD4 Monitoring for Pregnant Women



ANC services should be linked with ART care appointments for the mother

Figure 5.2: Monitoring of HIV-Positive Pregnant Women Summary

First Visit	For patient not yet on ART: ANC, baseline laboratory tests (CD4, syphilis, Hep B), Initiate ART if patient ready. For patient already on ART: review adherence and CD4 results, viral load if not done in past 6 months, ANC, syphilis,
2 Weeks	ART Care, Give baseline results
1 Month	ANC, ART Care, Creatinine
Monthly visits thereafter	ANC, ART Care
6 Months	ANC, ART Care, CD4, Viral Load
Labour and Delivery	
PNC Visits	Mother VL and CD4 every 6 months until baby weaned

5.7 Labour and Delivery

5.7.1 Services for Women during Labour, Delivery and Immediately After Delivery

Initiate lifelong ART in labour for women newly diagnosed or previously diagnosed HIV-positive but not initiated on ART regardless of WHO staging or CD4 count

Table 5.8: Services for Women During Labour, Delivery and Immediate Post-Partum

Service	Description
1. HIV testing and counselling	• Check the mother's ANC card for HIV status when she presents at the facility for delivery • HIV testing must be offered for the following: o Women whose status is unknown and in early labour or o Women who have tested HIV negative 8 weeks prior to onset of labour • If woman is HIV-negative, provide HIV prevention counselling and services
2. Routine obsteric services	• Relieve pain and relax the woman so that labour can progress faster • Use a partogram in monitoring progress of labour in order to improve the management and reduce the risk of prolonged labour • Avoid artificial rupture of membranes (AROM) as this increases the risk of HIV transmission • Avoid unnecessary invasive vaginal procedures and frequent/unnecessary vaginal examinations • Avoid episiotomy, except for specific obstetric indications • Give emotional support during labour for all women; if privacy is possible, allow family member • Actively manage the third stage of labour to reduce post-partum haemorrhage
3. Provide HIV care and treatment services	• Assess adherence to treatment and provide ART dose if it was not taken at the scheduled time • During labour, women on ART should be given their doses at their normal dose time • Initiate ART for newly diagnosed pregnant women (or previously diagnosed but not yet initiated)with current recommendation (TDF + 3TC + EFV) after counselling o Women should be given 2 week refill and down referred to their nearest facility • If a pregnant woman is not ready to be initiated on ART during pregnancy or labour, give NVP to the baby for 6 weeks and continue counselling the mother

Table 5.8: Services for Women During Labour, Delivery and Immediate Post-Partum (continued)

Service	Description
4. Provide Family Planning services and counselling as appropriate	• Support mother to identify her reproductive intentions. Provide information on full range of short and long acting reversible and permanent options and assist the mother to choose a method of contraception during her care immediately after delivery, considering her goals for repeat pregnancy(refer to *Family Planning Guidelines* as needed) • Before discharge from maternity: Counsel the mother on family planning (give chosen method at postpartum - see *Family Planning Guidelines)* • Emphasize consistent and correct use of condoms with every method chosen
5. Provide immediate post-partum care for mother	• Assess the tone and position of the fundus • Measure and document the women's pulse and blood pressure • Examine the perineum • Ensure the woman is warm • Encourage the woman to initiate suckling
6. Provide immediate post-partum care for baby	• Ensure effective breathing and circulation and resuscitate if necessary • Warm and dry baby to maintain adequate body temperature • Perform initial examination and encourage skin to skin contact as soon as possible • Administer prophylactic eye ointment, and Vitamin K • Support initiation of breastfeeding with attention to position and attachment
7. Ensure exposed babies are on nevirapine (NVP)	• Ensure all exposed infants (breastfeeding and not breastfeeding) are provided with nevirapine until 6 weeks: Dosing: o Birth weight < 2,500 grams: Give NVP 1.0 ml daily o Birth weight ⩾2,500 grams: Give NVP 1.5 ml daily • See also table 5.9 for special considerations for NVP provision for children

Caesarean Section (C/S)

- Routine C/S is no longer recommended for PMTCT purposes
- Newly diagnosed HIV-positive women must be initiated on ART at least 2 hours before an elective C/S for obstetric indications
- The woman should continue her ART medication post operatively (even during the nil PO period)

Table 5.9: Special Considerations for NVP in Exposed Infants

Special Considerations for Infant NVP prophylaxis *Provide dosing clips and syringe with all NVP	
Mother diagnosed HIV-positive during breastfeeding and is initiated on ART	Infant initiates NVP prophylaxis for at least 6 weeks
Child defaulted NVP prophylaxis before they are 6 weeks old	Counsel on importance of on-going prophylaxis and restart NVP for 6 weeks
Mother diagnosed HIV-positive during breastfeeding and refuses to be initiated on ART	Give child NVP for 6 weeks and continue counselling mother for ART

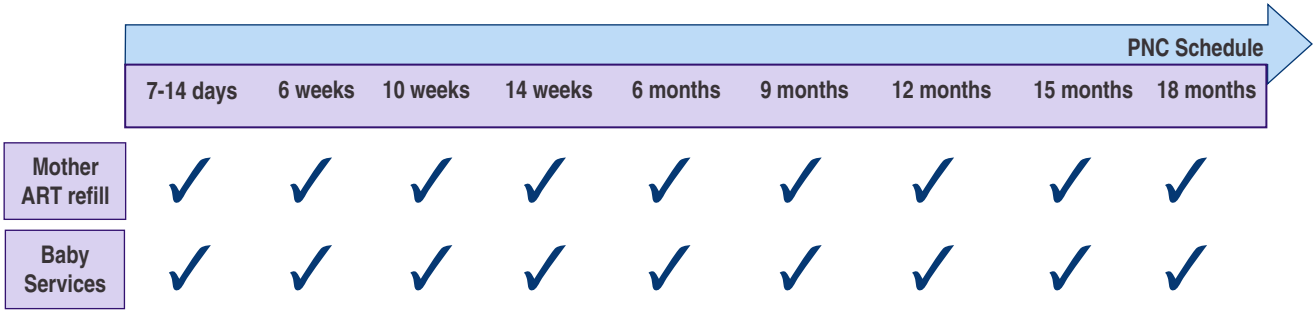
5.8 Services for Lactating Mothers and their Babies (Post-Natal Care)

Main Changes for Lactating mothers and their Babies

- All HIV-positive lactating women not yet on ART should be initiated on lifelong ART regardless of CD4 and/ or WHO clinical stage
- Mother and baby should be seen jointly as a pair until 18-24 months
- All lactating mothers who are HIV-negative should be re-tested at every PNC visit until end of breastfeeding
- All children should be tested for HIV at 9 months and at 18 months regardless of HIV exposure status

The diagram below shows the timeline for schedules of lactating mothers and their babies in the post-natal period. Mothers and their babies should be seen as a pair as much as possible.

Figure 5.3: Mother and Baby Appointment Schedule during PNC



PNC services should be linked with ART care appointments for the mother to encourage the mother and baby to present together during PNC

Table 5.10: Services for Mothers and their Babies during the Post-Natal Period

PNC visit (time post birth)	Services for Mother	Services for Baby
7-14 days	• Check for maternal health issues according to the standard of care for post-natal visits: PV bleeding, bimanual exam, caesarian section scar and family planning methods, including condom use • If HIV-negative: Re-test woman and provide counselling on HIV prevention • If HIV-positive: Provide ongoing ART counselling to woman and ensure ART adherence • If HIV-positive and not on ART: Continue counselling for ART initiation as soon as possible • Discuss infant feeding and assess adherence to infant NVP • Counsel on resuming sexual activity and return to fertility and promote condom use for dual protection	• Ensure infant is on NVP for 6 weeks • Provide routine PNC services for baby • Counsel on early infant male circumcision, refer to closest service

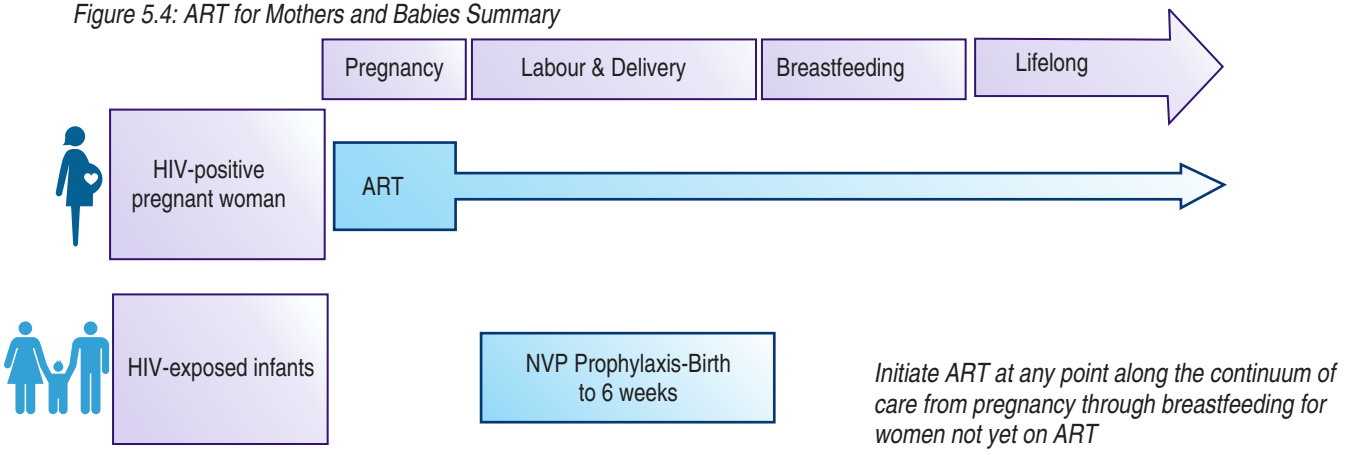
Table 5.10: Services for Mothers and their Babies during the Post-Natal Period (continued)

PNC visit (time post birth)	Services for Mother	Services for Baby
6 weeks	• Refill ART, provide counselling towards initiation as soon as possible if still pre-ART • Provide ART adherence counselling • Retest if HIV-negative • Offer/review family planning • Counsel the mother on resuming sexual activity, return to fertility, and use of dual FP method • For those using Lactation Amenorrhea Method (LAM); provide supportive counselling including transition to another method • Promote use of condoms and provide them • For the HIV-positive women; counsel and provide contraceptives to prevent unintended pregnancies • Emphasize the use of condoms to reduce the risk of HIV transmission to uninfected partner in case of discordant or unknown status of partner • Provide family planning methods, according to FP guidelines • Provide Cervical Cancer screening using VIA and repeat yearly thereafter • Refer male partner for VMMC	• Ensure correct documentation of the ARV regimen received by the mother and the baby on the infant card and child welfare register if not done previously • Stop NVP prophylaxis and record this on infant card and child welfare register • Counsel on infant feeding and nutrition • Start CTX prophylaxis for HIV-exposed infants and record on the infant card and the child welfare register • Perform the first DNA PCR test for HIV-exposed infants; record the DBS serial number on both the infant card and the child welfare register • If exposure status is unknown, conduct rapid test on infant if mother is not available (refer HTC guidelines- Chapter 2) • Schedule the next appointment in 4-6 weeks to give the DNA PCR results to the mother and record this appointment in the appointment book and on the infant card • Maintain suspicion for HIV infection • Provide routine services regardless of HIV status (immunization, growth monitoring etc.)
10 weeks	• Refill ART, provide counselling towards initiation ASAP if still pre-ART • Retest if HIV-negative • Refer male partner for VMMC • Offer/review family planning • Ensure cervical cancer screening has been done	• Continue CTX and provide refills • Give DNA PCR results: **If DNA PCR is positive:** counsel mother accordingly and link to care for immediate ART initiation **If DNA PCR is negative:** continue routine follow-up through final HIV status determination • Maintain suspicion for HIV infection • Counsel on early infant male circumcision • Continue infant feeding counselling • Provide routine services (immunization, growth monitoring etc.)

Table 5.10: Services for Mothers and their Babies during the Post-Natal Period (Continued)

PNC visit (time post birth)	Services for Mother	Services for Baby
9 months	• ART care	• HTC (rapid test) for all children (not only exposed) • Measles vaccination • Routine growth monitoring • Provide routine services (immunization, growth monitoring etc.)
Subsequent visits	• Refill ART, provide counselling towards initiation ASAP if still pre-ART • Viral load every 6 months if on ART • Retest if HIV-negative • Offer/review family planning	• Continue CTX prophylaxis and provide refills until final HIV status determination • Determine if infant is still breastfeeding • Continue infant feeding counselling • **If infant is not breastfeeding:** refer to EID testing algorithm for definitive HIV test • **If infant is still breastfeeding:** continue routine follow-up through final HIV status determination at 18 months • Schedule an appointment for the next visit and record this in the appointment book • Provide routine services (immunization, growth monitoring etc.)

Figure 5.4: ART for Mothers and Babies Summary



5.9 Care Services for Exposed Infants

Table 5.11: Care Services to be Provided for all HIV-Exposed Infants

Service	Description
1. Early Infant Diagnosis	• Provide HIV testing at six weeks or as early as possible thereafter • At follow-up visits, ensure that the caregiver has received the child's results and that they are documented on the Child Health Card • Immediately refer all HIV-positive infants for ART initiation • For infants who have tested negative, repeat testing six weeks after breastfeeding cessation or with any signs and symptoms of HIV infection • See the infant testing algorithm, Chapter 2 figure 2.2 on page 42
2. Growth and Developmental Assessment	• At each visit, check and document weight on the growth curve to assess whether growth is adequate. Measure head circumference. • Measure mid–upper arm circumference (MUAC) and height when there is concern for growth failure (see infant feeding recommendation on page 127) • Perform basic developmental assessment. If there is any concern for growth or developmental failure, repeat HIV testing, TB screening, and nutritional intervention • Document on the Child Health Card
3. Immunizations	• Immunize all HIV-exposed and HIV-infected infants according to the recommended schedule • If a child with confirmed HIV infection has not initially received BCG, withhold it • Give Vitamin A and albendazole at appropriate intervals
4. NVP Prophylaxis for HIV-exposed infants	• All HIV-exposed infants should be offered NVP prophylaxis for six weeks postpartum • The mother should be counselled to bring the child to the clinic if she notices any new signs or symptoms • At any time, if a child has signs or symptoms of possible HIV infection, retest the child (see infant testing algorithm on page 42) • If the mother has not yet initiated ART, she should be referred for initiation as soon as possible • NVP prophylaxis has very little potential to cause side effects. However parents should be counselled that if the infant develops a severe rash (that includes sores in the mouth and red eyes), they should bring the child to the health facility for evaluation

Table 5.11: Care Services to be Provided for all HIV-Exposed Infants (continued)

Service	Description
5. Cotrimoxazole Prophylaxis	• Give CTX to all HIV-exposed infants, starting from six weeks of age, to prevent Pneumocystis jirovecii pneumonia (PCP) and other potentially fatal infections • Continue treatment until HIV infection has been definitively ruled out AND the infant is no longer breastfeeding • CTX is generally well tolerated by infants. However parents should be counselled that if the child develops a severe rash (that includes sores in the mouth and red eyes), they should bring the child to the nearest health facility for evaluation • In the rare circumstance that a child has a history of a severe (Grade IV) adverse reaction to CTX or other sulfa containing drugs, or known severe kidney disease (Creatinine > 3 times normal) and/or hepatic disease (LFTs > 5 ULN), CTX should be avoided. Dapsone at a dose of 2 mg/kg once daily can be given as an alternative in these circumstances
6. INH Prophylaxis for Children with Known TB Contacts	• HIV-exposed infants who live with someone with active TB are at risk of TB infection • Investigate for TB and if TB is excluded, give Isoniazid Preventative Therapy (IPT) for six months at a dose of 10mg/kg • Pyridoxine (1-2mg/kg) should be given to prevent side effects of the Isoniazid (INH) • See TB program guidelines for more details about IPT and dosing • Children receiving IPT should be monitored closely for the development of active TB
7. Early Treatment of Infections	• Be actively alert for infections, and treat them early following guidelines for the integrated management of childhood illnesses (IMCI) • If necessary, refer children for higher levels of care • Urge caregivers to seek treatment promptly without fail if the child falls ill at home. Remind them that delay in treatment can lead to severe morbidity and mortality
8. Infant Feeding and Nutrition Counselling	• See section 'infant and young child feeding recommendations on page 127

Table 5.11: Care Services to be Provided for all HIV-Exposed Infants (continued)

Service	Description
9. Maternal and Family Health and Well-Being	• Assess the health and psychosocial well-being of family members and/or caregivers. The health of HIV-exposed infants is directly tied to the health of their caregivers • At each visit, refer the child's mother for CD4 count, ART initiation if eligible, and FP. Ask all caregivers about TB symptoms • Offer HTC for any family members who have not been tested • Provide psychosocial support to the family
10. Vigilance for HIV Infection and Retesting	Maintain a high level of suspicion for HIV infection. Watch for: • Growth failure (i.e. a child falling off the growth curve) • Poor development (i.e. delays in achieving or loss of developmental milestones). • Clinical signs or symptoms suggestive of HIV infection (see Annex 1) • If HIV is suspected, the child should be retested, should be staged both clinically and immunologically, and should be presumptively enrolled in HIV care and treatment
11. EIMC counselling	• Counsel parents on importance of EIMC for their infant and refer infant for EIMC at facilities where services are available

Steps to Successful Early Infant Diagnosis and Treatment

1. Record contact information of mother (cell phone or address)
2. Reinforce the importance of returning for test results
3. Encourage woman to bring partner to discuss test results
4. Emphasize that for all HIV-positive children, initiation of ART will be done urgently to keep the child alive and healthy
5. Ensure that counselling and support are available to the family

5.10 Infant and Young Child Feeding (IYCF) Recommendations

5.10.1 IYCF Recommendations Based on HIV Status of Mother

Table 5.12: Recommendations for Infant and Young Child Feeding Based on HIV Status of Mother

Situation	Recommendation
Mothers known to be HIV-negative or whose HIV status is unknown	• Exclusive breastfeeding for the first 6 months with addition of complementary feeding thereafter while breastfeeding continues for 24 months and beyond • HIV Testing should be offered for HIV-negative women and those of unknown status together with their partners at every PNC visit until cessation of breastfeeding
Mothers known to be HIV-positive and on lifelong ART whose infants are HIV-negative or of unknown HIV status	• Exclusive breast feeding for the first 6 months with addition of complementary feeding thereafter while breastfeeding continues for at least 12 months • At 12 months, if a nutritionally adequate and safe diet without breast milk can be provided, and a mother is considering stopping breastfeeding, a rapid HIV test should be done for the baby • If rapid test is negative, breastfeeding can be stopped gradually over one month and repeat HIV rapid test 6 weeks after complete cessation of breastfeeding • If the rapid test is positive, a confirmatory DBS (DNA-PCR) test should be conducted and the mother should be encouraged to continue breastfeeding while awaiting the result. If PCR result is positive, mothers are strongly encouraged to continue breastfeeding up to two years and beyond. The HIV-infected infant should be started on ART as soon as possible • If the DNA PCR test is negative, breastfeeding can be stopped gradually over one month
Mothers known to be HIV-positive and whose infants are HIV-positive	• Mothers should be encouraged to exclusively breastfeed for the first 6 months of life and continue breastfeeding up to two years and beyond • Complementary feeding should be introduced from six months while breastfeeding continues • HIV-infected infant should be started on ART as soon as possible.
HIV-infected mothers who are well counselled but are considering not to breastfeed	• Health care workers should conduct a one-on-one discussion/counselling session with each woman on how to feed their infants and consider her individual circumstances • Replacement feeding can be advised if the woman fulfils certain criteria. See replacement feeding section on page 128

5.10.2 IYCF Special Considerations

Expressing Breast Milk

Expressing milk is useful to:

- Leave breast milk for a baby when his mother goes out or goes to work
- Feed a low-birth-weight baby who cannot breastfeed
- Feed a sick baby, who cannot suckle enough
- Keep up the supply of breast milk when a mother or baby is ill
- Prevent overflow when a mother is away from her baby
- Help with breast health conditions, e.g. engorgement and mastitis
- Facilitate the transition to another method of feeding or to heat-treat breast milk

HIV infected mothers may consider expressing and heat-treating breast milk as an interim feeding strategy in special circumstances such as:

- When the mother is unwell and temporarily unable to breastfeed; has a temporary breast problem such as mastitis;
- To assist the mother to wean the baby from breastfeeding
- When the mother is on PEP

For more detailed information on heat treatment, see National IYCF guidelines

Replacement Feeding

- A mother who opts to replacement feed from birth should be informed of the need to provide nutritionally adequate and safe replacement feeds to enable normal growth and development of the child. The mother should also meet the conditions below.
- All HIV-exposed infants on replacement feeding should receive NVP prophylaxis from birth up to 6 weeks and then stop
- Alternative to breastfeeding according to the age of the infant:
    - For infants less than 6 months of age: exclusive commercial infant formula milk should be given as long as home conditions above are fulfilled
    - For children over 6 months of age: appropriate commercial infant formula; or full cream/whole/undiluted animal milk (boiled for infants less than 12 months) should be provided as part of a diet adequate in micronutrients. Infant meals should be provided 5-6 times per day. All children need complementary foods from 6 months of age.

5.10.3 Assessment for replacement feeding

YES	Assess the following conditions for safe formula feeding	NO
	Are safe water and sanitation assured in the home and in the community	
	Can the mother afford and reliably provide sufficient infant formula milk to support normal growth and development of the infant (about E500 per month)	
	Can the mother/caregiver prepare formula milk cleanly and frequently enough so that it safe and carries a low risk of diarrhoea and malnutrition	
	Can the mother exclusively give infant formula	
	Is the family supportive of exclusive replacement feeding	
	Can the mother or caregiver access health care that offers comprehensive child health services	

If YES **to** ALL, **exclusive replacement feeding can be recommended.**
If NO **to** ANY **one of the questions, recommend breastfeeding. Assure mother that lifelong ART makes breastfeeding safe.**

5.10.4 Wet Nursing

Infants who are orphaned or separated from their mothers may be given formula feeds. Wet nursing is no longer recommended. In extreme situations, when an orphaned infant less than 6 months does not have access to breast milk or formula, using modified goat or cow milk mixed with additional water and sugar can be used as a last resort (health workers should provide information on what to use and how to prepare). See infant and young child feeding guidelines.

When using home-prepared formula, in addition to diluting, adding sugar and boiling animal milk, it is necessary to add micronutrients. However the formulations for these micronutrients are not readily available and health workers may need to prescribe **micronutrients** that provide multiple vitamins and minerals.

Fresh cow's or goat's milk

40ml milk + 20ml water + 4g sugar = 60ml prepared formula

60ml milk + 30ml water + 6g sugar = 90ml prepared formula

80ml milk + 40ml water + 8g sugar (~teaspoon) = 120ml prepared formula

100ml milk + 50ml water + 10g sugar = 150ml prepared formula

5.10.5 Complementary feeding

Complementary feeding is extremely essential from six months of age, while breastfeeding continues for up to 12 months. After six months of age, breast milk alone is not enough but still contributes to about 50% of nutritional requirements between the age of 6 and 12 months. See infant and young child feeding guidelines.

Chapter 6:
ART for Children and Adolescents

6.1 When to Start

6.1.1 Medical Criteria

Age	Criteria
<5 years old	All HIV-positive children are eligible regardless of Cd4 **OR** Presumptive diagnosis in children less than 18 months (prioritize confirmation of infection with DNA-PCR)
>5 years old	All children with CD4 <500 cells/mm^3 **OR** WHO stage III or IV

Paediatric HIV and TB Hotlines Available to Clinicians

Paediatric HIV/TB Hotline: 7848-5571
- Toll-free number, available Monday through Friday, 08:00 until 16:00
- For clinicians to call with any questions about paediatric HIV care
- Answered by a physician at Baylor Clinic

Baylor clinic phone: 2409-6000

DBS Hotline: 7687-9925
- To obtain DBS results or for lab-related DBS questions

TB/HIV email: swazihivtb@gmail.com
- An e-mail address to address clinical questions to Baylor Physicians

6.1.2 Social Criteria

Identifying a primary caregiver, plus a secondary caregiver whenever possible, is essential for children initiating ART to ensure good adherence and treatment success. A psychosocial and readiness assessment should be conducted for both the child and their treatment supporter (see table 6.1). Identifying a secondary treatment supporter is important in order to have someone who can assist the child whenever the primary caregiver is unable to fulfil this responsibility.

Primary caregivers have to be made aware of duties regarding the care of the child (2012 Children's Welfare Act), as all care practices should be in the best interest of the child.

The parent/caregiver is primarily responsible for:

- Giving medications as prescribed
- Bringing the child for scheduled medical visits
- Providing on-going care of the child (nutrition, immunizations, disclosure, etc.)

Children who are eligibleto start ART should be initiated on ART as soon as possible, preferably within two weeks.

6.2 Assessment of Children Prior to ART Initiation

Table 6.1: Components of Paediatric Assessment Prior to ART Initiation

Assessment Component	Key Questions and Evaluations
Medical History	**At the Initial Visit** • Age of the child • Birth history, including maternal and infant PMTCT • Past medical history, including TB history • Any previous ART regimens and adherence history • **At the Initial Visit and Each Subsequent Visit** • Presenting complaint, if any • Review of symptoms • Growth and developmental history • Nutritional history *(see Chapter 6)* • Family/household history • Allergies • Current medications and traditional remedies
TB Screening	• Known TB contacts • Cough for > 2 weeks • Any cough with fever and/or poor weight gain/ weight loss • Poor weight gain or failure to thrive
Psychosocial Assessment	• Identify the child's caregivers • Consider disclosure to the child and family members • Discuss child and caregiver fears and concerns regarding ART • Where appropriate, explore the child's understanding of HIV • Assess the child's education and socialization • Evaluate potential barriers to adherence • Assess the economic situation of the child's household
Complete Physical Examination	• Weight and height plotted on child's growth curve • Head circumference measured (in children under 2 years of age, it may be indicative of cognitive or developmental delay) • Head-to-toe examination of all systems, looking for signs of HIV disease and OIs
Laboratory Testing	• CD4 count • Full blood count or Hb • Repeat confirmatory DNA PCR for infants
WHO Staging	• Clinical evaluation *(see Annex 7.1)*

6.3 What to Start

6.3.1 Recommended First-Line ART Regimens for Children

Once comprehensive clinical and psychosocial assessment is done (including adherence counselling) treatment can be initiated.

	< 3 Years	3 to <5 years		⩾5 to 12 Years And Older	
	ALL	NVP-exposed	**Not** NVP-exposed	<40kg	⩾40kg
Preferred	ABC + 3TC + LPV/r	ABC + 3TC + LPV/r	ABC + 3TC + EFV	ABC + 3TC + EFV	TDF + 3TC + EFV (adult FDC)
Alternative	AZT + 3TC + LPV/r	AZT + 3TC + LPV/r	AZT + 3TC + NVP	AZT + 3TC + NVP	AZT + 3TC+ NVP

The above recommendations apply to children initiating ART for the first time All children already on ART should remain on their current regimen. However, for children still on d4T-based regimen, efforts should be made to substitute d4T to an appropriate regimen based on their age and weight as soon as possible.

Table 6.2: Alternative First-Line for Special Situations in Paediatric Patients

Special Situation	Age/Weight	Regimen	Comments
Anemia before initiating	**ALL**	Use ABC or TDF	Refer to the table above for age/weight recommendations
Anaemia on AZT(Hb<8g/dl)	**ALL**	If VL undetectable: Use ABC	If changing from AZT to ABC, only substitute ABC once VL is undetectable
Severe NVP rash (grade 3, 4)	<3y Or <10Kg	**LPV/r**	EFV can also cause severe rash, if child using EFV, monitor as clinically appropriate
	⩾3y Or ⩾10Kg	**EFV**	
Caregiver inability to correctly dose LPV/r Syrup	**ALL**	**AZT + 3TC + NVP**	Provide close monitoring for clinical, immunologic, and viral failure
EFV side effects	**ALL**	—	Case by case basis, consult with a doctor or call the Baylor HIV hotline

6.3.2 TB Co-Infection

Screen all HIV positive children for TB at every visit using the TB screening questionnaire
Tuberculosis is a clinical stage 3 or 4 condition requiring ART

In HIV/TB co-infected children, initiate TB treatment before ART to avoid severe immune reconstitution inflammatory syndrome (IRIS). All HIV-infected children diagnosed with TB should be started on ART generally between two and eight weeks of starting anti-TB treatment.

Table 6.3: Alternative ART for Paediatric Patients on TB Treatment

Special Situation	Age/Weight	Regimen	Comments
TB Co-infection	**<3 years Or <10kg**	**ABC + 3TC + NVP Or AZT + 3TC + NVP Or ABC + 3TC + AZT**	• Children with **Hb<8 g/dl** should be started on ABC+3TC+NVP • Start NVP at full dose without lead-in dose For childrenexposed to NVP in the last 6 months use the paediatric AZT/3TC+ ABC tablets • For children with prolonged NVP exposure, switch to LPV/rbased regimen after completion of TB treatment. If VL detectable at time of ATT completion. Consult Baylor Hotline with any questions
	⩾3yrs And ⩾10kg	**ABC + 3TC + EFV Or AZT/d4T + 3TC + NVP Or ABC + 3TC + AZT Or AZT/d4T + 3TC + EFV**	• Children with **Hb<8 g/dl** should be started on ABC+3TC+NVP • **Start NVP at full dose without lead-in dose** • **Use EFV if child** can swallow the capsules and adherence to treatment is optimal • For children exposed to NVP in the last 6 months use the paediatric AZT/3TC+ ABC tablets • d4T is being phased out, see **page 136** of this chapter for further information
		Patients already on an NNRTI-based regimen	Continue the same regimen
Children on NVP or EFV-based regimen before initiating TB treatment	**ALL**	Continue NVP- or EFV-based regimen	**If patient was on an NVP- or EFV-based regimen, continue same regimen**
Child is on second-line therapy before initiating TB treatment	**ALL**	If current regimen contains **LPV/r**, continue with **1:1 ritonavir-boosting**	• Ritonavir 100 mg single capsules are available for older children that can swallow them. • Consult with a Dr. or call the hotline for cases in infants and young children to seek advice on the individual case.
Anaemia on AZT(Hb<8g/dl)	**ALL**	If virus load undetectable: Use ABC	If changing from AZT to ABC, only substitute ABC once VL is undetectable

For more information on the diagnosis and management of Tuberculosis see National Tuberculosis Guidelines.

6.3.3 d4T Phase Out

d4T is no longer widely available for paediatric patients in Swaziland. The use of d4T-containing regimens should be minimized to avoid adverse long-term side effects (e.g. lipodystrophy or lactic acidosis). Generally d4T can be safely used for a period of <9 months when children initiate ART with severe/moderate anaemia and Hb follow up is difficult. After that period d4T is substituted to ABC, AZT, or TDF (if child is >40 kg),maximizing the use of the ART FDCs. D4T is no longer recommended for long-term use in first-line.

Children with prior history of anaemia require Hb monitored at 1 month, 3 months and 6 months after switching to AZT. If AZT cannot be used or is not well tolerated use ABC instead (assure that the child is virologically suppressed before substituting to ABC).

> d4T is no longer recommended for long-term use in first-line
> Replace use of d4T with AZT after > 6 months if Hb> 8

6.3.4 Use of LPV/r

- Formulation and dosing: When using syrup formulation provide appropriate sized syringes with dosing clips and detailed instruction on administration in a format appropriate to the audience (verbal, written, pictures).
- If LPV/r is being used as first line therapy and there are adherence issues beyond solution, such as poor tolerability or side effects, consider using the FDC with NVP.
- Storage: Once syrup formulation is dispensed, keep refrigerated or in a cool, dry place (clay pot, under the bed, not near a window in direct sunlight, etc.) and dispense only enough for 8 weeks (two-month supply).

> If no refrigerator available at home, refills should be supplied for a maximum of 8 weeks for children on LPV/r syrup, recommending storage in a cool place

6.3.5 Use of NVP

When NVP is used in the treatment of children:

- Use lead-in dosing for routine initiation: Initiation of an NVP-based ART regimen requires a lead-in period of two weeks for hepatic enzyme induction

Table 6.4: Example of Lead-in Dosing for Routine NVP Initiation Using AZT-based FDCs

	AM	PM
First 2 Weeks	AZT+3TC	AZT+3TC+NVP
After 2 Weeks (if no adverse reactions)	AZT+3TC+NVP	AZT+3TC+NVP

In patients on TB treatment or in patients switching to NVP from EFV start NVP with full dose (NVP BD)

6.4 ART Treatment Monitoring

ART monitoring in children will assist in:

- Evaluating the child's response to therapy
- Diagnosing any new conditions
- Monitoring for short- and long-term treatment side effects
- Assessing changes in the family unit that might affect the child's care
- Addressing disclosure and ensure that children's understanding of their condition evolves as they mature

6.4.1 Clinical Monitoring

Once infants, children or adolescents are on ART, the frequency of clinical monitoring depends on their response to treatment. Standard monitoring follows the schedule in Table 6.5. During the first 3-6 months after initiation, frequent visits are crucial to monitor for immune reconstitution inflammatory syndrome (IRIS) and for acute ART toxicities and adherence issues. Long-term follow up focuses on toxicities, adherence and empowerment.

Orphans and vulnerable children need special attention to assure good treatment outcomes. If a social situation compromises adherence to treatment, consider engaging another caregiver or child welfare services.

Figure 6.1: Virological and Immunological Follow up in Stable Paediatric ART Patients

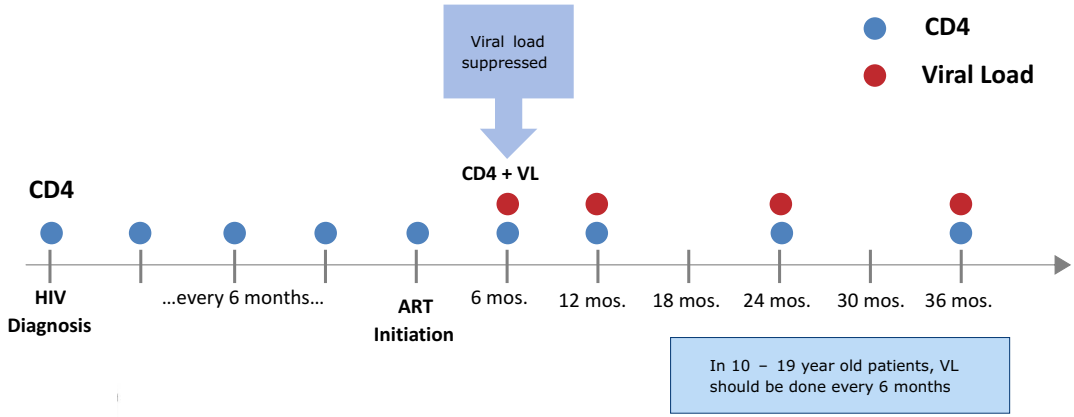


Table 6.5: Recommended Clinical and Laboratory Monitoring for Paediatric Patients

	Baseline	2 weeks	1 month	3 months	6 months	9 months	12 months	Thereafter
CD4 count or %	X				X			Every 6 months
Viral Load	NONE				X		X	Every year if <10 years Every 6 months if 10-19 years
Haemoglobin	X		X	X	X		X	Every 6 months
AST/ALT								As indicated
Creatinine	TDF only				TDF only		TDF only	Every 6 months if on TDF
Growth and development educational achievement and behavior	X		Weight only	X	X	X	X	All visits
Adherence and correct dosing, side effects/toxicity	X	X	X	X	X	X	X	All visits
OIs Including TB	X	X	X	X	X	X	X	All visits
Social history/ Psychosocial factors	X	X	X	X	X	X	X	All visits

6.5 Treatment Failure and When to Switch: Second and Third-Line Regimens

6.5.1 Treatment Failure

ART failure is defined as suboptimal response or a lack of sustained response to therapy using clinical, immunologic, and/or virologic criteria. For treatment failure to occur, the child should have received the ART regimen for at **least 6 months** and demonstrated optimal adherence.

Table 6.6: Features of Treatment Failure

Failure	Definition	Comments
Clinical failure	**Children** New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4 clinical condition with exception of TB) after months of effective treatment **Adolescents** New or recurrent clinical event indicating severe immunodeficiency (WHO clinical stage 4 condition) after 6 months of effective treatment	• The new clinical condition must be differentiated from immune reconstitution inflammatory syndrome occurring after initiating ART • For adolescents, certain WHO clinical stage 3 conditions (pulmonary TB and severe bacterial infections) may also indicate treatment failure
Immunological Failure	**Younger than 5 years** Persistent* CD4 levels below 200 cells/mm^3 or <10% **5 – 10 years** Persistent CD4 levels below 100 cells/mm^3 **10 – 19 years** CD4 count falls to the baseline (or below) or persistent CD4 levels below 100 cells/mm^3	• These immunological criteria have low sensitivity and positive predictive value for identifying individuals with virological failure
Virological failure	Plasma viral load above 1000 copies/ml based on two consecutive viral loads taken at least 3-6 months apart, in a patient who is adherent to medications, with stepped up adherence support after the first viral load test	• An individual must be taking ART for at least 6 months before it can be determined that a regimen has failed • Assessment of VL should be carried out by a multi-disciplinary team to give this final diagnosis

**SeeTable 6.8: Stepped-up Adherence Support Package for Children and Adolescents on ART*

6.5.2 How to Prevent and Manage Treatment Failure in Children

If causes of failure remain unaddressed, ART resistance will eventually develop.
Maximize adherence to retain children and adolescents on first-line.

Table 6.7: Interventions to Prevent Treatment Failure

Component	Interventions
Clinical component	• Assure correct doses of treatment at every visit • Assure adequate timing of dosing, children should never take the meds to school, unless adequate support is provided by a reliable teacher • Monitor drug interactions • Identify previous ARV exposure (NVP, past treatments) • Identify poor adherence • Ensure optimal storage conditions of the drug formulations
Psychosocial component in children, adolescents and caregivers	• Identify psychological/mental conditions: depression, drug fatigue, self-stigma and refer appropriately • Address disclosure with age-appropriate messages • Refer to teen clubs or children support groups where available • Establish a close and transparent relationship with the child/adolescent • Empower and educate the child/adolescent to be part of their treatment plan

A careful, step-by-step assessment, involving a multidisciplinary team or the Baylor clinical team through the HIV hotline, is required to evaluate the causes of treatment failure in a child or adolescent and to determine the appropriate management strategy, with the goal being to preserve the use of first-line therapy in as many children as possible.

6.5.3 Basic Steps for Management of Treatment Failure in Children

All providers should consider the following steps when managing treatment failure in children/adolescents:

Identify cause of treatment failure

- Poor adherence: disclosure, recent changes in caregivers, drug fatigue, depression, timing of taking ARVs
- Suboptimal ARV levels from underdosing or drug–drug interactions
- Previous exposure to NVP, previous ARV treatments resulting in drug resistance

Provide appropriate intervention

- Intensify adherence interventions - Stepped-Up Adherence Counselling (SUAC)*
- Correct medication doses or minimize drug–drug interactions
- Screen and treat OIs, and address barriers to treatment
- Perform laboratory tests: CD4, viral load per recommendations (see

Assessment by MDT meeting

- Involve different members of your team in the management of the child; counsellor, nurse, doctor
- Involve relevant members of the child's family
- Involve the child in his/her own care with age-adapted messages

Retain on first line or switch to second line

- Within the MDT decide if there is a need to extend the use of first line or switch to second line

** See Table 6.8: Stepped-Up Adherence Support Package for Children and Adolescents on ART*

6.5.4 When to Switch: Second-Line Therapy

Figure 6.2: Viral Load Algorithm for Management of Treatment Failure in Paediatric Patients

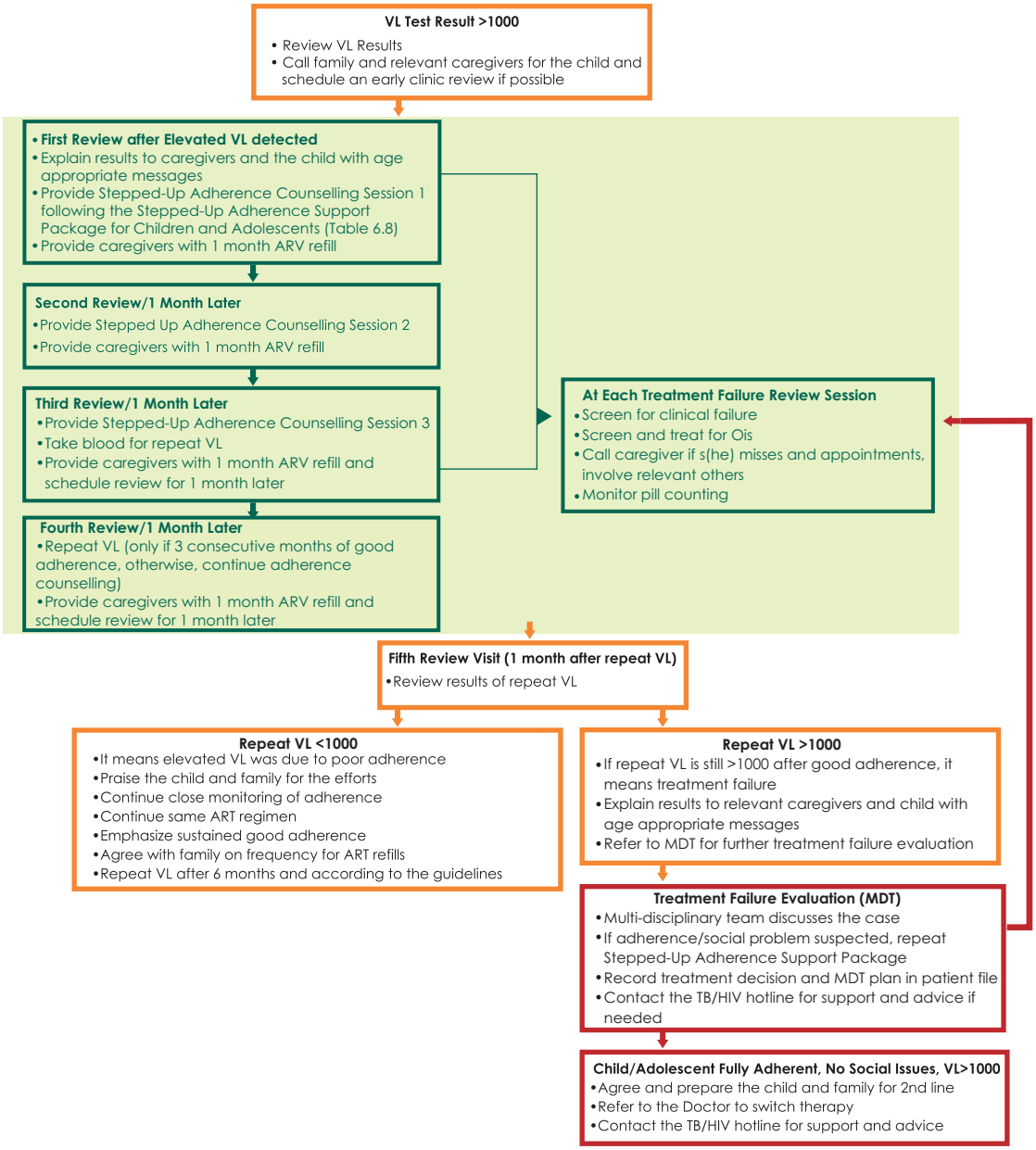


Table 6.8: Stepped-Up Adherence Support Package for Children and Adolescents on ART

Psychosocial-aspects	• Assess **age-appropriate disclosure** and offer counselling. Use paediatric **job aids** for counselling. • **Engage the family** in care. At each visit identify who is the primary caregiver and who is the treatment supporter. Immediately invite and counsel any new caregiver and/or treatment supporter, inquiring if other resources are available to assist in drug administration responsibilities. Work with a family approach to address any family members' medical or social problems. Arrange family meetings. Be alert to changes in home that influence poor adherence, such as re-location, change in caregivers etc. • **Empowerment:** encourage questions/discussion. Listen to the child's own story. Focus on positive things, encourage a positive attitude to living with HIV. Address myths, misperceptions and spread knowledge. • Involve older children in important decisions to better understand why certain decisions are made. Make short term plans, set up goals with the patient and/or caregiver and follow up how goals were achieved. • Integrate medication taking into recurring daily activity (e.g. brushing teeth before bed or getting dressed each morning).
Other Psychosocial aspects of care	• Encourage caregivers to always **supervise and support** children/adolescents when taking medicines, not only remembering but always watching the children taking the medicines in a supportive manner. On a regular basis follow up what time medicines are taken and if the child can be supervised at that time by the primary caregiver. Otherwise **adjust** the time with the family. Do not allow children to bring/drink medicines at school unless **a reliable teacher** agrees to support them. • Encourage teen **support group** participation, map the closest ones and **facilitate referrals**. Start/support peer support counselling groups; conduct a series of biweekly/monthly sessions facilitated by committed psychosocial support staff who knows the patient well. • If possible conduct **home visits** to help understand the social environment and offer relevant support. • Screen for mental conditions: depression, alcohol or drugs use, home based violence, sexual violence, peer bullying.
Clinical/follow up	• Make sure to regularly update contact details for clients; phone numbers and address. • Actively rule out **opportunistic infections** or other medical conditions. • Provide adherence counselling and follow up issues every visit. Encourage use of an alarm, cell phone, watch etc., **as reminders to take medication** (caregivers or adolescents themselves). Encourage use of a pillbox and monitor use and maintenance. • **Simplify ART regimens** if possible and monitor (call Baylor HIV/TB Hotline). Address potential medication side-effects (call Baylor HIV/TB Hotline). Make sure the patient has adequate lab monitoring including **CD4 and viral load**. Only repeat viral load after at least 3 months of recorded **good adherence** according to the guidelines. Call the patient back if labs are found to be abnormal and require immediate action. • Encourage to still take medications even if late or on an empty stomach rather than skipping pills. Repeat doses that were spit out or vomited within 30 minutes. • Set up and use a system at your facility to **avoid patients being lost to follow-up**, both pre-ART and for clients who defaulted ART and to call back clients who missed appointments.

6.5.5 Recommended Second-Line ART Regimens

Switch to a second-line regimen only when issues of adherence and treatment support have been fully addressed by a multidisciplinary team.
Disclosure should not be prerequisite for starting second line unless it is a primary barrier to adherence

Set up an **Adherence Committee** (MDT: doctor, nurse, expert client, social worker, etc.) at your facility for challenging cases and for internal referrals where clients with complex problems can be discussed and an action plan formulated
Call the Baylor HIV/TB Hotline with any questions on Paediatric HIV/TB investigations, care and treatment

	Preferred Second-Line Regimen	
First-Line Regimen	**Children <12 years**	**Children ⩾12 years**
AZT+3TC+NVP AZT+3TC+EFV d4T+3TC+NVP d4T+3TC+EFV	ABC+3TC+LPV/r	TDF+3TC+LPV/r (if ⩾40 kg) **OR** ABC+3TC+LPV/r (if<40kg)
ABC+3TC+LPV/r AZT+3TC+LPV/r d4T+3TC+LPV/r	• If child < 3 years: keep current regimen, reinforce adherence, reassess after 6 months • If child > 3 years consult MDT or call Baylor hotline for second line failure assessment	
TDF+3TC+NVP TDF+3TC+EFV ABC+3TC+EFV	AZT+3TC+LPV/r	AZT+3TC+LPV/r **OR** ATV/r

6.5.6 Third-Line ART for Children and Adolescents

Management of these children is complex. Evaluation for third-line ART needs to be done by paediatric specialists and the recommendation is to contact the Baylor Clinicians in Mbabane, Manzini or Hlatikhulu. It is highly recommended to call the paediatric hotline to consult on each individual case.

Third-Line Drugs in Children:

Darunavir/ritonavir (DRV/r) + Etravirine (ETV) + Raltegravir (RAL)

6.6 Special Considerations for Adolescents

Adolescence is a period of transitioning from childhood to adulthood and covers 10-19 years, with many physical, mental, and emotional changes that could potentially impact chronic conditions like HIV and ART treatment regardless of whether infection was acquired at birth or later in life.

Most HIV-infected adolescents have special psychosocial issues that may affect treatment adherence or lead to risk-taking behaviours, such as:

- Denial and fear related to their HIV diagnosis
- Belief of invincibility due to the persistence of concrete thought process
- Misunderstandings related to their status and health needs
- Self-stigma
- Lack of belief in the efficacy of ARVs, drug fatigue
- Distrust of family, practitioners and the health care system
- Low self-esteem and chaotic, unstructured lifestyles

6.6.1 Health Care Consent and Assent for Children and Adolescents

- Anyone 12 years or older can give informed consent for medical care such as HTC, FP, medical male circumcision as per 2012 *Swaziland Child Welfare Act*
- Children <12 years can provide informed consent if they are considered an emancipated minor or mature adult (i.e., are the head of a household, a parent or if pregnant, are being treated for a STI, are accessing FP services, and/or are sexually active)
- Though children and young adolescents less than 12 years may not give informed consent for testing, their agreement should be sought via age-appropriate counselling

Consent for health services, including HIV care can be given by parents, guardians, caregivers, health care workers or social workers in the best interest of the child.

SEE CONSENT CONSIDERATIONS IN HTC CHAPTER 2

6.6.2 Adolescents and Disclosure

Disclosing HIV Status to an Adolescent

- **Disclosure is not a one-time event but a process** that allows for a patient to receive truthful information regarding their health at an age and developmentally appropriate level and that over time will include specific relevant details such as the name of the condition (HIV AIDS), how transmitted, what is needed to avert progression, the role of ART, importance of adherence, safe sex, reproductive choices etc
- Communication promotes honesty and trust within the adolescent-adult-family-clinical team relationships and facilitates dialogue about chronic treatment and positive prevention
- Benefits include improved self-esteem, a sense of autonomy and empowerment, and enhanced psychological adjustment
- The role of a health care worker in disclosure is to guide the family members and the child in the process addressing the fears, barriers and assuring protection and support
- In general, all adolescents should be linked to a regular ART support group (i.e. Teen Clubs) where issues relevant to their age group are discussed and support is given. Home visits can be provided to ensure that the patient adheres well to ART and to address challenges with insight into the home environment
- If the adolescent's adherence is repeatedly poor, treatment supporters, caregivers, and supportive family members who are aware of the adolescent's HIV status can be called on for help

> When disclosing or counselling an adolescent, consider the patient's social, family, and medical histories, taking into account his/her age and psychosocial maturity, the mode of HIV transmission, prior knowledge of their infection and past experiences

Table 6.9: Special Considerations in Medical Care of HIV Positive Adolescents

Treatment issues	Psychosocial issues
• Correct treatment dosing • Maximize use of FDCs to minimize pill burden • Treatment empowerment • Close treatment monitoring • Routine viral load monitoring every 6 months	• Disclosure / peer disclosure • Barriers to adherence • Community/peer support/teen clubs • Sexuality, safe sex, family planning • Substance abuse

6.7 Elements of a Well-Functioning Paediatric HIV Program

Table 6.10: Basic Elements for a Paediatric Program at Site Level

Paediatric testing	• DBS kits, HTC kits • Disclosure materials
Care and treatment	• Paediatric medication formulations • NVP clips and syringes • Pill cutters/ Pill boxes • Paeditric ART Dosing charts
Patient education	• Paediatric counselling materials • IEC material on paediatric ART • Disclosure counselling materials
Job aids	• WHO Staging posters • Neurological developmental stages • DBS posters • ART guidelines • Nutritional assesment charts
Phlebotomy	• 1ml tubes for laboratory tests • Butterfly needles for phlebotomy • Viral load required materials
Materials for teen club	• Curriculum for the teen clubs • Material on how to establish a teen club and run it
PEP paediatric materials	• Counselling tools • PEP drugs package
Marketing materials on our telemedicine options	• DBS hotline flyers, HIV care hotline flyers

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Annexes

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7.1 WHO Clinical Staging

Adults and Adolescents[a]	Children
Clinical Stage 1	
Asymptomatic Persistent generalized lymphadenopathy	Asymptomatic Persistent generalized lymphadenopathy
Clinical Stage 2	
Moderate unexplained weight loss (<10% of presumed or measured body weight) Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis) Herpes zoster Angular cheilitis Recurrent oral ulceration Papular pruritic eruption Fungal nail infections Seborrhoeic dermatitis	Unexplained persistent hepatosplenomegaly Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis) Herpes zoster Lineal gingival erythema Recurrent oral ulceration Papular pruritic eruption Fungal nail infections Extensive wart virus infection Extensive molluscum contagiosum Unexplained persistent parotid enlargement
Clinical Stage 3	
Unexplained severe weight loss (>10% of presumed or measured body weight) Unexplained chronic diarrhoea for longer than 1 month Unexplained persistent fever (intermittent or constant for longer than 1 month) Persistent oral candidiasis Oral hairy leukoplakia Pulmonary tuberculosis Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia) Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis Unexplained anaemia (<8 g/dl), neutropaenia (<0.5 x 109/l) and/or chronic thrombocytopaenia (<50 x 109/l)	Unexplained moderate malnutrition[b] not adequately responding to standard therapy Unexplained persistent diarrhoea (14 days or more) Unexplained persistent fever (above 37.5°C, intermittent or constant, for longer than one 1 month) Persistent oral candidiasis (after first 6 weeks of life) Oral hairy leukoplakia Lymph node tuberculosis Pulmonary tuberculosis Severe recurrent bacterial pneumonia Acute necrotizing ulcerative gingivitis or periodontitis Unexplained anaemia (<8 g/dl), neutropaenia (<0.5 x 109/l) or chronic thrombocytopaenia (<50 x 109/l) Symptomatic lymphoid interstitial pneumonitis Chronic HIV-associated lung disease, including bronchiectasis

7.1 WHO Clinical Staging (continued)

Adults and Adolescents[a]	Children
Clinical Stage 4[c]	
HIV wasting syndrome Pneumocystis (jirovecii) pneumonia Recurrent severe bacterial pneumonia Chronic herpes simplex infection (orolabial, genital or anorectal of more than 1 month's duration or visceral at any site) Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) Extrapulmonary tuberculosis Kaposi sarcoma Cytomegalovirus infection (retinitis or infection of other organs) Central nervous system toxoplasmosis HIV encephalopathy Extrapulmonary cryptococcosis, including meningitis Disseminated nontuberculous mycobacterial infection Progressive multifocal leukoencephalopathy Chronic cryptosporidiosis Chronic isosporiasis Disseminated mycosis (extrapulmonary histoplasmosis, coccidioidomycosis) Lymphoma (cerebral or B-cell non-Hodgkin) Symptomatic HIV-associated nephropathy or cardiomyopathy Recurrent septicaemia (including nontyphoidal Salmonella) Invasive cervical carcinoma Atypical disseminated leishmaniasis	Unexplained severe wasting, stunting or severe malnutrition[d] not responding to standard therapy Pneumocystis (jirovecii) pneumonia Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia) Chronic herpes simplex infection (orolabial or cutaneous of more than 1 month's duration or visceral at any site) Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) Extrapulmonary tuberculosis Kaposi sarcoma Cytomegalovirus infection (retinitis or infection of other organs with onset at age more than 1 month) Central nervous system toxoplasmosis (after the neonatal period) HIV encephalopathy Extrapulmonary cryptococcosis, including meningitis Disseminated nontuberculous mycobacterial infection Progressive multifocal leukoencephalopathy Chronic cryptosporidiosis (with diarrhoea) Chronic isosporiasis Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidioidomycosis, penicilliosis) Cerebral or B-cell non-Hodgkin lymphoma HIV-associated nephropathy or cardiomyopathy

[a]In the development of this table, adolescents were defined as 15 years or older. For those aged less than 15 years, the clinical staging for children should be used.
[b]For children younger than 5 years, moderate malnutrition is defined as weight-for-height <–2 z-score or mid-upper arm circumference ⩾ 115 mm to <125 mm.
[c]Some additional specific conditions can be included in regional classifications, such as penicilliosis in Asia, HIV-associated rectovaginal fistula in southern Africa and reactivation of trypanosomiasis in Latin America.
[d]For children younger than 5 years of age, severe wasting is defined as weight-for-height <–3 z-score; stunting is defined as length-for-age/height-for-age <–2 z-score; and severe acute malnutrition is either weight for height <–3 z-score or mid upperarm circumference <115 mm or the presence of oedema.

7.2 Procedures for Virological Monitoring

Steps in routine viral load (VL) monitoring

1. All patients on ART should have a first viral load at 6 months post ART initiation and a second viral load 6 months later. If viral load is suppressed on both results, repeat yearly thereafter (adolescents should repeat it every 6 months). If viral load is consistently >1000 copies/ml follow the treatment failure algorithms in Figure 4.2 for adults and Figure 6.2 for children and adolescents.
2. At every visit, check if the patient has had a viral load in the last year – if not, refer for viral load testing.
3. Record 'viral load taken' on patient's Chronic Care File and Appointment Card, and organize a follow-up appointment. Ideally this should be one month later, in which case, give only a one month supply of ARVs. Confirm that the patient's contact details are correct incase you need to contact the patient if result is detectable.
4. Explain the results to the patients and inform the patient of the next steps.
5. If at any point in time the viral load becomes >1000 copies/ml, proceed with the treatment failure algorithms in Figure 4.2 for adults and Figure 6.2 for children and adolescents.
6. If a clinician suspects therapeutic failure, he/she can request viral load testing for any patient on ART, irrespective of whether the patient is due for routine monitoring at that time. In the case of viral load result >1000 copies/ml, proceed with stepped-up adherence counsellingand follow the respective treatment failure algorithms.

7.3 Overview of ARV drugs

Generic Name	Standard Adult Dose	Adult formulation	Paediatric Formulation	Food Restrictions / Special	Contra-Indications
Nucleoside Reverse Transcriptase Inhibitors (NRTI)					
Abacavir (ABC)	300mg Every 12 hours	300mg tabs	20mg/ml Susp	With or without food	Previous hypersensitivity reactions, advanced kidney or liver disease
Didanosine (ddI)	250mg every 24 hours or 125mg every 12 hours if <60kg 400mg every 24 hours or 200mg 12 hourly if >60kg	200mg Table 250mg tabs 400mg tabs	25mg tabs, 125mg tabs,	1 hour before or 2 hours after a meal Do not take with acidic juices, soda or milk	History of Pancreatitis, kidney or liver disease, neuropathy
Emtricitabine (FTC)	200mg once a day	200mg Caps	–	With food	Kidney and liver disease
Lamivudine (3TC)	150 mg every 12 hours or 300 mg once daily	150 mg tabs	10mg/ml Syr	With or without food	Acute or chronic pancreatitis
Stavudine (d4T)	30 mg every 12 hours if <60kg 40mg every 12 hours if >60kg	20mg Caps, 30 mg Caps	15mg Caps	With or without food	Lactic acidosis, hepatic steatosis
Stavuadine (d4T)	300 mg every 12 hours	300 mg tabs	10mg/ml Syr	With or without food, with adequate fluid (water)	Lactic acidosis
Nucleotide Reverse Transcriptase Inhibitors (NtRTI)					
Tenofovir (TDF)	300 mg every 24 hours	300 mg tabs	–	With or without food	Kidney disease

7.3 Overview of ARV drugs (continued)

Generic Name	Standard Adult Dose	Adult formulation	Paediatric Formulation	Food Restrictions / Special Considerations	Contra-Indications
Non- Nucleoside Reverse Transcriptase Inhibitors (NNRTI)					
Efavirenz (EFV)	600 mg at night	200mg caps/tabs 600 mg caps/tabs	50mg caps/tabs 30mg/ml susp	Without food, at bedtime on an empty stomach	-
Etravirine	200mg every 12 hours	100mg Caps, 200mg Caps	25mg tabs, 125mg tabs	With food	Severe liver disease, history of Stevens-Johnson syndrome
Nevirapine (NVP)	200 mg every 24 hours for 14 days, then 200 mg every 12 hours	200 mg tabs	–	With or without food	Severe liver disease, history of Stevens-Johnson syndrome
Rilpivirine	200 mg every 24 hours for 14 days, then 200 mg every 12 hours	25 mg	–	With food	Severe liver disease, history of Stevens-Johnson syndrome
NRTI/NtRTI Fixed Combinations					
Tenofovir + Lamivudine	200 mg every 24 hours for 14 days, then 200 mg every 12 hours	300mg + 300mg tabs	–	See Tenofovir and Lamivudine	
NNRTI/NRTI Fixed Combinations					
Stavudine + Lamivudine + Nevirapine	One tablet every 12 hours	30mg + 150mg + 200mg Tabs	30mg + 150mg + 200mg Tabs	See Zidovuine, Lamivudine, Nevirapine	
Zidovudine + Lamivudine + Nevirapine	One tablet every 12 hours	30mg + 150mg + 200mg Tabs	30mg + 150mg + 200mg Tabs	See Zidovuine, Lamivudine, Nevirapine	
NRTI/NRTI Fixed Combinations					
Zidovudine + Lamivudine	One tablet every 12 hours	–	60mg + 30mg Tabs	See Abacavir, Lamivudine	
Stavudine + Lamivudine	One tablet every 12 hours	30mg + 150mg Tabs	12mg + 60mg Tabs	See Stavudine, Lamivudine	
Zidovudine + Lamivudine	One tablet every 12 hours	300mg + 150mg Tabs	60mg + 30mg Tabs	See Zidovudine, Lamivudine	

7.3 Overview of ARV drugs (continued)

Generic Name	Standard Adult Dose	Adult formulation	Paediatric Formulation	Food Restrictions / Special Considerations	Contra-Indications
NtRTI/NRTI/NNRTI Fixed Combinations					
Tenofovir + Lamivudine + Efavirenz	One tablet every 24 hours	300mg + 300mg + 600mg Tabs	50mg caps/tabs 30mg/ml susp	See Tenofovir, Lamivudine, Efavirenz	
Tenofovir + Lamivudine + Nevirapine	One tablet every 24 hours (copack)	300mg + 300mg + 200mg tabs	–	See Tenofovir, Lamivudine, Nevirapine	
Tenofovir + Lamivudine + Efavirenz	One tablet every 24 hours	300mg + 200mg +600mg Tabs	–	See Tenofovir, Emtricitabine, Efavirenz	
Tenofovir + Emtricitabine + Rilpivirine	One tablet every 24 hours	300mg + 200mg + 25mg	–	See Tenofovir, Emtricitabine, Rilpivirine	
Protease Inhibitors (PIs)					
Darunavir	600mg with 100mg Ritonavir every 12 hours or 800mg with 100mg Ritonavir every 24 hours	400mg tab, 600mg tab	–	With Food	Use with caution in Liver Disease
Indinavir (IDV)	800mg every 8 hours	400mg Caps	–	Without food – take two hours before or one hour after a meal avoid taking within an hour of taking Didanosine	Kidney or liver disease
Lopinavir (boosted with Ritonavir) (LPV + r)	LPV + R (200mg + 50mg) Tabs every 12 hours	100mg + 25mg Tabs 200mg + 50mg Tabs	80mg + 20mg Syr	With Food	Diabetes, liver and heart problems
Ritonavir (RTV)	To Boost other PIs 100 - 200mg every 12 hours or 24 hours	100mg Caps	–	With Food	–
Saquinavir (SQV/r)	1000mg with 100mg Ritonavir every 12 hours	200mg Caps	–	With Food	–
Atazanavir (ATV/r)	300mg atazanavir with 100mg ritonavir every 24 hours	300mg Tabs	–	Better with food	Advanced Liver disease, heart problems, diabetes

7.4 Drug Combinations To Be Avoided

Drug Combination	Reason
D4T + AZT (+ 3rd drug)	Proven antagonism
D4T + ddI (+ 3rd drug)	Overlapping toxicities
TDF + 3TC + ABC	High incidence of virologic failure
TDF + 3TC + ddI	High incidence of virologic failure; increased risk of side effects
TDF + ddI + NNRTI	High incidence of virologic failure; increased risk of side effects

7.5 Potential ARV interactions with other drugs

Drug		
Zidovudine (AZT)	Codeine, clarithromycin, dapsone, methadone, rifampicin, phenytoin, phenobarbital, valproate, amphotericin B, fluconazole	Stavudine (D4T) – Proven antagonism, overlapping toxicities
Abacavir (ABC)	Rifampicin, methadone, metronidazole, phenobarbital, phenytoin	–
Lamivudine (3TC)	Lamivudine (3TC), Amphotericin B	–
Stavudine (d4T)	Amphotericin B, co-trimoxazole, isoniazid, methadone, hydroxyurea	Zidovudine (AZT) – Proven Antagonism, overlapping toxicities Didanosine (ddI)
Didanosine (ddI)	Amphotericin B, hydroxyurea, methadone, ribavirin	Emtricitabine
Tenofovir (TDF)	Acyclovir, amphotericin B, co-trimoxazole, cimetidine, furosemide, hydroxyurea, streptomycin	Lamivudine (3TC) + Abacavir (ABC) – High virological failure Lamivudine (3TC) + Didanosine (ddI) - High incidence of virologic failure; increased risk of side effects Didanosine (ddI) + NNRTI - High incidence of virologic failure; increased risk of side effects
Etravirine (ETV)	Rifampicin, St John's wort	Unboosted PIs ATV/r, FPV/r, or TPV/r, other NNRTIs
Raltegravir (RAL)	Antacids, carbamazepine, H2 antagonists, hydroxyurea, phenobarbital, phenytoin, PPIs, rifampicin	Fosamprenavir (fAVP)

7.5 Potential ARV interactions with other drugs (continued)

Drug	Potential interaction with	Avoid combination with
Nevirapine (NVP)	Artemisin, amiodarone, buprenorphine, carbamazepine, clarithromycin, codeine, dexamethasone, diazepam, digoxin, erythromycin, estradiol, ethinylestradiol, fluconazole, furosemide, garlic, gliclazide, glipizide, glitazones, halofantrine, haloperidol, itraconazole, ketamine, ketoconazole, levonorgestrel, lorazepam, medroxyprogesterone (IM and oral), methadone, miconazole, norethisterine, milk thistle, phenobarbital, phenytoin, prednisolone, quinine, rifabutin, rifampicin, Saint John's wort, simvastatin, valproate	Etravirine (ETV) - Co-administration decreased etravirine concentration. Co-administration is contraindicated. Atazanavir (ATV) – co-administration is not recommended, increases nevirapine exposure and decreases atazanavir concentration.
Efavirenz (EFV)	Artemisin, codeine, buprenorphine, cimetidine, clarithromycin, diazepam, ergometrine, estradiol, ethinylestradiol, ketamine, furosemide, garlic, gliclazide, glipizide, halofantrine, haloperidol, ketoconazole, levonorgestrel, lumefantrine, lorazepam, midazolam, milk thistle, phenobarbital, phenytoin, prednisolone, quinine, rifabutin, rifampicin, St John's wort	Etravirine (ETV) – Co-administration decreased etravirine concentration. Co-administration is contraindicated
Lopinavir (LPV/r)	Artemisin, codeine, buprenorphine, cimetidine, clarithromycin, diazepam, ergometrine, estradiol, ethinylestradiol, ketamine, furosemide, garlic, gliclazide, glipizide, halofantrine, haloperidol, ketoconazole, levonorgestrel, lumefantrine, lorazepam, midazolam, milk thistle, phenobarbital, phenytoin, prednisolone, quinine, rifabutin, rifampicin, St John's wort	–
Atazanavir (ATV/r)	Amiodarone, antacids, carbamazepine, clarithromycin, colchicine, dexamethasone, H2 receptor antagonists, midazolam, PPIs, phenobarbital, rifampicin, sildenafil, simvastatin, tricyclic antidepressants, St John's wort, warfarin (monitor INR)	Etravirine (ETV), Nevirapine (NVP)
Darunavir (DRV/r)	Amiodarone, antacids, carbamazepine, clarithromycin, colchicine, dexamethasone, H2 receptor antagonists, midazolam, PPIs, phenobarbital, rifampicin, sildenafil, simvastatin, tricyclic antidepressants, St John's wort, warfarin (monitor INR)	–

7.6 Most Common Adverse Drug Reactions to First-line Drugs

Common ART Adverse Drug Events, Management & Prevention

Clinicians should alert patients to the potential of experiencing toxicities to their medication and advise on when to report to their health care providers. Adverse Drug Events should be documented and recorded on the prescribed ADR reporting form and forwarded to the Pharmacovigilance Unit of the Ministry of Health at the Central Medical Stores for analysis. The following table lists the adverse drug reactions of commonly used ARV drugs as well as guidelines on how to manage and prevent them.

Generic Name	Adverse Reactions	Frequency	Signs and Symptoms	Management	Prevention
Zidovudine (AZT)	Minor symptoms	High	Nausea, vomiting, abdominal pain, diarrhoea, headaches; at the beginning of the treatment	Symptomatic treatment only if not subsiding or if leading to complication (dehydration)	Take AZT with food
	Lipodystrophy	High	Nausea, vomiting, abdominal pain, diarrhoea, headaches; at the beginning of the treatment	If clearly marked, switch to TDF	Regular exercise
	Myalgia	High	Nausea, vomiting, abdominal pain, diarrhoea, headaches; at the beginning of the treatment	If clearly marked, switch to TDF	None
	Leucopoenia	High	Leucopoenia< 750/ml	Follow up, if high grade, with structured ART interruption, monitoring, and reintroduction of ART (TDF)	None
	Red cell megaloblastia	High	None	Follow up, if high grade, with structured ART interruption, monitoring, and reintroduction of ART (TDF)	None
	Nail discoloration	Medium	Black lines perpendicular to nail growth line (fingers, toes)	None	None
	Bone marrow* suppression	Medium	Anaemia, bicytopoenia or pancytopoenia	If high grade, implement structured ART interruption, monitoring, and reintroduction of ART (TDF)	None

Common ART Adverse Drug Events, Management & Prevention (continued)

Name	Adverse Reactions	Frequency	Signs and Symptoms	Management	Prevention
Zidovudine (AZT)	Hepatitis*	Low	Nausea, vomiting, jaundice, right flank pain, or asymptomatic + raised ALTs	Follow up, if high grade, with structured interruption of ART, monitoring, and reintroduction of ART without AZT	Avoid alcohol and other hepatotoxic drugs
	Lactic acidosis*	Low	Fatigue, rapid loss of weight, abdominal and limb cramps, nausea, in a very adherent patient (more commonly female, obese, pregnant) Critical stage: dyspnoea	Stop all ART and follow up on the weight gain; usually after one month, reintroduce ART with TDF. If dyspnoea: hospitalisation Critical stage: dyspnoea	Weight check at each consultation, patient's education
	Myopathy	Low	Fatigue, rapid loss of weight, abdominal and limb cramps, nausea, in a very adherent patient (more commonly female, obese, pregnant) Critical stage: dyspnoea	Check creatinine kinase (CK); if high grade, switch AZT to TDF; massage, stretching	None
Lamivudine (3TC)	Pancreatitis	Low	Epigastric pain, loss of appetite	If high grade, implement structured ART interruption; when subsided, reintroduce regimen without 3TC, d4T, or ddI	Avoid alcohol and other pancreatotoxic drugs
	Parestheria/ peripheral neuropathy	Low	Numbness, pins and needles, burning sensation of the limbs	Pyridoxine, amitriptyline. If high grade, switch regimen to one without 3TC, d4T, and ddI	Avoid alcohol and other neurotoxic drugs
Abacavir (ABC)	Hypersensitivity reaction	Low	Fever, rash, headache, sore throat, cough, shortness of breath	Stop the medication immediately, treat symptoms	None
	Lactic acidosis	Low	Nausea, vomiting, abdominal discomfort, fatigue, muscle weakness in arms and legs	Stop the medication immediately, treat symptoms	None
	Minor symptoms	Medium	Loss of appetite, headache, malaise, nausea,vomiting, diarrhea	Continue medication, symptoms improve within a few weeks of starting ART	None

Common ART Adverse Drug Events, Management & Prevention (continued)

Generic Name	Adverse Reactions	Frequency	Signs and Symptoms	Management	Prevention
Didanosine (ddI)	Lactic acidosis	Medium	Nausea, vomiting, abdominal discomfort, muscle weakness and tiredness, shortness of breath	Stop all ART, treat symptoms and re-introduce ART with another NTRI e.g. TDF	Avoid stavudine when taking didanosine
	Pancreatitis	Low	Nausea, vomiting, abdominal pain	Stop all ART, treat symptoms	Avoid alcohol
	Peripheral neuropathy	Medium	Pain, tingling, numbness, burning sensation in hands and or feet	Stop DDI and substitute with another NRTI that does not cause neuropathy, e.g. AZT	–
	Minor symptoms	High	Nausea, headache, dry mouth, CNS symptoms (anxiety, insomnia, irritability, restlessness)	Continue treatment, symptoms subside within weeks of starting ART	None
Emtricitabine (FTC)	Lactic acidosis	Low	Nausea, vomiting, abdominal discomfort, muscle weakness and tiredness, shortness of breath	Stop all ART, treat symptoms and re-introduce ART with another NTRI e.g. TDF	None
	Minor symptoms	Low	Headache, diarrhoea, nausea, rash, stomach pain, indigestion	Continue treatment. Symptoms usually subside within a few weeks	None
Stavudine (d4T)	Minor symptoms	High	Numbness, pins and needles, burning sensation of the limbs	Pyridoxine, amitriptyline. If high grade, switch regimen to one without D4T or DDI	Avoid alcohol and other neurotoxic drugs
	Lipodystrophy	High	Shrinking of lower limbs and buttocks, accumulation of fat around the abdomen, gynaecomastia, buffalo hump	If clearly marked, switch to TDF	Regular exercise
	Lipodystrophy	Low	Epigastric pain, loss of appetite	If high grade, implement structured ART interruption; when subsided, reintroduce regimen without 3TC, d4T, or ddI	—

Common ART Adverse Drug Events, Management & Prevention (continued)

Generic Name	Adverse Reactions	Frequency	Signs and Symptoms	Management	Prevention
Stavudine (d4T)	Lactic acidosis	Low	Fatigue, rapid loss of weight, abdominal and limb cramps, nausea, in a very adherent patient (more commonly female, obese, pregnant) Critical stage: dyspnoea	Stop all ART and follow up on the weight gain; usually after one month, reintroduce ART with TDF. If dyspnoea: hospitalisation	Weight check at each consultation, patient's education
	Liver failure*	Low	Jaundice, fatigue, pruritus, drowsiness, restlessness, confusion, coma.	Emergency hospitalisation	Avoid alcohol and other hepatotoxic drugs
Tenofovir (TDF)	Reduction in bone mineral density	–	–	–	Avoid concomitant corticosteroids
Efavirenz (EFV)	CNS adverse effects	**50%** of patients (less common in kids)	Tiredness, dizziness, impaired concentration drowsiness, vivid dreams	Generally resolve after 2-4 weeks. Avoid alcohol as may worsen CNS side effects.	Take dose at bed time to minimize side effects.
Nevirapine (NVP)	Rash	Females have greater risk than males	–	If rash occurs in the first 14 days do not increase dose until it resolves (up to 28 days). If rash persists after 28 days choose alternate ARV. Stop treatment if rash is severe or Stevens-Johnson Syndrome develops.	Do not use antihistamines or systemic corticosteroids to prevent rash, they will be ineffective and may increase the chance of rash occurring.
Lopinavir (LPV/r)	Rash, diarrhoea	High	–	–	–
Atazanavir (ATV/r)	Unconjugated hyperbilirubinaemia Cholelithiasis	–	Jaundice - yellowing of the eyes and skin Abdominal pain. History of kidney stones increases risk and patients may present with cholelithiasis and kidney stones concurrently	Reversible on stopping atazanavir	–

Common ART Adverse Drug Events, Management & Prevention (continued)

Generic Name	Adverse Reactions	Frequency	Signs and Symptoms	Management	Prevention
Darunavir (DRV)	DRV has a sulphonamide moiety which may predispose to Stevens Johnson syndrome and erythema multiforme Hepatotoxicity	10%	Skin rash Diarrhoea, nausea Headache Transaminase elevation Fat maldistribution Hyperglycaemia	–	–
Ritonavir (RTV) (as a pharma-cokinetic booster)	GI intolerance Paraesthesia Hyperlipidaemia Hepatitis	–	Nausea, vomiting, diarrhoea Fat maldistribution Taste perversion Hyperglycaemia	–	–
Raltegravir (RAL)	Pyrexia, CPK elevation, muscle weakness, and rhabdomyolysis	–	Headache, rash, diarrhoea and nausea	–	–
Etravirine (ETV)	Hypersensitivity reactions have been reported , characterized by rash, constitutional findings , and sometimes organ dysfunction, including hepatic failure	Rash: 2% discontinuation because of rash during clinical trials	Rash, Nausea	–	–

7.7 General Grading of ARV Side Effects and Toxicities

Grading of side effects and toxicities guides management and helps determine what action to take and if the client needs to be referred to higher levels of care.

Grade	Description	Action
GRADE 1 Mild	Transient or mild discomfort; no limitation in activity; no medical intervention/therapy required.	Client remains on therapy. Client can stay at that level of care Repeat the test if necessary. Reassess clinically within 2 weeks.
GRADE 2 Moderate	Mild to moderate limitation in activity-some assistance may be needed; no or minimal medical intervention/therapy required.	Client remains on therapy. Client can stay at that level of care Repeat the test. Reassess clinically within 2 weeks.
GRADE 3 Severe	Marked limitation in activity; assistance usually required; medical intervention/therapy required; hospitalization possible.	Seek expert medical advice as it might be necessary to stop ARVs. Refer to higher level of care. Repeat test within a week if necessary.
GRADE 4 Life threatening	Extreme limitation in activity, significant assistance required; significant medical intervention/therapy required; hospitalization or hospice care probable.	Seek specialist advice. Stop ALL drugs immediately.

7.8 Measures of Severity for ARV Toxicities

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Severe and potentially life-threatening (Grade 4)
General Guidance on Estimating Severity Grade				
Characterization of symptoms and general guidance on management	Symptoms causing no or minimal interference with usual social and functional activities.[a–c]	Symptoms causing greater than minimal interference with usual social and functional activities; may require minimal intervention and monitoring.	Symptoms causing inability to perform usual social and functional activities; requires medical care and possible hospitalization.	Symptoms causing inability to perform basic self-care functions: requires medical or operative intervention to prevent permanent impairment, persistent disability or death.
[a]Values are provided for children in general except where age groups are specified. [b]Usual social and functional activities in young children include those that are appropriate for their age and culture (e.g. social interactions, play activities, learning tasks). [c]Activities appropriate for age and culture (e.g. feeding self with culturally appropriate eating implement, walking or using hands)				
Haematology (standard international units in italics)				
Absolute neutrophil count	750–<1000/mm^3 0.75 x 109–<1 x 109/L	500–749/mm^3 0.5 x 109–0.749 x 109/L	250–500/mm^3 0.25 x 109–0.5 x 109/L	<250/mm^3 <0.250 x 109/L
Haemoglobin	8.5–10.0 g/dl 1.32–1.55 mmol/L	7.5–<8.5 g/dl 1.16–<1.32 mmol/L	6.5–<7.5 g/dl 1.01–<1.16 mol/L	<6.5 g/dl <1.01 mmol/L Or severe clinical symptoms attributable to anaemia (eg, cardiac failure), refractory to supportive therapy.
Platelets	100,000–<125,000/mm^3 100 x 109–125 x 109/L	50,000–<100,000/mm^3 50 x 109–<100 x 109/L	25,000–<50,000/mm^3 25 x 109–<50 x 109/L	<25,000/mm^3 <25 x 109/L Or bleeding.
Gastrointestinal				
ALT (SGPT)	1.25–2.5 x ULN	2.5–5.0 x ULN	5.1–10.0 x ULN	>10.0 x ULN
AST (SGOT)	1.25–2.5 x ULN	2.5–5.0 x ULN	5.1–10.0 x ULN	>10.0 x ULN
Bilirubin (>2 weeks old)	1.1–1.5 x ULN	1.6–2.5 x ULN	2.6–5.0 x ULN	>5.0 x ULN
Lipase	1.1–1.5 x ULN	1.6–3.0 x ULN	3.1–5.0 x ULN	>5.0 x ULN
Pancreatic amylase	1.1–1.5 x ULN	1.6–2.0 x ULN	2.1–5.0 x ULN	>5.0 x ULN

7.8 Measures of Severity for ARV Toxicities (continued)

	Mild (Grade 1)	Moderate (Grade2)	Severe (Grade 3)	Severe and potentially life-threatening (Grade 4)
Clinical				
Diarrhoea ⩾1 year of age	Transient or intermittent episodes of unformed stools OR increase of ⩽3 stools over baseline per day.	Persistent episodes of unformed to watery stools OR increase of 4–6 stools over baseline per day.	Grossly bloody diarrhoea OR increase of ⩾7 stools per day OR intravenous fluid replacement indicated.	Life-threatening consequences (e.g. hypotensive shock) <1 year of age
<1 year of age	Liquid stools (more unformed than usual) but usual number of stools.	Liquid stools with increased number of stools OR mild dehydration.	Liquid stools with moderate dehydration.	Liquid stools resulting in severe dehydration with aggressive rehydration indicated OR hypotensive shock.
Nausea	Not applicable.	Symptomatic AND hospitalization not indicated (other than emergency treatment).	Symptomatic AND hospitalization not indicated (other than emergency treatment).	Life-threatening consequences (i.e. circulatory failure, haemorrhage, sepsis).
Vomiting	Transient or intermittent vomiting with no or minimal interference with oral intake.	Frequent episodes of vomiting with no or mild dehydration.	Persistent vomiting.	Life-threatening consequences (e.g. hypotensive shock).

7.8 Measures of Severity for ARV Toxicities (continued)

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Severe and potentially life-threatening (Grade 4)
Allergic/Dermatological				
Acute systemic allergic reaction	Localized urticaria (weals) lasting a few hours.	Localized urticaria with medical intervention indicated OR mild angioedema.	Generalized urticaria OR angioedema with medical intervention indicated OR symptomatic mild brochospasm.	Acute anaphylaxis OR life-threatening brochospasm or laryngeal oedema.
Cutaneous reaction–rash	Localized macular rash.	Diffuse macular, maculopapular, or morbilliform rash OR target lesions.	Diffuse macular, maculopapular, or morbilliform rash with vesicles or limited number of bullae OR supervicial ulcerations of mucous membrane limited to 1 site.	Extensive or generalized bullous lesions OR Stevens-Johnson syndrome OR ulceration of mucous membrane involving 2 or more distinct mucosal sites OR toxic epidermal necrolysis (TEN).
Neurological				
Alteration in personality, behavior, or moodb	Alteration causing no or minimal interference with usual social and functional activities.[b]	Alteration causing greater than minimal interference with usual social and functional activities.[b]	Alteration causing inability to perform usual social and functional activitiesb AND intervention indicated.	Behaviour potential harmful to self or others OR life-threatening consequences.
Altered mental status	Changes causing no or minimal interference with usual social and functional activities.[b]	Mild lethargy or somnolence causing greater than minimal interference with usual social and functional activities.[b]	Onset of confusion, memory impairment, lethargy, or somnolence causing inability to perform usual social and functional activities.[b]	Onset of delirium, obtundation, or coma.

7.8 Measures of Severity for ARV Toxicities (continued)

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Severe and potentially life-threatening (Grade 4)
Neurological (continued)				
Neuromuscular weakness (including myoathy and neuropathy)	Asymptomatic with decreased strength on examination OR minimal muscle weakness causing no or minimal interference with usual social and functional activities.[b]	Muscle weakness causing greater than minimal interference with usual social and functional activities.[b]	Sensory alteration or paraesthesia causing greater than minimal interference with usual social and functional activities.	Disabling muscle weakness causing inability to perform basic self-care functions OR respiratory muscle weakness impairing ventilation.
Neurosensory alteration (including painful neuropathy)	Asymptomatic with sensory alteration on examination OR minimal paraesthesia causing no or minimal interference with usual social and functional activities.	Sensory alteration or paraesthesia causing greater than minimal interference with usual social and functional activities.	Sensory alteration or paraesthesia causing inability to perform usual social and functional activities.	Disabling sensory alteration or paraesthesia causing inability to perform basic self-care functions.[c]
[b]Usual social and functional activities in young children include those that are appropriate for their age and culture (e.g. social interactions, play activities, learning tasks). [c]Activities that are appropriate for age and culture (e.g. feeding self with culturally appropriate eating implement, walking, or using hands).				
Other Laboratory Functions (standard international units listed in italics)				
Cholesterol (fasting paediatric< 18 years old)	170–<200 mg/dl 4.40–5.15 mmol/L	200–300 mg/dl 5.16–7.77 mmol/L	>300 mg/dl >7.77 mmol/L	Not applicable
Glucose, serum, high: non-fasting	116–<161 mg/dl 6.44–<8.89 mmol/L	161–<251 mg/dl 8.89–<13.89 mmol/L	251–500 mg/dl 13.89–27.75 mmol/L	>500 mg/dl >27.75 mmol/L
Glucose, serum, high: fasting	110–<126 mg/dl 6.11–<6.95 mmol/L	126–<251 mg/dl 6.95–<13.89 mmol/L	251–500 mg/dl 13.89–27.75 mmol/L	>500 mg/dl >27.75 mmol/L
Lactate	<2.0 x ULN without acidosis	2.0 x ULN without acidosis	Increased lactate with pH <7.3 without life-threatening consequences or related condition present	Increased lactate with pH <7.3 with life-threatening consequences (eg, neurological findings, coma, or related condition present)
Triglycerides (fasting)	Not applicable	500–<751 mg/dl 5.65–<8.49 mmol/L	751–1200 mg/dl 8.49–13.56 mmol/L	>1200 mg/dl >13.56 mmol/L

7.9 Infant HIV Testing Algorithm

Test Anytime if Child is Sick or HIV is Suspected; All infants may be exposed to HIV until stopping breastfeeding

Age of Infant	Infants & Young Children Eligible for Testing	How to Test the Infant or Young Child
6-8 Weeks	***All Exposed infants*** *Offer test to mother and infant if exposure status unknown*	DNA PCR TEST → HIV Positive / HIV-Negative, Still Exposed • For infant: Give co-trimoxazole, stop NVP at 6 weeks • Encourage EBF for 6 months, then BF + complementary foods until at least 12 months and safe to stop BF • For mother: Ensure on ART, support adherence & family planning; encourage family testing
9 Months	***All infants*** *Offer test to mother and infant, regardless of exposure status, unless known to be HIV-positive*	RAPID TEST → Reactive → DNA PCR TEST → HIV Positive / HIV-Negative, Still Exposed RAPID TEST → Not Reactive
12 Months	***All Exposed infants*** *unless known to be HIV-positive*	RAPID TEST → Reactive → DNA PCR TEST → HIV Positive → *Encourage continued breast-feeding for best nutrition* DNA PCR TEST → HIV-Negative, Still Exposed → *If safe, encourage ending breast feeding over the course of one month to stop exposure* RAPID TEST → Not Reactive
18 to 24 Months	***All Children*** *Offer test to mother and child, regardless of exposure status, unless known to be HIV-positive*	*Follow adult testing algorithm:* RAPID TEST → Reactive: HIV-positive / Not Reactive: HIV Negative *Confirm all reactive results with second rapid test*
After Stopping Breastfeeding	***All Exposed Infants and Young Children*** *unless known to be HIV-positive*	**<9 months: DNA PCR 6weeks post-BF** **9-18 months: Rapid Test and confirm with DNA PCR 8 weeks post-BF** **>18 months: Rapid testing 8 weeks post-BF (adult algorithm)**

7.9 Infant HIV Testing Algorithm (continued)

Child is HIV-Positive: Positive DNA PCR or Reactive rapid tests > 18 months

- For infant: refer or initiate ART – early initiation increases child survival
- Continue co-trimoxazole
- Continue breastfeeding as long as possible
- For mother: ensure initiated on ART and support adherence & offer family planning and encourage family testing
- If child <18 months, re-confirm diagnosis with second DNA PCR, but do not delay ART initiation

Child is Still HIV-Exposed: Reactive rapid tests for mother or infant

- For infant: Continue co-trimoxazole
- Encourage exclusive breastfeeding for 6 months & complementary foods until 12 months and safe to stop breastfeeding
- For mother: Ensure initiated on ART and support adherence, & offer family planning and family testing

Child is HIV-Negative: Negative DNA PCR or non-reactive rapid test + confirmatory test 8 weeks after stopping breastfeeding)

- For infant: Stop co-trimoxazole
- If mother is positive: Ensure initiated on ART and support adherence, & offer family planning.
- If other safe feeding options exist, breastfeeding should be slowly ceased over the course of one month to remove ongoing exposure to HIV.

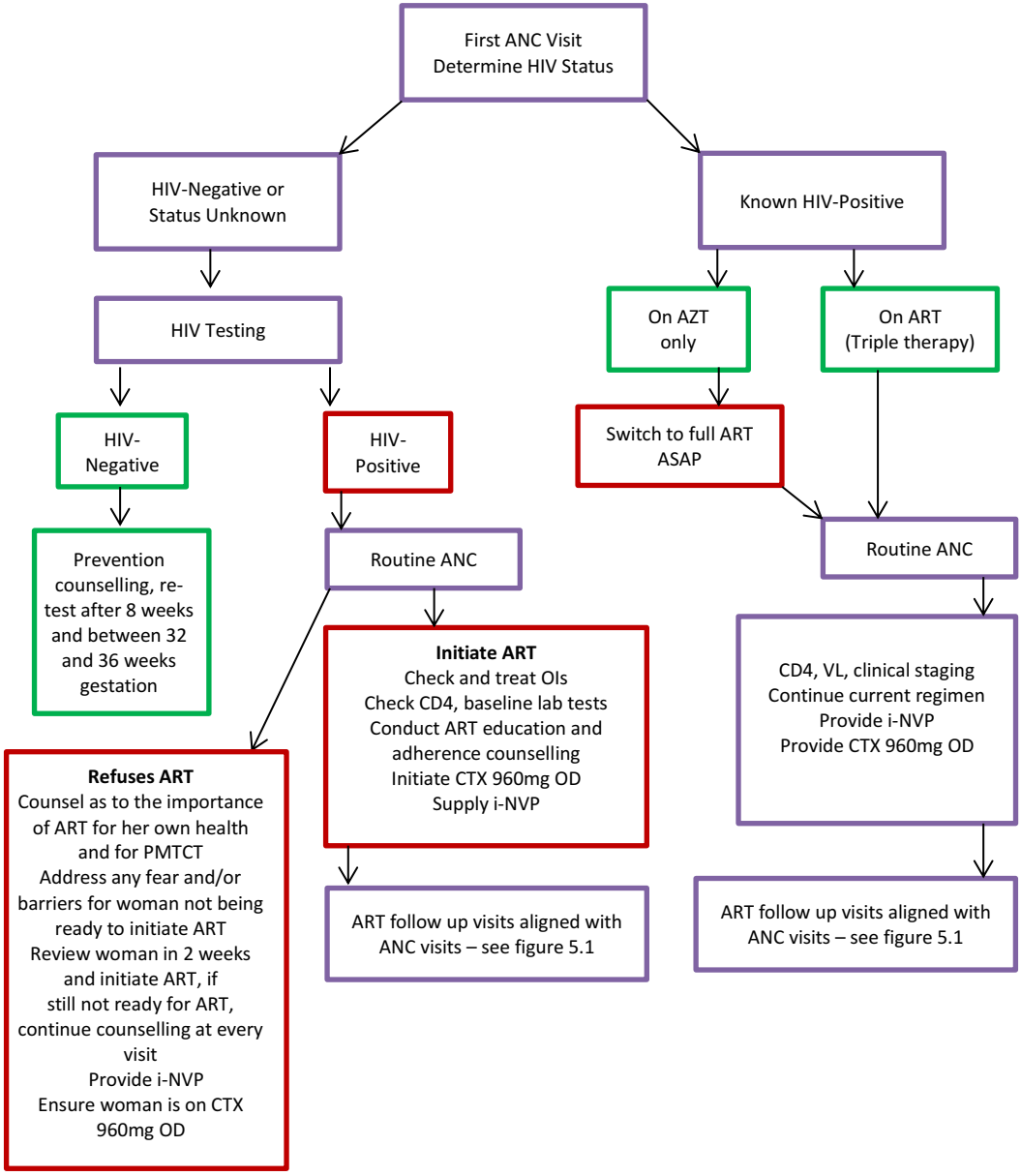
7.10 Paediatric ARV Dosing Card

ART Regimen	3 – 3.9 kg	4 – 5.9 kg	6 – 9.9 kg	10 – 13.9 kg	14 – 19.9 kg	20 –24.9 kg	25 – 39.9 kg	⩾40 kg
AZT/3TC/NVP[1] (60/30/50) Triple Paed FDC	1 BD	1 BD	1.5BD	2 BD	2.5BD	3 BD	Adult FDC 1 BD	Adult FDC 1 BD
AZT/3TC (60/30) Dual Paed FDC	1BD	1BD	1.5BD	2 BD	2.5BD	3 BD	Adult Dual 1 BD	Adult Dual 1 BD
ABC/3TC (60/30)	1 BD	1 BD	1.5BD	2 BD	2.5BD	3 BD	Adult Dual 1 BD	Adult Dual 1 BD
LPV/r[2]	1mL BD 80/20mg/mL syr or 2 BD 40/10mg Pellet	1.5mL BD 80/20mg/mL syr or 3 BD 40/10mg Pellet	1.5mL BD 80/20mg/mL syr or 3 BD 40/10mg Pellet	2mL BD 80/20mg/mL syr or 2 AM, 1PM 100/25 mg tab or 4 BD 40/10mg Pellet	2.5mL BD 80/20mg/mLs yr or 2 BD 100/25 mg tab or 5 BD 40/10mg Pellet	2 BD 100/25 mg tab or 1 BD 200/50mg tab or 6 BD 40/10mg Pellet	3 BD 100/25 mg tab or 2 AM, 1PM 200/50mg tab	4 BD 100/25 mg tab or 2 BD 200/50mg tab
NVP	5mL BD 10mg/mL syr or 1 BD 50mg tab	5mL BD 10mg/mL syr or 1 BD 50mg tab	7.5 mL BD 10mg/mL syr or 1.5 BD 50mg tab	10mL BD 10mg/mL syr or 2 BD 50mg tab or 0.5 BD 200mg tab	2.5 BD 50mg tab or 1 AM, 0.5PM 200mg tab	3 BD 50mg tab or 1 AM, 0.5PM 200mg tab	1 AM, 1PM 200mg tab	1 AM, 1PM 200mg tab
EFV	Not recommended			200mg PM	300mg PM	300mg PM	400mg PM	600mg PM
ABC (60)	1BD	1BD	1.5BD	2BD	2.5 BD	3BD	Adult tablet 1 BD	Adult tablet 1 BD
TDF/3TC/EFV Adult FDC	Not recommended							1 OD PM
d4T/3TC/NVP[1] (12/60/100) Triple Junior FDC	0.5BD	0.5BD	1 AM, 0.5PM	1 BD	1.5AM, 1 PM	1.5BD	Adult FDC 1 BD	Adult FDC 1 BD
d4T/3TC (12/60) Dual Junior FDC	0.5BD	0.5BD	1 AM, 0.5PM	1 BD	1.5AM, 1 PM	1.5BD	Adult Dual 1 BD	Adult Dual 1 BD

[1]NVP requires lead-in dosing in most cases when initiating for the first time. However, for patients who are on TB medication, do **not** use lead-in dosing

[2] LPV/r tablets must be administered intact and cannot be split or crushed.

7.11 HIV Testing and ART Initiation during ANC



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