MINISTRY OF HEALTH

Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya

2016 Edition

Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infections in Kenya

2016 Edition

The Guidelines on use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya 2016 edition contain relevant information required by health care providers in the use of ARVs as of the date of issue. All reasonable precautions have been taken by NASCOP to verify the information contained in this guideline document.

For clarifications contact National AIDS and STI Control Program (NASCOP) on P.O. Box 19361 00202, Nairobi Kenya, Tel: +254 (020) 2630867, Email: info@nascop.or.ke, Website: www.nascop.or.ke

The recommended citation for this document is as follows:
Ministry of Health, National AIDS & STI Control Programme. Guidelines on use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya 2016. Nairobi, Kenya: NASCOP, July 2016. Print.

Design and Layout: James Ngechu - ICAP

ISBN: 13 978-9966-038-15-9

Foreword

The 2016 edition of the 'Guidelines on use of Antiretroviral Drugs for Treating and Preventing HIV infection in Kenya' reflect substantial changes and a paradigm shift in the treatment and prevention of HIV infection. Over the past decades HIV has continued to be a growing public health problem globally and in Kenya. Over 1.5 million Kenyans are estimated to be living with HIV, 900,000 of who were on antiretroviral therapy by the end of 2015.

In recent years, strong evidence has emerged that shows the benefits of starting antiretroviral therapy (ART) early among HIV infected persons in comparison to delaying treatment. Early ART initiation is associated with better individual patient level outcomes including reduced risk of death and severe HIV associated illness; and broader population level prevention benefits. In addition, studies have demonstrated the efficacy of pre-exposure prophylaxis among various populations setting the agenda for expanded biomedical tools for HIV prevention. This evidence and wider availability of safer efficacious medicines, including increasing access to monitoring tools and technologies provide countries including Kenya with opportunities to expand the use of antiretroviral drugs (ARVs) for prevention. Furthermore achieving universal access appears more feasible with more targeted approaches for identifying persons living with HIV, reducing levels of stigma and increasing domestic investments in HIV control providing further support to expand use of ARVs. Recommendations presented in these guidelines are largely in line with the World Health Organization Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: recommendations for a public health approach, 2016 edition; and also with global and local evidence and implementation considerations.

Key areas covered include a summary of HIV testing and linkage recommendations, standard care for people living with HIV (PLHIV), antiretroviral therapy for all children, adolescents and adults living with HIV including special populations; prevention of mother to child transmission of HIV; patient centred differentiated care; adherence and monitoring; and the use of ARVs in pre-exposure prophylaxis among HIV uninfected persons at risk of HIV acquisition.

These guidelines are an important tool meant to be used by teams of multi-disciplinary healthcare professionals and are presented in a simplified manner using a public health approach to HIV prevention and treatment.

It is my hope that this guidance document provides the much needed framework and impetus to move towards universal access for HIV services and the agenda for ending AIDS by 2030 as a key national health strategic objective.

Dr Jackson Kioko
Ag Director of Medical Services
Ministry of Health

Acknowledgements

These guidelines have been developed through the collaborative effort of many individuals and multiple institutions. The review and revision has been done through extensive consultations and the commendable efforts of multiple stakeholders, individuals and institutions led by the Ministry of Health.

I acknowledge with appreciation institutions and organizations, both local and international, government ministries and departments whose members spent many hours to ensure this document is what it is.

I take this opportunity to appreciate the efforts of the Ministry of Health Officials at NASCOP and other organizations who coordinated and provided leadership to the whole process of review of the guidelines. Special compliments to the secretariat who under the coordination of Irene Mukui of NASCOP guided the entire review process namely by organization: NASCOP: Shobha Vakil, Laura Oyiengo, Maureen Kimani, Barbara Mambo, Dorothy Mwagae, Linda Misiko, Rose Wafula; CDC: Abraham Katana; CHS: Angela Mcligeyo; ICAP: Maureen Syowai; UNICEF: Teresa Alwar and WHO: Brian Chirombo, and the consultants Jared Mecha and Jeremy Penner who synthesized all inputs and compiled the guidelines. In addition I thank the key members who conducted evidence reviews, participated in the development of recommendations, and undertook reviews and provided technical inputs into these guidelines.

Financial support for the review process and printing of this document was provided by US Government through the Centers for Disease Control & Prevention-Kenya; the Centers for Disease Control & Prevention-Atlanta HCTB Branch HOP Funding through ICAP; and support for costing the implementation of guidelines provided by the USAID-funded Health Policy-plus.

Dr Martin Sirengo
Head, National AIDS & STI Control Program
Ministry of Health

Table of Contents

List of Tables

List of Figures

Acronyms and Abbreviations

Abbreviations and Names of Antiretroviral Drugs

3TC	Lamivudine
ABC	Abacavir
ATV	Atazanavir
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
DRV	Darunavir
DRV/r	Darunavir/ritonavir
DTG	Dolutegravir
EFV	Efavirenz
ETR	Etravirine
FTC	Emtricitabine
LPV	Lopinavir
LPV/r	Lopinavir/ritonavir
NVP	Nevirapine
RAL	Raltegravir
RTV	Ritonavir
TDF	Tenofovir Disoproxil Fumarate

Other Acronyms and Abbreviations

ACE-I	Angiotensin-converting enzyme inhibitor
ADR	Adverse drug reaction
AIDS	Acquired immunodeficiency syndrome
ALT	Alanine transaminase
ANC	Antenatal care
ARB	Angiotensin-receptor blocker
ART	Antiretroviral therapy
ARV	Antiretroviral drug(s)
AST	Aspartate transaminase
BD	Twice daily
BF	Breastfeeding
BMI	Body Mass Index
BP	Blood Pressure
CAG	Community ART Groups
CCC	Comprehensive Care Centre
CHV	Community Health Volunteer
CITC	Client-initiated HIV testing and counselling
CM	Cryptococcal meningitis
CMV	Cytomegalovirus
CNS	Central nervous system
CPT	Cotrimoxazole Preventive Therapy
CrCl	Creatinine Clearance
CTX	Cotrimoxazole
CYP450	Cytochrome P450
DAAs	Direct acting antiviral therapies
DBS	Dried Blood Spot
DMS	Director of Medical Services
DNA	Deoxyribonucleic acid
DOT	Directly observed therapy
DS	Double strength
DRT	Drug Resistance Testing
DTG	Dolutegravir

ECP	Emergency contraceptive pill
EFV	Efavirenz
EID	Early Infant Diagnosis
eMTCT	Eliminate Mother to Child Transmission
EPTB	Extra pulmonary tuberculosis
FBC	Full blood count
FBS	Fasting Blood Sugar
FDC	Fixed dose combination
FLP	Fasting Lipid Profile
FP	Family Planning
GIT	Gastro-intestinal tract
GOK	Government of Kenya
GBV	Gender-Based Violence
HAART	Highly active antiretroviral therapy
Hb	Hemoglobin
HBV	Hepatitis B virus
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C virus
HCW	Health care worker
HEI	HIV Exposed Infant
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HTS	HIV Testing Services
ICF	Intensified case finding
IEC	Information, education and communication
INH	Isoniazid
INSTI	Integrase Strand Transfer Inhibitor
IPT	Isoniazid preventative therapy
IRIS	Immune reconstitution inflammatory syndrome
ITN	Insecticide treated mosquito nets
IUD	Intrauterine device
KEPI	Kenya Expanded Program of Immunization
KS	Kaposi's sarcoma
LEEP	Loop electrosurgical excision procedure
MNCH/FP	Maternal, neonatal and child health/family planning
MDT	Multi-disciplinary team
MEC	Medical Eligibility Criteria
MOH	Ministry of Health
MSM	Men who have sex with men
MUAC	Mid-upper arm circumference
NAC	Nutritional Assessment, Counselling and Support
NASCOP	National AIDS and STI Control Program
NCD	Non-Communicable Diseases
NHRL	National HIV Reference Laboratory
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NSPs	Needle and syringe programmes
NtRTI	Nucleotide reverse transcriptase inhibitor
OD	Once daily
OI	Opportunistic infection
OPD	Outpatient department
OST	Opioid substitution therapy
OVC	Orphans and vulnerable children
PCP	Pneumocystis jirovecii pneumonia

PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PGL	Persistent generalized lymphadenopathy
PHQ-9	Patient Health Questionnaire-9
PHDP	Positive Health, Dignity, and Prevention
PI	Protease inhibitor
PITC	Provider initiated HIV testing and counselling
PLHIV	People living with HIV
PML	Progressive multifocal leucoencephalopathy
PMTCT	Prevention of mother-to-child transmission
PPE	Papular pruritic eruptions
PrEP	Pre-exposure prophylaxis
PTB	Pulmonary tuberculosis
PWID	People who inject drugs
R/NHCSC	Regional or National HIV Clinical Support Centre
RNA	Ribonucleic acid
RPR	Rapid Plasma Reagin
sCrAg	Serum cryptococcal antigen
SRH	Sexual and Reproductive Health
SS	Single strength
STI	Sexually transmitted infection
TB	Tuberculosis
TWG	Technical Working Group
VIA	Visual Inspection with Acetic Acid
VILI	Visual Inspection with Lugol's Iodine
VL	Viral Load
VMMC	Voluntary Medical Male Circumcision

1. Summary of Key Recommendations

1.1. HIV Testing Services (HTS) and Linkage to Care and Prevention

- HIV testing should be voluntary and conducted ethically in an environment where Consent, Confidentiality, Counselling, Correct results and Connection (linkage) can be assured
- To optimize access to testing services, HIV testing can be conducted in 3 different settings:
  - Facility-based
  - Community-based
  - Self-testing
- Birth testing of infants born to known HIV-positive mothers
  - HIV DNA PCR testing should be done at birth or at first contact thereafter, within 2 weeks of birth
    - If positive, start ART (AZT/3TC/NVP) and take samples for confirmatory HIV DNA PCR and baseline viral load at the time of ART initiation
- The package of HIV testing services consists of:
  - Pre-test counselling
  - HIV testing
  - Post-test counselling
  - Linkage to HIV prevention, care and treatment
  - Assessment for other health related needs e.g. TB, family planning (FP) etc.
- HTS providers should adopt the 6 approaches which are known to improve linkage to care and treatment
  - Information
  - Disclosure
  - Address barriers to linkage
  - Establishing systems to facilitate linkage
  - Care coordination and integration
  - Documentation (using linkage registers)

1.2. Initial Evaluation and Follow-up for PLHIV

- Initial Clinical Evaluation of PLHIV entails:
  - Taking a complete medical history
  - Conducting a thorough physical examination
- Appropriate laboratory investigations - Laboratory assessment is not a prerequisite to ART initiation
  - PLHIV should be categorized as being either stable or unstable both at baseline and during follow up. This will determine the level of care to be provided

1.3. Standard Package of Care for PLHIV

Consists of 8 components:

1. Antiretroviral therapy

- All PLHIV qualify for ART irrespective of CD4 cell count or percentage, WHO clinical stage, age, pregnancy status, or comorbidities
- ART should be initiated as soon as the patient is ready to start, preferably within two weeks from time of HIV diagnosis (subject to patient readiness)

2. Positive Health, Dignity, and Prevention

- All patients should be provided with Disclosure of HIV status; Partner/family testing and engagement; Condom use; Family planning, Sexually Transmitted infections and Treatment adherence
- All females aged 15-49 years and emancipated minors accessing HIV care services should be screened for Gender Based Violence (GBV) as part of the standard package of care for PLHIV
- All PLHIV should be provided with health education and counselling

3. Screening for and prevention of specific opportunistic infections

- All PLHIV should receive lifelong cotrimoxazole prophylactic therapy (CPT) unless they have allergy to sulfa drugs or develop toxicity from CPT
- During pregnancy, CPT should be initiated irrespective of the gestational age and should continue throughout pregnancy, breastfeeding, and thereafter for life
- Dapsone, when used as a substitute for cotrimoxazole (CTX) is only recommended for patients in WHO Stage 4 and/or absolute CD4 count < 200 cells/ml (or % CD4 count < 14%), and should be discontinued once a patient achieves a sustained CD4 count of > 200 cells/μL for at least 6 months
- All PLHIV should be screened for TB at every visit using the Intensified Case Finding (ICF) tool
- All adult PLHIV with a baseline CD4 count of ≤ 100 cells/ml should be screened for cryptococcal meningitis (CM) using the serum CrAg test

4. Reproductive health services

- Pregnancy status should be determined for all women of reproductive age at every visit
- All HIV positive women between the ages of 18 - 65 years should be screened for cervical cancer

5. Screening for and management of non-communicable diseases

- Lifestyle modifications are always the first line of prevention and management for hypertension, diabetes mellitus, and dyslipidaemia

6. Mental health screening and management

- All PLHIV should receive basic screening for depression before initiating ART, as indicated and annually thereafter if not indicated
- All adults and adolescents should be screened for alcohol and drug use before initiating ART and regularly during follow-up

7. Nutrition services

- All PLHIV should receive nutritional assessment, counselling, and support tailored to the individual needs of the patients

8. Prevention of other infections

- PLHIV (including children) should receive vaccination as recommended by the Vaccine and Immunization Program

1.4. Adherence Preparation, Monitoring and Support

- The adherence preparation, monitoring, and support that a patient requires should be tailored to their level of adherence and the stage of ART initiation and follow-up
- Whenever possible, follow-up should be provided by the same care provider or team of care providers (e.g. same clinician and counsellor) at every visit. This is particularly important during the first 6 months in care
- For all children/adolescents, the level of disclosure should be assessed at the first visit. Ongoing care should include a plan for age-appropriate disclosure
- All patients are at risk of new or worsening barriers to adherence, so adherence monitoring, counselling and support should continue despite viral suppression
- Every service delivery point that is providing ARVs for patients (whether ART, PEP, or PrEP) must have a functional system for identifying patients who miss appointments and for taking action within 24 hours of a missed appointment
- In patients failing ART, do not change regimens until the reason/s for treatment failure have been identified and addressed

1.5. Antiretroviral Therapy in Infants, Children, Adolescents, and Adults

- The goal of ART is to suppress viral replication with the aim of reducing the patient's VL to undetectable levels
- **All individuals with confirmed HIV infection are eligible for ART, irrespective of CD4 cell levels, WHO clinical stage, age, pregnancy or breastfeeding status, co-infection status, risk group, or any other criteria, PROVIDED that the individual is willing and ready to take ART and adhere to follow-up recommendations**
- ART should be started in all patients as soon as possible (preferably within 2 weeks of confirmation of HIV status
- **Preferred first-line ART for infants, children, adolescents and adults**
  - < 2 weeks : AZT + 3TC + NVP
  - 2 weeks - < 3 years: ABC + 3TC + LPV/r
  - 4 weeks - < 3 years : ABC + 3TC + LPV/r
  - 3 - 15 years (< 35 kg body weight) : ABC + 3TC + EFV
  - 3 - 15 years (≥ 35 kg body weight) : TDF + 3TC + EFV
  - >15 years : TDF + 3TC + EFV
- **Routine viral load (VL) testing is recommended for monitoring ART and identifying treatment failure. The VL test should be carried out at 6 and 12 months after initiation of ART and annually thereafter if the VL is < 1000 copies/ml**
- Treatment failure is defined by a persistently high viral load ≥ 1000 copies/mL (two viral loads measured within a 3-month interval with adherence support between measurements) after at least 6 months of using ART

1.6. Prevention of Mother to Child Transmission of HIV

- Prevention of mother-to-child transmission of HIV (PMTCT) should be offered as part of a comprehensive package of fully integrated, routine antenatal care interventions
- **ART should be initiated in all pregnant and breastfeeding women living with HIV, regardless of gestation, WHO clinical stage and at any CD4 cell count, and continued lifelong**
- ART should be started, ideally, on same day as HIV diagnosis with ongoing enhanced adherence support including community-based case management and support

- For newly initiated ART in pregnant and breastfeeding women, obtain VL 6 months after initiation, if >1000 copies/ml, intensify adherence, repeat the VL after 1 month and if still ≥1000 copies/ml, change to an effective regimen. If < 1000 copies/ml, repeat viral load every 6 months until end of breastfeeding then follow-up as for general population
- For HIV positive women on ART for > 6 months, obtain a VL as soon as pregnancy is confirmed. If the VL ≥ 1000 copies/ml, intensify adherence, repeat the VL after 1 month and if still above 1000 copies/ml, change to an effective regimen. If < 1000 copies/ml, repeat viral load every 6 months until end of breastfeeding then follow-up as for general population

1.7. TB/HIV Co-infection Prevention and Management

- All healthcare settings should implement TB infection control guidelines to reduce the risk of transmission of TB between patients, visitors and staff
- Symptom-based TB screening using the ICF tool MUST be performed on all PLHIV at every clinic visit to rule out active TB; patients who screen positive (presumptive TB cases) must complete definitive diagnostic pathways and patients who screen negative should be evaluated for isoniazid preventive therapy (IPT)
- **The Xpert MTB/Rif test is the recommended first test for diagnosis of TB and rifampicin resistance in all presumptive TB cases**
- Those who are diagnosed with TB/HIV co-infection should be on CPT as part of the comprehensive package of care for TB/HIV co-infection
- Patients diagnosed with TB/HIV co-infection should start anti-TB immediately and initiate ART as soon as anti-TB medications are tolerated, preferably within 8 weeks
- Patients with TB/HIV co-infection who are already on ART should start anti-TB immediately and continue ART, making any required adjustments to the ART regimen based on predicted drug interactions
- Always assess for ART failure in patients who develop TB after being on ART for ≥ 6 months

1.8. HBV/HIV and HCV/HIV Co-infection Prevention and Management

- All HIV positive persons should be screened for HBV infection, using serum HBsAg, as part of initial evaluation
    - HIV positive infants, HIV exposed infants (HEI), children, adolescents and adults without evidence of hepatitis B infection (HBsAg negative) should be vaccinated against hepatitis B with the standard vaccination regimen
    - All HIV infected patients who are co-infected with hepatitis B should be started on ART irrespective of CD4 cell count, WHO clinical stage and stage of liver disease
    - The recommended first-line ART in HIV/HBV co-infection is TDF + 3TC + EFV
- HCV serology should be offered to individuals at risk of HCV infection
- The recent introduction of direct acting antiviral therapies (DAAs) for treatment of HCV has simplified the management of HIV/HCV co-infection

1.9. ARVs for Post-exposure Prophylaxis (PEP)

PEP should be offered as soon as possible (< 72 hours) after high risk exposure.

- The recommended ARV agents for PEP are:
  (TDF + 3TC + ATV/r) for 28 days (Adults)
  (ABC + 3TC + LPV/r) for 28 days (Children)

1.10. Oral Pre-Exposure Prophylaxis (PrEP)

- Oral PrEP containing TDF should be offered to HIV negative individuals at substantial ongoing risk of HIV infection
- PrEP may be offered to the HIV seronegative partner in a sero-discordant relationship during attempts to conceive (as part of a pre-conception care plan for the couple)
- The recommended ARV regimen for use as PrEP is: TDF 300 mg and Emtricitabine 200 mg once daily (given as a FDC)
- PrEP does not eliminate the risk of HIV infection; and it does not prevent STIs or unintended pregnancies
- PrEP should only be offered after thorough assessment to establish eligibility, readiness for effective use, required follow-up and absence of contraindications to TDF and/or FTC

1.11. People Who Inject Drugs (PWID) and HIV

- PWID should be offered regular HIV testing and counselling and be linked to comprehensive HIV prevention, care and treatment services including harm reduction counselling and support
- Drug Resistance Testing (DRT), if available, is advisable prior to initiation of ART but should not delay initiation of ART
- Screening, diagnosis, treatment and prevention of STIs should be offered routinely as part of comprehensive HIV prevention and care for PWID
- PWID should have the same access to TB prevention, screening and treatment services as other populations at risk of or living with HIV
- PWID should be screened for HBV (by HBsAg) and HCV (by HBV serology) at first contact, and appropriate action taken per the national guidelines
- All PWID should be linked to Needle and Syringe Programmes (NSP) to access sterile injecting equipment

2. HIV Testing Services and Linkage to Care and Prevention

(Refer to the 2015 'Guidelines for HIV Testing Services in Kenya' for comprehensive guidance and recommendations on HIV testing services).

HIV testing services (HTS) provide the first critical link to comprehensive HIV prevention, care and treatment. Additionally, this initial step provides opportunities to offer other interventions such as sexual and reproductive health services, TB screening and referral, substance abuse screening and referral, information and referral for voluntary medical male circumcision, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) and other combination HIV prevention services.

HIV testing should be voluntary and conducted ethically in an environment where the five Cs of Consent, Confidentiality, Counselling, Correct results and Connection (linkage) can be assured.

2.1 Settings for HIV Testing

Facility-based testing:

- **Routine opt-out provider initiated HIV testing and counselling (PITC) should be offered to ALL clients (including infants, children, adolescents and adults) visiting health facilities regardless of the reasons for contact with the health facility**
- As much as possible, PITC should be integrated into care pathways at all service delivery points including adult and paediatric inpatient units, outpatient units, maternal and child health clinics, SRH/FP clinics, TB clinics, specialty clinics, and GBV care units. Patients starting HIV care should receive disclosure counselling and support followed by family testing

Community-based testing:

- Targeted community based HTS offers additional opportunities to identify and link to care and treatment PLHIV of unknown HIV status. This setting is especially important for testing children and partners of index clients through family-based testing and counselling; outreach to key populations as well as orphans and vulnerable children (OVCs), and; adolescents.

HIV self-testing (HIVST):

- HIVST allows individuals to collect their own specimen, perform the test, and interpret the results on their own. If positive, a confirmatory test must be performed by a trained HTS provider (facility-based or community-based) following the national testing algorithm
- Uptake of HIVST is improved with availability of easy-to-use testing methods such as oral/saliva-based tests. These can be issued from health facilities and pharmacies or through outreach programs
- HIVST may have the greatest benefit in reaching specific populations such as key populations, partner testing for pregnant women attending ANC; contacts of patients treated for STIs; highly stigmatized populations; healthcare workers; and frequent re-testers
- Providing HTS under different scenarios (Table 2.1) increases opportunities for access to knowledge of HIV status and to a range of HIV prevention, care and treatment services.

Table 2.1: Recommendations for HTS in Different Settings

Scenario	Recommendation
Birth testing of infants born to known HIV-positive mothers (Figure 2.1)	• All infants born to mothers known to be HIV-positive should be started on infant ARV prophylaxis and offered routine HIV DNA PCR testing at birth or at first contact thereafter, but not later than 2 weeks after birth • Infants with an initial positive HIV DNA PCR result should be presumed to be HIV infected and started on ART, with a confirmatory HIV DNA PCR and baseline viral load taken at the time of ART initiation (ART initiation is based on the first result) • Infants with initial negative results should continue infant ARV prophylaxis and followed up as HIV-exposed infants. The HIV DNA PCR should be repeated at the 6-week immunization visit, or at the earliest opportunity for infants seen after 6 weeks of age
HIV testing and counselling of infants and children aged less than 18 months (Figure 2.2)	• HIV exposure status of all infants should be established at first contact • To establish HIV exposure status of a child less than 18 months of age, conduct HIV antibody testing for mothers with unknown status or who previously tested negative during antenatal care, or on the child (if the mother declines testing/not available) • The 6-week immunization visit offers an excellent opportunity to establish the HIV exposure status of ALL children • All HEIs should be started on infant ARV prophylaxis and offered routine HIV DNA PCR testing at first contact • Infants with an initial positive HIV DNA PCR result should be presumed to be HIV infected and started on ART in line with national guidelines, with a confirmatory HIV DNA PCR and baseline viral load taken at the time of ART initiation (ART initiation is based on the first result) • Infants with initial negative results should continue infant ARV prophylaxis and followed-up as HEIs
HIV testing and counselling of children older than 18 months till age 9 years (Figure 2.3)	• Conduct HIV testing and counselling (with parental assent) for all children of unknown HIV status presenting to the health facility irrespective of reason for their visit to the health facility. If the child is known to be HIV negative from previous testing and has no new risk factors/ exposures then repeat testing is not required until adolescence • Conduct HIV testing and counselling for all children of HIV infected adults as soon as possible, within one month of confirming the HIV positive status of the adult
HIV testing and counselling of adolescents (10 - 19 years)	• Conduct HIV testing and counselling for all adolescents presenting to the health facility irrespective of reason for their visit to the health facility. Adolescents aged 15 years and above and emancipated minors can provide self-consent. For younger adolescents, obtain their assent and parental/caregiver consent • For those that test negative, re-testing should be recommended annually unless there is a new exposure risk • Link HIV-negative adolescents to comprehensive HIV prevention services based on risk assessment • Link all adolescents identified as HIV positive to comprehensive care and treatment services • All adolescents should be counselled about the potential benefits and risks of disclosure of their HIV status and empowered and supported to determine if, when, how and to whom to disclose • For sexually active adolescents with partners, HIV testing and counselling should be offered to their partners (and their children for HIV positive adolescents) • All adolescent males who test HIV negative should be counselled about the prevention benefits of VMMC and linked to VMMC services

HIV testing and counselling for pregnant and breastfeeding women	• All pregnant women (unless known HIV positive) should be counselled and tested for HIV during their first ANC visit and repeat testing conducted in the third trimester for all women who test HIV negative at the first ANC visit. The test (if negative) should be repeated at labour and delivery. • All breastfeeding mothers (unless known HIV positive) should be counselled and tested at 6 weeks postnatal visit. The HIV test (if negative)should be repeated 6 months and thereafter as per general population • Mothers should be counselled about the schedule for repeat HIV testing in pregnancy and postnatal as part of routine ANC and postnatal education • All pregnant and breastfeeding women who are not tested, opt-out or decline HIV testing during the first contact should be offered HIV counselling and testing in subsequent visits with appropriate linkage and referral for prevention, care and support services • All HIV positive and breastfeeding women enrolled into care should receive counselling and support (assisted disclosure), case managed linkage and follow-up • All spouses/partners of pregnant and breastfeeding women should be offered HIV testing and counselling and to all children if the mother is HIV positive
HIV testing and counselling of sexual partners & children of index clients (HIV positive person who is newly diagnosed or already in HIV care)	• All PLHIV enrolled into HIV care should receive disclosure counselling and be supported to disclose their HIV status (assisted disclosure) • HIV testing and counselling should be encouraged (facility-based or community-based) for all partners and children younger than 14 years of index clients, with linkage to prevention, care and treatment services as appropriate
HIV testing and counselling of key and vulnerable populations	• Conduct HIV testing and counselling for all clients from key and vulnerable populations presenting to the health facility irrespective of the reason for their visit to the health facility, or through targeted outreach testing, or through testing at key and vulnerable population service delivery points (e.g. drop-in centres) • For key populations that test negative, re-testing should be recommended every 3 months • Link all who test HIV positive to prevention, care and treatment services • For sexually active adults with partners, HIV testing and counselling should be offered to their partners (and children for those that are HIV positive) • All adult males accessing HTS should be counselled about the prevention benefits of VMMC and linked to VMMC services if they agree
HIV testing and counselling of adults	• Conduct HIV testing and counselling for all adults presenting to the health facility irrespective of reason for their visit to the health facility • For those that test negative, re-testing should be recommended annually unless there is a new risk exposure • Link all adults identified as HIV positive to prevention, care and treatment services • For sexually active adults with partners, HIV testing and counselling should be offered to their partners (and children for those that are HIV positive) • All adult males who test HIV negative should be counselled about the prevention benefits of VMMC and linked to VMMC services if they agree
Community-based testing	• Targeted community-based HIV testing and counselling can be especially useful for children and partners of index clients; adolescents; as well as for outreach to key populations (sex workers, truckers, MSMs, and intravenous drug users) and OVCs • All HTS clients should be linked to HIV prevention, care and treatment services
HIV self-testing (HIVST)	• HIVST can be offered to any adult who wants to know their HIV status outside of a formal HTS setting, usually in private • HIVST may have the greatest benefit in reaching specific populations, such as: men; partner testing for ANC attendees; contacts of patients treated for STIs; highly stigmatized populations; healthcare workers; frequent re-testers; etc. • If positive, a confirmatory test must be performed by a trained HTS provider (facility-based or community-based) following the national testing algorithms

2.2 Age-Specific HIV Testing Algorithms

2.2.1 Birth Testing and Early Infant Diagnosis

A. Birth Testing

Birth testing is defined as HIV testing (with DNA PCR) at birth or first contact within 2 weeks after birth, for infants born to known HIV-positive mothers.

HIV DNA PCR testing should be done at birth or first contact thereafter within two weeks of birth for infants born to HIV positive mothers

Birth testing has the potential to greatly improve survival for infants who are infected during pregnancy and around labour and delivery by identifying them early for rapid ART initiation. For birth testing to be effective, facilities and programmes must provide the necessary resources, capacity, and infrastructure for optimum function of EID with a turn-around-time of ≤ 7 days for infant DBS PCR results.

Where capacity is limited to provide birth testing for all new-borns, it should be prioritized for the following infants at highest risk of antenatal HIV infection:

- Mother has been on ART for < 6 months
- Mother's most recent viral load (VL) before delivery was ≥ 1,000 copies/mL
- No maternal VL available within the past 6 months
- Mother known or suspected to be failing current ART regimen
- Pre-term infants
- Low birth-weight infants

A new-born with a negative HIV DNA PCR at birth (or within 2 weeks of birth) should continue infant ARV prophylaxis and be followed as an HEI (Figure 2.1). A repeat HIV DNA PCR test should be performed at 6 weeks and subsequent testing as recommended for all HEIs, following the EID algorithm (Figure 2.2).

A new-born with a positive HIV DNA PCR is presumed to be HIV positive and should be started on ART immediately. A confirmatory HIV DNA PCR and baseline viral load should be taken at the time of initiating ART (initiation of ART is based on the first result). A positive 2nd PCR test confirms HIV infection; continue ART and routine follow-up as for HIV-positive infants. If the 2nd PCR is negative, these are discordant results: the infant should continue ART and send a 3rd DBS sample to NHRL to confirm HIV status.

Figure 2.1 Birth Testing Algorithm

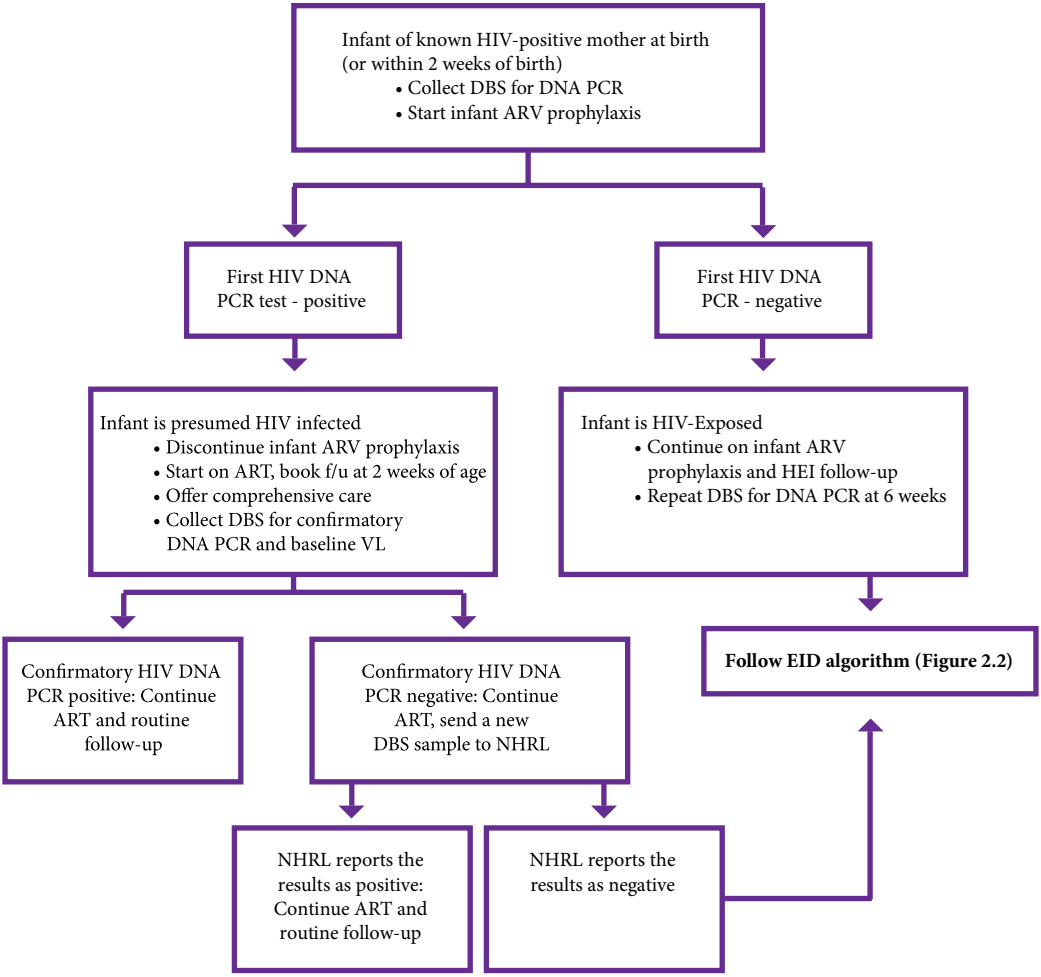
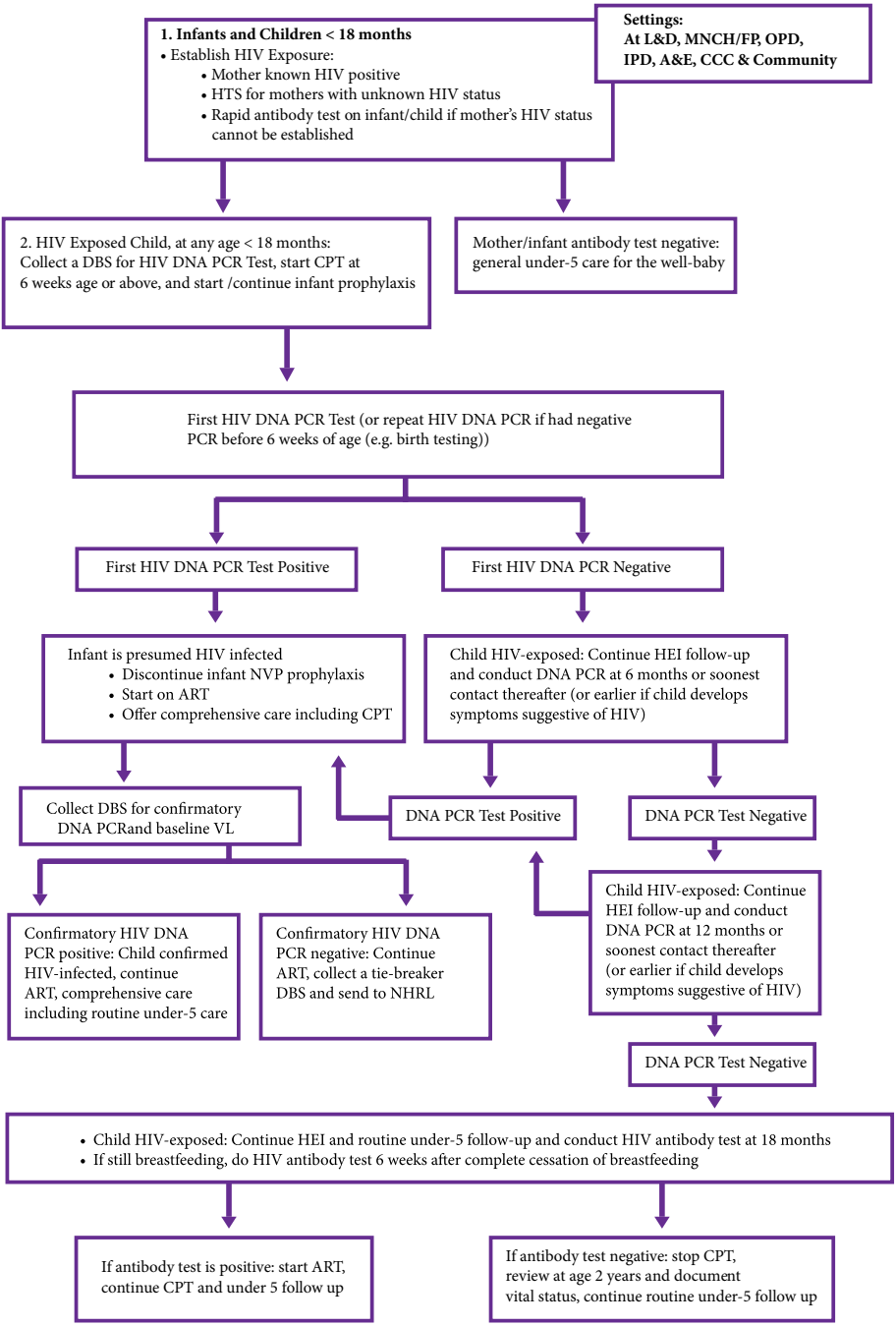


Figure 2.2: Algorithm for Early Infant Diagnosis



1. HIV Exposed Infant

HIV exposure of an infant or child can occur in utero, at labour and delivery and through breast milk. The HIV exposure of ALL children aged <18 months old should be ascertained at first contact. A positive HIV antibody test in a child younger than 18 months of age confirms HIV exposure.

2. Confirmation of HIV infection in HIV Exposed Infants and Children < 18 Months Old

All HEIs younger than 18 months old should be tested with DNA PCR within 6 weeks or first contact, and if negative then another DNA PCR at 6 months, and if negative then another DNA PCR at 12 months. **This replaces previous guidelines to perform antibody testing for infants at 9 months**. An antibody test should be performed for all HEIs at 18 months, and also 6 weeks after complete cessation of breastfeeding.

Presumptive Diagnosis of Severe HIV Disease in Children under 18 Months

Occasionally, children less than 18 months of age present to hospital with severe illness; and a rapid HIV antibody test confirms HIV exposure. Lack of immediate availability of HIV DNA PCR results for confirmation of HIV infection could result in undue delay in starting life-saving ART. In such children, a presumptive diagnosis of HIV infection can be made using the criteria in Table 2.2. ART can be initiated while awaiting HIV DNA PCR results to confirm HIV infection.

Table 2.1: Recommendations for HTS in Different Settings

Child < 18 months of age; HIV antibody test positive and symptomatic with:
2 or more of the following:
- Oral candidiasis/thrush
- Severe pneumonia
- Severe sepsis

OR, any of the following
- Any WHO Clinical Stage 4 condition (Annex 1)
- Recent maternal death or advanced HIV disease in mother
- Child's CD4 < 20%

2.2.2 Diagnosis of HIV Infection in the Older Child (>18 months), Adolescents and Adults

Serial testing, using approved rapid HIV antibody testing kits, is used to diagnose HIV infection in children older than 18 months, adults and adolescents (refer to the HTS guidelines for the HIV testing algorithm using rapid test kits).

- Offer adequate information to all clients and obtain consent (verbal consent is adequate, but should be documented) prior to the HIV test. Individuals 15 years and older and emancipated minors can provide self-consent. Clients who opt-out (i.e. refuse to test) should be counselled and continuously offered PITC with each visit and/or referred for community-based testing and/or HIV self-testing
- Clients who test HIV negative should be assessed and counselled on HIV risk reduction behaviours and linked to combination HIV prevention services (such as VMMC, RH/FP, condoms, PrEP, etc.) depending on individual risk profile. Table 2.4 provides recommendations for re-testing those who test HIV negative

For breastfed HEIs older than 18 months, the HIV antibody test should be performed at least 6 weeks from the last day of breastfeeding (to factor in the window period of an infection that may occur around the time of cessation of breastfeeding).

2.3 Package of HIV Testing Services

An HIV testing and counselling session consists of:

- A pre-test session
- HIV test
- A post-test session
- Assessment for other health-related conditions or needs
- Referral and linkage to other appropriate health services

The HIV testing service package is summarized in Table 2.3.

Table 2.3: Summary of HIV Testing Services Package

Pre-test counselling/Pre-test information

Client-initiated HT (CITC)

- Introduction and orientation to session
- Risk assessment
- Consent for the test

Provider Initiated HT (PITC) in health facility setting

- Introduction and information on importance of testing for HIV
- Consent for the test
- Test preparation

Perform test using approved rapid HIV antibody test kit

Post-test counselling for negative results

- Risk reduction plan
- Linkage to other HIV prevention services
- Re-testing where applicable (Table 2.4)

Post-test counselling for positive results

- Enrolment into comprehensive care and treatment**
- Risk reduction and positive living counselling
- Partner/family testing

Assessment of other health-related conditions or needs

HTS provider should assess all clients for other health related conditions/issues, e.g.:

- Tuberculosis
- Family planning
- Gender-based violence
- STIs and cancer screening
- Alcoholism
- VMMC
- eMTCT
- Psychosocial issues
- Non-communicable diseases

Referral and linkage

- Linkages and referrals should be documented as part of the client's health record
- Where possible, the HIV positive client should be escorted to the CCC and enrolled into care on the same day of HIV testing. Successful linkage should be documented in the referral and linkage register

*Clients who test HIV negative should have a risk assessment and be offered/referred to appropriate combination prevention services including TB screening, STI screening and treatment, family planning, provision of condoms, VMMC, cervical cancer screening, GBV recovery services, alcohol and substance abuse services, pre-exposure prophylaxis (PrEP), PEP, mental health and psychological support, and couples counselling and testing

****Linkage from testing HIV positive to enrolment into HIV care is the responsibility of the HTS provider**

Post-Test Counselling in the Era of Test-and-Treat

With the 2016 ART guidelines **all PLHIV now qualify for ART** irrespective of WHO Clinical Stage, CD4 count, age, gender, pregnancy status, co-infection status, etc.

Post-test counselling should, at a minimum, include three key messages that begin the ART treatment preparation process for all PLHIV:

- Treatment (called antiretroviral therapy or ART) is available and is recommended for everyone with HIV
- Starting treatment as soon as possible (preferably within two weeks of testing positive for HIV) reduces the chance of your illness getting worse or of passing HIV to others
- If you take your ART properly and do not miss pills you can expect to live a long and productive life

Table 2.4: Recommendations for Re-testing Clients Testing HIV Negative

Scenario/Population	Recommendation for Re-testing
General population	Re-test annually (for children, re-testing is only required if there is a new exposure)
Key populations	Re-test every 3 months in case of frequent instances of high risk exposure
Negative partner in discordant union	Re-test at the initiation of ART for the HIV positive partner, and every 3 months until HIV-postive partner achieves viral suppression. Once viral suppression is confirmed re-testing can be performed every 6 months. Other prevention services should still be recommended, including consistent and correct use of condoms. Assess for eligibility and willingness for PrEP
HIV negative pregnant women	Test in first trimester or first contact; re-test in the third trimester, and again during labour and delivery, at 6 weeks and at 6 months post-partum
HIV negative breast feeding mothers	Re-test after delivery at 6 weeks, at 6 months then follow testing recommendations for general population
Persons who had a most recent (e.g. less than a month) specific exposure incidence	Test at initial presentation and re-test at 4 weeks, after which annual re-testing applies
Symptomatic STI patients	Test at initial presentation and re-test at 4 weeks, after which annual re-testing applies
HIV Negative PWID	Re-test every 3 months
Individuals on pre-exposure Prophylaxis (PrEP)	Re-test every 3 months

2.4 Linkage from HIV Testing to Care and Treatment

Every effort should be made to ensure patients with confirmed HIV infection are linked to care and treatment expeditiously. The HTS providers should manage this process actively by employing approaches known to improve linkage to care (Table 2.5)

Table 2.5: Approaches to Improve Linkage to Care and Treatment

Strategy	Action
Information	Quality post-test counselling should include information about the nature and availability of additional HIV-related services, describe next steps in care and treatment including entire treatment plan and follow-up visits and schedule. The benefits of immediate assessment and early initiation of ART should be emphasized. Involve the patient in the decision making process regarding care and treatment (especially where and when to start ART)
Disclosure	Disclosure to a trusted 'significant other' promotes linkage and adherence to treatment. Encourage and help the patient to discuss HIV status with a trusted friend or close relative. Encourage adolescents to identify and invite a supportive adult or friend to support them
Barriers to Linkage	During post-test counselling, identify and address any barriers to linkage
System to Facilitate Linkage	• The HTS provider is responsible for linkage into care • Same day enrolment into care • As much as possible, linkage should be done to on-site care and treatment services through patient escorts. Where this is not possible (due to patient preference or the services are not available), the testing facility should book the appointment with the receiving facility and follow-up to ensure the patient registers at the receiving facility. Provide the patient with referral information, referral form and contact details of the facility • Deploy retention and loss-to-follow up tracking system to ensure linkage is successful. These include enlisting the help of peer or buddy systems, SMS reminders, phone calls and community outreach workers to escort HIV positive clients to enrolment • Early preparation and assessment for ART, with early initiation of ART strengthens engagement in care
Care Coordination and Integration	Coordinate and treat mother-baby pairs, partners and families together. Integrate common services offered to PLHIV (TB diagnosis and treatment, SRH/FP, cervical screening, nutrition etc.). Where referrals are necessary, such referrals should be coordinated (communication and documentation between referring and receiving service delivery points)
Linkage Register	Maintain a linkage register at all testing points in the facility and community. Track and report on progress with linkage on a monthly basis. Discuss linkage at MDT meetings

3. Initial Evaluation and Follow-up for PLHIV

All PLHIV qualify for ART irrespective of CD4 cell count or percentage, WHO clinical stage, age, pregnancy status, or comorbidities. ART should be initiated as soon as the patient is ready to start, preferably within two weeks from time of HIV diagnosis. Thus, the initial evaluation of PLHIV is also the baseline assessment for ART initiation.

In order to provide targeted services based on presentation (Section 3.3), during the initial evaluation, all PLHIV should be categorized as presenting with advanced HIV disease or as presenting well. Patients with advanced disease require more intensive evaluation for and management of OIs, and once ART is started they are at higher risk for developing immune reconstitution inflammatory syndrome.

Similarly, during follow-up after starting ART, PLHIV should be categorized as being either stable or unstable (clinically, virologically and psychosocially) in order to best meet the specific needs of each patient for treatment and follow-up and improve patient outcomes. This would minimize inconvenience and unnecessary follow-up for those patients who do not need it, thus reducing costs and time related to clinic visits. It would also allow resources to be focussed on those patients who require additional attention (Section 3.5).

The following strategies can improve efficiency and effectiveness for initial patient evaluation, treatment preparation, and ongoing adherence support to improve patient outcomes:

- Providing comprehensive and accurate information prior to ART initiation (preferably by trained counsellors); and allowing the patient to make an informed choice about starting treatment and staying in care
- Group counselling of newly diagnosed patients and use of pamphlets, infographics and audio-visual aids to deliver patient education and preparation
- Task-shifting/sharing to trained lay providers for counselling, treatment preparation and literacy, education and linkage
- Orienting new patients to the HIV care process and introducing them to the multidisciplinary team involved in their management
- Efficiently conducting enrolment, clinical evaluation, investigations, initial patient education and counselling on the same day
- Increasing the overall number of healthcare providers in the multidisciplinary team with counselling skills through structured facility-based training
- Implementing family care models and other tailored services (e.g. child and adolescent friendly clinics) to facilitate disclosure and reduce stigma

3.1 Initial Clinical Evaluation of PLHIV

All patients enrolling into HIV care should have a complete medical history taken, a thorough physical examination and appropriate laboratory investigations. Findings from this initial evaluation should be documented legibly in a retrievable health record management format (electronic or paper-based) to facilitate long-term follow-up of the patient. Table 3.1 summarizes important aspects of the initial medical history and physical examination for PLHIV. Additional history should be taken and physical examination performed when clinically indicated.

Table 3.1: Initial Clinical Evaluation for PLHIV (History and Physical)

History		Comments
Current and past medical history	The initial visit provides the opportunity to establish a meaningful patient-provider relationship; the clinician should elicit concerns and expectations with open, non-judgmental and clear communication	
	• Presenting complaints/current symptoms • Include symptoms of TB and TB contacts	• Inquire about symptoms due to co-existing HIV-related and non-HIV-related disease and co-morbidities that will require immediate intervention • Completion of the Intensified Case Finding (ICF) tool
	• Date of first positive HIV test • Past and current co-morbidities (e.g. TB, cryptococcal meningitis, hypertension, diabetes, kidney and liver disease) • Current medications, including herbs • Drug allergies, especially sulfa allergy • ARV exposure history • History of hospitalizations • Family history of chronic disease or cancer	• Document history of TB • Document previous or current ARV use (including for PMTCT, PEP, PrEP and ART) • Establish current medications (prescription, non-prescription, and herbal) likely to adversely interact with ARVs • Establish reasons for hospitalizations
Psychosocial history	• Education, employment, family, marital status • Past treatment for mental illnesses; current symptoms of depression • Substance use including alcohol, tobacco, miraa (khat), marijuana, narcotics, injection drug use • Nutritional history and adequacy of nutritional intake and household food security	• Establish and document social support structures • Establish possible presence of mental health concerns • Encourage disclosure to trusted 'significant others' and sexual partners • Elicit and begin to address possible barriers to adherence • Link to additional facility and community support resources, including psychosocial support groups, peer mentors, harm reduction services for PWIDs, etc
Sexual and reproductive history	• History of STIs • Symptoms of STIs • Sexual practices • Partner HIV status and disclosure to sexual partner(s) • Pregnancy history and age of all living children • Menstrual history, family planning and plans for pregnancy • Cervical cancer screening	• Discuss secondary prevention and avoidance of re-infection with STIs • HIV and ART status of sexual partner/s • Encourage contact tracing and HIV testing for sexual partners and all children of HIV-infected women and all children whose mothers' HIV status is unknown

Table 3.1 (Continued): Initial Clinical Evaluation for PLHIV (History and Physical)

Physical Examination		Comments
General impression, vital signs and anthropometric measurements	Assess general mood, measure and record weight, height, MUAC (in children and pregnant women), temperature, pulse rate, BP, respiratory rate, pulse oximetry (if patient has respiratory complaints or has difficulty in breathing)	• Calculate BMI as: Weight (kg)/ Height2(m) • Use z-scores for children
General examination	Conjunctiva and palms for pallor or jaundice; swollen lymph nodes (cervical, axillary, inguinal); mouth (for Kaposi's sarcoma (KS) lesions, oral hairy leucoplakia, candidiasis, tooth decay); skin (for drug eruptions, herpes zoster, dermatitis, PPE, folliculitis, fungal infections, molluscum, and KS)	• Prompt treatment of inter-current illness contributes towards success of ART and reduction in early morbidity and mortality • Asymmetric or rapidly enlarging lymph nodes will require fine needle aspiration cytology or biopsy • Cervical cancer screening (if not done in the past year), and appropriate management
Systemic examination	Central Nervous System (focal defects, retina); Mental State Examination (for mental status) abdomen (for liver or splenic enlargement); respiratory (for dullness to percussion; crackles or wheezes); cardiovascular (for peripheral pulses, oedema, heart sounds); if specific symptoms: genitourinary/anorectal system (for ulcers, discharge, condylomata/warts). Speculum examination with cervical cancer screening for females	
Summary	Problem list with differential diagnosis and management plan for each problem (including investigations, treatment, referrals, and follow-up)	• Assign and document the initial WHO Clinical Stage and manage presenting illnesses • Growth and developmental milestone must be assessed and used for WHO staging in children • Differential between patients with advanced disease versus those who are clinically well, to guide acuity of follow-up

3.2 Initial Laboratory Evaluation of PLHIV

Laboratory assessment is not a prerequisite to ART initiation. It should not cause undue delay in starting ART following treatment preparation and clinical evaluation by history and physical examination.

The comprehensiveness of laboratory tests will depend on presence and/or type of suspected concurrent illness. Table 3.2 summarizes the recommended baseline laboratory investigations for all PLHIV. Additional investigations should be based on clinical indication. ART should not be delayed if a laboratory test is not available.

Table 3.2: Baseline Laboratory Investigations for PLHIV

	Test	Comments
HIV specific	Confirm and document positive HIV test result	• Refer to Section 2 on HTS
	CD4 cell count	• Recommended • If CD4 ≤ 100 cells/μL then laboratory should perform a serum cryptococcal antigen (sCrAg) on the same sample to rule out cryptococcal meningitis before starting ART
	Viral load (HIV-1 RNA)	• Baseline viral load (VL) is only recommended (where available) for HEIs after 1st PCR test is positive. Specimen for baseline VL can be drawn before or at time of initiating ART; obtaining a VL should not delay ART initiation
	Serum Cryptococcal Antigen (sCrAg)	• Obtain serum CrAg in all adults with a CD4 count ≤ 100 cells/μL • If positive, manage as per the cryptococcal meningitis screening algorithm (Figure 4.1 in Section 4)
	HIV Drug Resistance Testing (DRT)	• Not recommended as a baseline investigation
Others	Hb (preferably full blood count if available)	• Recommended • If baseline Hb < 9.5 g/dL then AZT should be avoided
	Pregnancy status	• Pregnancy status should be determined for all women of reproductive age (based on history of last menstrual period, and if delayed then a urine pregnancy test should be performed)
	Urinalysis (for protein & glucose)	• Recommended
	Creatinine	• Recommended • Calculate Creatinine Clearance (CrCl): if CrCL ≤ 50 mL/min then TDF should be avoided (see Table 6.5 in Section 6). Refer to section 9.1 for use of TDF in HIV/HBV co-infection
	RPR (syphilis serology)	• Recommended (for all PLHIV with a history of being sexually active)

Table 3.2 (continued): Baseline Laboratory Investigations for PLHIV

	Glucose	• Recommended
	Plasma lipid profile	• Recommended
	HBsAg	• Recommended • If negative, patients should be immunized for HBV as soon as they achieve confirmed viral suppression (see Section 4.8.1 and Section 9); if positive refer to Section 9 for management of HIV/HBV co-infection
	HCV antibody	• Recommended for PWID or for patients with history of injection drug use
	ALT	• Not a recommended baseline investigation unless there is a specific clinical reason (e.g. patient with history of hepatitis, signs or symptoms of liver disease, or risk of liver disease - alcoholics, HBV/HCV infection, hepatotoxic drugs etc)

It is not possible for ALL facilities providing ART to offer all the laboratory tests recommended for HIV care and treatment. If a facility does not have on-site capacity to carry out any particular test, arrangements should be made to transport specimens to a local or regional reference laboratory. Facilities are encouraged to join or form regional networks of laboratories to improve access to laboratory services.

3.3 Differentiated Care for Patients who Present with Advanced HIV Disease versus those who Present Well

Patients who enrol into care with advanced disease may require a different level of care than those who enrol while still clinically and immunologically well.

Table 3.3: Differentiated Care Based on Initial Patient Presentation

Patients who Present with Advanced HIV Disease: WHO Stage 3 or 4, or CD4 count ≤ 200 cell/μL (or ≤ 25% for children ≤ 5 years old)	
Package of Care	• Standard Package of Care (Section 4) • Intensive management of presenting illnesses • Priority for identification, management and prevention of OIs • Priority for ART initiation • Close monitoring for development of immune reconstitution inflammatory syndrome (IRIS)
Location of Services	• Management at any ART service delivery point; all facility levels • Initial management and ART initiation by trained and experienced HCW • Consultation with MDT, TWG, mentors, and senior clinicians as needed (including telephone consultation such as Uliza! Clinicians' HIV Hotline) • Referral to a higher-level facility when feasible if consultation is not adequate to stabilize the patient
Focus of Treatment Preparation Counselling	• ART is required to prevent further damage to the immune system • Starting ART soon will decrease risk of disease progression, including wasting and OIs • ART is the most important treatment to restore health
Frequency of Follow-up	• Weekly follow-up until ART initiation, and then at week 2 and 4 after ART initiation, and then monthly for the first 6 months of ART • More frequent visits or hospitalization may be required to stabilize acute medical conditions and address psychosocial and other concerns
Patients who Present Well: WHO Stage 1 or 2, and CD4 count > 200 cell/μL (or > 25% for children ≤ 5 years old)	
Package of Care	• Standard Package of Care (Section 4), including OI screening, prevention and treatment
Location of Services	• Management at any ART service delivery point; all facility levels • Initial management and ART initiation by trained and experienced HCW
Focus of Treatment Preparation Counselling	• ART is the most important treatment to maintain good health and an active life • Starting ART soon will decrease risk of developing wasting and other infections
Frequency of Follow-up	• Weekly follow-up until ART initiation, and then at week 2 and 4 after ART initiation, and then monthly for the first 6 months of ART • Additional visits as required to address any medical or psychosocial concerns

3.4 Follow-up of PLHIV during the First Year of ART

Follow-up of patients on ART is determined by the duration the patient has been on treatment, how well they understand the treatment and their response to ART. Follow-up includes scheduled clinical appointments, unscheduled clinical assessments for patients with concerns/complaints, and routine and as-needed laboratory monitoring.

In order to initiate all PLHIV on ART within the shortest time possible (preferably within 2 weeks), newly enrolled patients should be seen in clinic every week until ART initiation.

After ART initiation, patients need to be monitored closely for development of adverse drug events, identify and address barriers to adherence, and development of IRIS (particularly for those who initiate ART with advanced immune suppression). A reasonable follow-up schedule for most patients is: 2 weeks and 4 weeks after ART initiation, then monthly until viral suppression is confirmed (Table 3.4). If VL is detectable at 6 months they will need additional assessments for and management of the reason/s for treatment failure, with close follow-up until viral suppression is achieved (Section 6). Patients with confirmed viral suppression can be followed-up every 1-3 months based on patient preference and clinician judgement, with additional unscheduled visits any time the patient has a concern. Clinical follow-up can be spaced further apart once the patient has been on ART for a year or more and meets the criteria as "stable" (Section 3.5). Children and adolescents should be followed up at least every 1-3 months.

When possible, follow-up for a particular patient should be provided by the same care provider or team of care providers (e.g. same clinician and same counsellor) at every visit. This is particularly important during the first 6 months in care.

Table 3.4 summarizes the recommended minimum routine follow-up schedule for PLHIV; however, additional clinical and laboratory follow-up should be performed whenever clinically indicated (based on history and physical examination, when the results of the investigations have the potential to change clinical management).

Table 3.4: Summary of Clinical and Laboratory Monitoring for PLHIV[1]

	Initial Visit	Pre-ART visits	Week (after ART)		Months (after ART)						
Appointment[2]	0	Every week3	2	4	2	3	4	5	6	Every 1-3 months, depending on stability	Every 3-6 months if stable4
History and physical exam[5]	+		+	+	+	+	+	+	+	At each visit	Every 3-6 months (every 1-3 months for children and adolescents)[4]
Adherence assessment and support[6]	+	+	+	+	+	+	+	+	+	At each visit	At each visit
TB Screening	+	Every visit, using ICF screening tool									
CD4 count	+	• Baseline, and then only if develops treatment failure (to assess for risk of OIs) • For patients on secondary prophylaxis for cryptococcal meningitis (CM), repeat CD4 every 6 months until CD4 >100 cells/μL for two consecutive measures 6 months apart, after which CM prophylaxis and CD4 monitoring can be discontinued									
HIV Viral Load[7]		For PCR positive HEIs: at the time of ART initiation and as per the general recommendations For all: at month 6 and month 12 then annually thereafter if VL<1,000 c/mL									
HIV Viral Load (pregnant/ breastfeeding)		• If on ART for at least 6 months, VL done at confirmation of pregnancy (regardless of when previously done), then every 6 months until end of breastfeeding if VL is <1,000 c/mL									
		• If starting ART during pregnancy, VL at 6 months after initiation, and then every 6 months until end of breastfeeding if VL is <1,000 c/mLs									
CrAg	+	Baseline for adults with CD4 ≤ 100 cells/μL (as reflex testing by laboratory), then only if clinical suspicion of CM									
Hb	+	Baseline then symptom directed; if on AZT, baseline then weeks 2, 4, and 12									
Pregnancy Status	+	At every visit for women of reproductive age (by history +/- urine pregnancy test)									
Urinalysis (protein & glucose)	+	Baseline, then annually if on TDF									
Creatinine	+	Baseline, then annually if on TDF									
Glucose	+	Baseline, then annually									
Plasma lipid profile	+	Baseline, then annually									
HBsAg	+	Baseline, followed by immunization for all patients who screen negative (after viral suppression is confirmed)									
RPR	+	Baseline, then annually in those at risk									
Drug Resistance Testing	-	Not recommended at baseline; DRT recommended once treatment failure confirmed on a PI-based 1st line regimen, or failure on 2nd line or subsequent regimens									
ALT	-	Not recommended for routine baseline or follow-up unless specific clinical indication									
Cervical Cancer	All women age 18-65 years who have ever been sexually active: at baseline, 6 months, then annually (see Section 4.4.4)										
HCV	Baseline for PWIDs or with a history of injection drug use										

1. Recommended investigations should not delay ART initiation

2. This is the minimum recommended appointment schedule. Clinicians and patients should be encouraged to schedule additional appointments as needed. Patients should be encouraged to return to the HIV clinic for unscheduled appointment whenever an acute issue arises, instead of seeking care at another facility. Early after initiation of ART, every appointment should include:
   - Continued adherence counselling and support (started at the initial visit)
   - Assessment of adherence and correct storage of medication
   - Assessment for and management of early side effects of the drugs, and patient counselling on the same

3. All PLHIV qualify for ART and should be initiated within 2 weeks, as soon as they meet ART readiness criteria. Patients should be followed every week until ART initiation for ongoing management of acute medical issues and for treatment preparation and ART readiness assessment. ART initiation is especially urgent for infants and young children

4. See section 3.5 for appointment spacing for patients who are stable on ART

5. In children and adolescents, weight and height should be measured and recorded at every visit, with weight-based dosing of ARVs confirmed at every visit.
   In adults, weight and height should be measured at the initial visit to calculate BMI, and thereafter, weight should be measured at every visit to update the BMI calculation. BP, temperature and respiratory rate should also be measured and recorded at every visit. Measure and record oxygen saturation (by pulse oximetry) in patients with respiratory complaints.

6. The first 2- 4 visits are critical for assessing and supporting adherence to ART, managing adverse drug reactions and treating any acute illnesses including IRIS. Adherence should be assessed at every contact with the clinic. See Section 5 for specific adherence preparation, monitoring and support procedures for each visit

7. Indications for Viral load (VL) testing
   - Preferred approach for monitoring ART in all patients on ART (performed at 6 months, 12 months and annually thereafter if <1000 copies/ml
   - As a baseline test for HEI's whose first PCR test is positive
   - To rule out treatment failure before single-drug substitutions (see Figure 6.2 in Section 6)

Refer to the VL algorithm (Figure 6.3 in Section 6) for management of patients with VL ≥ 1,000 copies/ml

Laboratory tests, though desirable, are not a pre-requisite for initiation and routine monitoring of ART in clinically stable patients. Targeted laboratory tests may be necessary to identify and manage inter-current disease or adverse drug reactions.

3.5 Follow-up of PLHIV beyond the First Year of ART

3.5.1 Differentiated Care for Stable and Unstable Patients beyond the First Year of ART

After the first year of ART, most patients will have developed good adherence habits, have adequate coping mechanisms and support systems in place, and will have achieved full virological suppression. With their improved self-care, these "stable patients" require less intensive follow-up and monitoring than other patients, allowing facility resources to be focussed on patients who have not achieved these milestones as well as those newly enrolling into HIV care (Table 3.5). Less intense follow-up for stable patients may also decongest health facilities, reduce patient costs and inconvenience, and improve quality of care by allowing more time for sick and/or unstable patients.

Table 3.5: Differentiated Follow-up of Patients beyond the First Year of ART

Unstable Patients	
Unstable Patients (any of the following): • On their current ART regimen for < 12 months • Any active OIs (including TB) in the past 6 months • Poor or questionable adherence to scheduled clinic visits in the past 6 months • Most recent VL ≥ 1,000 copies/mL • Has not completed 6 months of IPT • Pregnant or breastfeeding • BMI < 18.5 • Age < 20 years* • Healthcare team has concerns about providing longer follow-up intervals for the patient** **Note: children and adolescents may be clinically stable, however they are not eligible for longer follow-up periods because of the need for weight-based dose adjustments and close monitoring of support systems.** ***However, older adolescents who do not require dose adjustments maybe considered for longer follow-up appointments if deemed stable**	
Package of Care	• Standard Package of Care (Section 4) • Case management to address reason/s for not meeting stable eligibility criteria
Location of Services	• Management at any ART service delivery point; all facility levels • Consultation with MDT, CSC, mentors, and senior clinicians as needed (including telephone consultation with Uliza! Clinicians' HIV Hotline • Referral to a higher-level facility when feasible if consultation is not adequate to stabilize the patient
Focus of Counselling	• ART is the most important treatment to improve health and return to an active life • Targeted counselling to address reason/s they have not meet stable eligibility criteria
Frequency of Follow-up	• Every 1-3 months, based on clinical judgement and the specific reason/s they have not met stable eligibility criteria • Additional visits as required to address any medical or psychosocial concerns

Stable Patients	
Stable Patients (must have achieved ALL of the following): • On their current ART regimen for ≥ 12 months • No active OIs (including TB) in the past 6 months • Adherent to scheduled clinic visits for the past 6 months • Most recent VL < 1,000 copies/mL • Has completed 6 months of IPT • Non-pregnant/not breastfeeding • BMI ≥ 18.5 • Age ≥ 20 years • Healthcare team does not have concerns about providing longer follow-up intervals for the patient** **Note: some patients may not meet all eligibility criteria but could benefit from specific aspects of the stable-patient package of care, such as community-based ART delivery (e.g. patients with disabilities)**	
Package of Care	• Standard Package of Care (Section 4) • Viral load monitoring (and any other routine investigations) timed to coincide with patient appointments (e.g. the annual VL can be drawn 2-4 weeks before the patient's clinical follow-up visit so that the results are ready for discussion and decision-making during the visit) • Re-assessment of criteria as a stable patient at every visit (and move to "unstable" category if any criteria not met)
Location of Services	• Clinical review and ART prescription from any ART service delivery point; all facility levels • Fast-track distribution of ART between clinical appointments, which can be facility-based or community-based
Focus of Counselling	• Encourage patient to continue with what is working; they are doing well • Reminders that any significant life event or major change in daily routine could interfere with adherence
Frequency of Follow-up	• Maximum of 6 month intervals between facility-based clinical review • ART can be distributed for up to 3 months (through fast-track pick-up at facility or through community-based distribution) between clinical review appointments • Patients on injectable contraception should be provided FP through a fast-tracked process between clinical follow-up visits; oral contraceptives and condoms should be distributed with ART • Additional visits as required to address any medical or psychosocial concerns • Closer follow-up based on patient preference

**The healthcare team can consider other criteria such as mental illness, alcohol or substance abuse, unstable co-morbid conditions, inadequate support systems, etc., if they feel the patient requires closer follow-up, despite meeting the other criteria listed

3.5.2 ART Prescription, Dispensing, and Distribution for Stable Patients

ART should only be dispensed for up to 3 months at a time, to control for national and facility supply chains, safe drug storage and conditions that may reduce expiration period, and to minimize loss or diversion of ARVs.

ART Refill Prescriptions for Stable Patients

For stable patients returning for clinical assessments more than 3 months apart, ART, CPT and condoms (and any other medications, such as oral contraceptive pills) should be prescribed and dispensed for 3 months; for stable patients an additional prescription should be provided to last until the next clinic visit (ART refill prescription).

To dispense/distribute ART refills outside of clinical follow-up appointments the health facility must have a system in place to track ART refills, and identify patients who default from the ART refill or receive the ART refill late (e.g. ART refill diary, similar to an appointment diary).

ART Refill Dispensing For Stable Patients

- ART can only be dispensed by a licenced healthcare professional
- ART can be dispensed in quantities of up to 3 months based on a valid prescription, and documented using the Pharmacy Dispensing Tool
- Dispensing of ART refills (prescriptions outside of the clinical follow-up appointments) must be accompanied by completion of the ART Distribution Form (Table 3.6)

ART Refill Distribution for Stable Patients

- ART for distribution must be **dispensed** (pre-packaged for individual patients) by a healthcare professional, as described above, and documented in the Pharmacy Dispensing Tool, with additional documentation of the person distributing the refill
- ART refills can be distributed by healthcare professionals or trained lay health workers (peer educators, community health volunteers, treatment supporters, etc.)
- ART can be distributed in quantities of up to 3 months
- Distribution of ART refills, whether facility-based or community-based, must be accompanied by completion of the ART Distribution Form

Table 3.6: ART Distribution Form for Stable Patients

ART Distribution Form for Stable Patients				
Patient Name:	Patient CCC No:	Distribution Date:		Completed at time of dispensing
Patient Phone No:	Name of Person Distributing the ART:			
ARVs being distributed:		Quantity (days):		
Other drugs/supplies being distributed and quantity				
☐ CPT, quantity (days):	☐ Oral Contraception, quantity (days):	☐ Condoms, quantity (days):		
☐ Other: , quantity (days):	☐ Other: , quantity (days):			
Patient review checklist (if yes to any of the questions below, dispense ART and refer back to clinic for further evaluation; book appointment and notify clinic)				Completed at time of distribution
Any missed doses of ARVs since last clinic visit: ☐Yes ☐No; If yes, how many missed doses:				
Any current/worsening symptoms:				
Fatigue: ☐Yes ☐No Cough: ☐Yes ☐No	Fever: ☐Yes ☐No Rash: ☐Yes ☐No	Nausea/vomiting: ☐Yes ☐No Genital sore/discharge: ☐Yes ☐No	Diarrhoea: ☐Yes ☐No Other:	
Any new medications prescribed from outside of the HIV clinic: ☐Yes ☐No; if yes, specify:				
Family planning method used:	Pregnancy status: ☐Pregnant ☐Not Pregnant ☐Not Sure			
Signature of patient upon receipt of the ARVs:				

ART Refill Distribution Points for Stable Patients

The health facility is responsible for ART prescription, dispensing, and distribution for all patients enrolled into care. ART distribution for stable patients can take place at the health facility or through a community distribution system, depending on patient preference and health facility systems and resources. No patient should be pressured into receiving ART at a community-based distribution point or through a fast-track process.

Models of ART refill distribution for stable patients are summarized in Tables 3.7 and 3.8.

Table 3.7: Facility-based ART Refill Distribution for Stable Patients

Facility-based ART Refill Distribution for Stable Patients
• Facility-based ART refill distribution for stable patients should involve a fast-tracked process to minimize patient waiting times, preferably with medications pre-packed and patient labelled • Each facility must clearly define its fast track process and communicate this to staff and patients; the process should be reviewed quarterly for quality (waiting times, patient satisfaction, compliance to criteria (follow-up intervals; unstable patients are not fast-tracked), etc.) • The fast-track refill pick-up may operate during normal hours as well as on designated out-of-hours times/days (e.g. early mornings, weekends) • If the patient has any concerns they should be encouraged to call the facility or come for an unscheduled visit • If the patient has any red-flags raised on the ART Distribution Form they should be referred to the clinician for review • The Pharmacy Dispensing Tool, ART Distribution Form and ART Refill Diary are the minimum documentation that must be completed during the refill. The Pharmacy Dispensing Tool must be updated by a healthcare profession; the ART Distribution Form and ART Refill Diary can be completed by a healthcare professional or a trained lay health worker at the facility
Examples
• Patient goes directly to the pharmacy window to pick up ART refill, without stopping at reception, triage, etc.; ART Distribution Form and ART Refill Diary completed at the pharmacy window • Patient goes to reception, triage, and then pharmacy dispensing window, without clinician review • Facility-based peer educator or CHV operates a fast-track dispensing room at the facility: pharmacy dispenses and pre-packs ART for patients who are scheduled for refills for the day; peer educator/CHV takes all the patient packs for the day to a distribution room; peer educator/CHV distributes ART as patients arrive for refills, with completion of the ART Distribution Form and updating of the ART Refill Diary

Table 3.8: Community-based ART Refill Distribution for Stable Patients

Community-based ART Refill Distribution for Stable Patients
• Community-based ART distribution for patients can take various forms depending on the health facility resources and systems, community-based support structures, and patient preferences • Patient must voluntarily enrol into any community-based refill distribution program • Each patient must specify who is allowed to distribute the ART to them (or who can pick up the ART refill on their behalf; if someone is picking up the ART on their behalf, that person must bring the patient card and prescription to the facility at time of refill pick-up) • If patient has any concerns they should be encouraged to call the facility or come for an unscheduled visit • If the patient has any red-flags raised on the ART Distribution Form they should be referred to the clinician for review • A system for communication between the distributor and facility must be clearly defined (e.g. reporting any problems identified during distribution, failure to deliver the ART, etc.) • The Pharmacy Dispensing Tool, ART Distribution Form and ART Refill Diary are the minimum documentation that must be completed each time a patient receives their ART refill. The Pharmacy Dispensing Tool must be updated by a healthcare professional; the ART Distribution Form and ART Refill Diary can be completed by a healthcare professional or a trained lay health worker
Examples
• CHVs are assigned specific patients; CHVs distribute ART and complete the ART Distribution Form during home visits; home visit/refill schedule is coordinated by the pharmacy team; CHVs maintain ART Refill Diary; Pharmacy Dispensing Tool updated at the facility • Community ART Groups (CAGs) are formed (preferably self-formed by patients); each CAG consists of around 6 patients; every month a different member picks up pre-packed ART for all other group members (patient packs that are dispensed from pharmacy); facility visit for ART pick-up coincides with that patient's 6-monthly clinical follow-up visit; person picking/distributing ART for the month completes the ART Distribution Form with each CAG member; ART Refill Diary and Pharmacy Dispensing Tool updated at the facility

Before implementing a community-based ART distribution program, a health facility must work with the CHMT to design a program that meets the criteria listed in Table 3.9, and the plan must be approved by the County HIV Technical Working Group before implementation.

Table 3.9: Criteria for a Health Facility to Implement a Community-Based ART Distribution Program

Health facilities must meet ALL of the following criteria before implementing a community-based ART distribution program:
Leadership • Community-based ART distribution plan reviewed and approved by the CHMT/County HIV TWG • Focal person at facility identified to oversee community-based ART distribution **Finance** • Has sufficient financial resources to implement and monitor community-based ART distribution **Human Resources** • Has identified appropriate personnel for distributing ART, which could include: - Healthcare professionals - Lay health workers/peers • Has capacity to train and supervise ART distributors on the following minimum competencies: - Modes of transmission of HIV - Basics of how ART works - Adherence requirements and support systems - Common and serious side effects of ART - Completion of the ART Distribution Form **Service Delivery** • Uptake of routine VL monitoring is ≥ 90% • Has functional system in place for fast-tracked facility-based ART distribution for stable patients **Commodity Management** • Currently has ≥ 3 months stock of ARV on site • Has capacity (including personnel and supplies) to pre-pack and label individual patient medications (including ART, CPT, condoms, and any other medications) for all patients who will receive community-based ART **Health Information Systems** • Has a functioning system in place to monitor and report patient-level outcomes (including retention, viral suppression, and mortality) • Has capacity to monitor and report on community-based ART distribution outcomes, including collecting and compiling ART Distribution Forms for monthly summary reports

4. Standard Package of Care for PLHIV

All PLHIV should receive a package of services that are known to promote health, improve the quality of life, prevent further HIV transmission, and prevent HIV disease progression and mortality.

The standard package of care for PLHIV includes antiretroviral therapy, psychosocial support, screening and prevention of specific opportunistic infections, reproductive health services, screening for and management of non-communicable diseases, mental health screening and management, nutritional services, and prevention of other infections (Table 4.1).

Table 4.1: Components of the Standard Package of Care for PLHIV

Component of Standard Package of Care	Subcomponents
Antiretroviral therapy (ART)	• Patient preparation • ART • Monitoring (clinical and laboratory)
Positive health, dignity and prevention	• Positive health, dignity and prevention components - Disclosure - Partner/family testing - Condom use - Family planning - STI screening, prevention, and treatment - Adherence counselling and support • Gender-based violence screening and support • HIV education/counselling
Specific opportunistic infection screening and prevention	• Cotrimoxazole prophylactic therapy • Tuberculosis (TB) - Intensified case finding - Isoniazid preventive therapy - ART for TB/HIV co-infected patients • Cryptococcal meningitis
Reproductive health services	• Sexually transmitted infections screening and management • Family planning and pre-conception services • Maternal healthcare • Cervical cancer screening
Non-communicable diseases screening and management	• Hypertension • Diabetes mellitus • Dyslipidaemia • Chronic kidney disease • Other NCDs
Mental health screening and management	• Depression • Alcohol and drug use/addiction
Nutritional services	• Assessment • Counselling and education • Management and support
Prevention of other infections	• Immunizations • Malaria • Safe water, sanitation and hygiene

Table 4.1 (continued): Components of the Standard Package of Care for PLHIV

Standard Package of Care for HIV-Exposed and HIV-Infected Infants

- Determine HIV status at first contact through HTS/EID and link to HIV care
- Provide ARV prophylaxis for all HEIs and ART for all HIV-infected children (**confirming correct weight-based dosing of ARVs at every visit**); perform baseline clinical and laboratory assessment
- Provide nutritional assessment, counselling and support (NACS, Section 4.7) and monitor growth and development of the child (Annex 3)
- Ensure that all immunizations are provided following the national schedule (Section 4.8.1)
- Assess clinically at every visit, treat infections early, identify and manage adverse drug reactions aggressively and refer appropriately where specialized care is required
- Screen for opportunistic infections and provide prophylaxis (cotrimoxazole, isoniazid), deworm every 6 months (starting at age 1 year) and provide supplemental Vitamin A every 6 months (starting at age 6 months)
- Educate the caregiver on all aspects of care for the child including infant feeding, immunizations, personal hygiene, adherence, child disclosure, and follow-up requirements
- Provide age-appropriate psychosocial support for the family and child and refer to community-based support programmes as appropriate
- Ensure that the mother/caregiver and family members are receiving appropriate care, support and treatment
- Provide intensive case management for mother/infant pair until 2 years postpartum; identify defaulters and prioritize this population for tracking

Refer to the "**A Healthcare Worker Toolkit 2016" (A Guide for Caring for Children and Adolescents Living with HIV in Kenya**) which has detailed job aids for every step of the continuum of care for HIV-exposed and HIV-infected children.

Standard Package of Care of Adolescents Living with HIV

Clinical care

- Provide HIV counselling and testing services at all service delivery points and linkage to HIV care
- Provide ART to all HIV-infected adolescents
- Perform baseline clinical and laboratory assessment
- Assess clinically at every visit, treat infections early and refer appropriately where specialized care is required
- Screen for opportunistic infections and provide prophylaxis (cotrimoxazole, isoniazid)
- Provide NACS and monitor growth and development
- Provide/refer for HPV vaccine

Adherence and psychosocial support

- Perform a baseline psychosocial assessment
- Assess for and support disclosure of HIV status to the adolescent (Annex 5)
- Enrol in age-appropriate psychosocial support groups
- Provide treatment literacy and life skills counselling
- Provide adherence counselling
- Support appropriate transition into adult HIV care and treatment

Prevention of HIV transmission

- Encourage partner/family testing and support for disclosure
- Assess for and manage drug and alcohol use
- Perform a sexual risk assessment and STI screening and treatment, and linkage of sexual partner to PrEP where applicable
- Assess for and manage gender based violence
- Provide reproductive health services, including pregnancy screening, pregnancy intention assessment, family planning and linkage to PMTCT for pregnant adolescents

Referrals, linkages and support for continuum of care

- Provide intra-facility & inter-facility referrals as needed e.g. for specialized care
- Link with youth community groups, targeting youth out and in school
- Link to other services: legal centres, paralegal services, gender based violence recovery centres, educational institutions, bursary/scholarship programs, income generating activities, constituency development funds, vocational training centres for skills development, etc.

The **Adolescent Package of Care in Kenya 2014** has detailed job aids for every step of the continuum of care of adolescents living with HIV.

4.1 Antiretroviral Therapy

ART is now recommended for all PLHIV, regardless of WHO stage, CD4 count, age, pregnancy status, or comorbidities/co-infections. Once a diagnosis of HIV infection is confirmed, ART should be initiated within the shortest time possible (preferably within 2 weeks), once patient readiness has been determined. Other sections of these guidelines deal with initial evaluation and monitoring (Section 3), patient preparation and adherence support (Section 5), and specific recommended ART regimens (Section 6).

4.2 Positive Health, Dignity and Prevention (PHDP)

PHDP is a framework that emphasizes the health and rights of PLHIV, including reducing risk of onward transmission of HIV. Within PHDP are 6 core domains of counselling and education that should be provided at the health facility to PLHIV and caregivers (Table 4.2). Complementary community-based PHDP should also be implemented.

Table 4.2: Domains and Components for PHDP Counselling

PHDP Domain	Components
Disclosure of HIV status	• Assessment of disclosure status, particularly to sexual partners • Assisted disclosure • Note: for children and adolescents, it is also necessary to evaluate for and support age-appropriate HIV disclosure to the child/adolescent
Partner/family testing and engagement	• HIV testing of sexual partners • HIV testing of other family members at risk • Enrolment of positive partners/family members into HIV care • Engagement of negative partners and family members in care and support for index patient
Condom use	• Correct and consistent condom use • Provision of condoms at every visit
Family planning	• Assessment of pregnancy intention • Pre-conception counselling • Dual contraception until ready for pregnancy (see Section 4.4.2, Reproductive Health Services for specific clinical guidelines)
Sexually transmitted infections	• Screening for symptoms of STIs • Prevention of STIs (see Section 4.4.1, Reproductive Health Services for specific clinical guidelines)
Treatment adherence	• Benefits/importance of: - Adherence to clinical care - Adherence to ART (see Section 5, Adherence Preparation, Monitoring and Support for specific tools and protocols)

Additional services that should be offered to PLHIV beyond the above components include;

4.2.1. Screening for Gender-Based Violence (GBV)

National data shows that almost 50% of women aged 15-49 years have experienced physical or sexual violence in their lifetime. Resources for supporting patients who have experienced GBV are increasing in Kenya, but the first step is to identify patients who require this support. Basic screening questions for GBV have been found to be acceptable to patients and healthcare workers in Kenya, if the provider shows a respectful attitude and when confidentiality is assured.

All females aged 15-49 years and emancipated minors accessing HIV care services should be screened for GBV as part of the standard package of care for PLHIV.

The following script can be used for screening:

"Many people do not realize that violence can lead to all kinds of health problems. Because violence is so common in many women's lives, and because there is help available for women being abused, we now ask all female patients about their experiences with violence.

1. *Within the past year, have you been hit, slapped, kicked, or physically hurt by someone in any way?*
2. *Are you in a relationship with a person who physically hurts you?*
3. *Are you in a relationship with a person who threatens, frightens, or insults you, or treats you badly?*
4. *Are you in a relationship with a person who forces you to participate in sexual activities that make you feel uncomfortable?*
5. *Have you ever experienced any of the above with someone you do not have a relationship with?"*

If a patient answers yes to any of these questions: provide them with some immediate counselling support (supportive messages such as "*what happened to you is not your fault; many women are in the same situation as you; there are resources available to help you deal with the current difficulty; if you feel like you are in immediate danger we can involve the police or local administration*" and support with problem-solving if they are currently in an abusive relationship), and refer to the nearest Gender-Based Violence Recovery Centre or mental health team for further assessment and counselling.

Men, elderly, and children may also suffer gender-based or domestic abuse and should be assessed if there is any clinical suspicion. For children, screening is best done by observing the child playing, drawing, telling stories, etc.

4.2.2 HIV Education/Counselling

All PLHIV and caregivers should receive focused education about HIV and its treatment to empower them to succeed in management of the infection. Self-management is critical to the successful treatment of any chronic illness, including HIV. Key messages for HIV education and adherence counselling are described in Section 5 of these guidelines.

In addition to PHDP and HIV education, psychosocial counselling and support for PLHIV and caregivers should include:

- Mitigation of fear, anger, self-stigma and discrimination
- Alleviation of grief, bewilderment and stress among partners and family members
- Behaviour change in support of healthy living and prevention of further HIV transmission
- Skills-building on how to live a healthy and productive life
- Identification and treatment of depression and substance abuse

HIV education and counselling can be offered in multiple settings, including: facility-based individual, couples, family, and/or group counselling, and through community-based counselling and peer support groups.

4.3 Specific Opportunistic Infection Screening and Prevention

4.3.1 Cotrimoxazole Prophylactic Therapy (CPT)

All PLHIV should receive lifelong CPT (Table 4.3) unless they have an allergy to sulfa drugs or develop toxicity from CPT. CPT is effective in preventing specific OIs for patients with low CD4 counts (PCP and toxoplasmosis), as well as reducing risk for common bacterial infections, sepsis, diarrhoeal illness and malaria.

Table 4.3: Daily Dose of Cotrimoxazole Preventive Therapy

Weight (kg)	If using oral suspension (240mg per 5ml)	If using single strength tablet 480 mg (SS)	If using double strength tablet 960 mg (DS)
1 – 4	2.5 ml	¼ SS tab	--
5 – 8	5 ml	½ SS tab	¼ DS tab
9 – 16	10 ml	1 SS tab	½ DS tab
17 – 30	15 ml	2 SS tabs	1 DS tab
> 30	20 ml	2 SS tabs	1 DS tab
Adult (any weight)		2 SS tabs	1 DS tab

During pregnancy, CPT should be initiated irrespective of the gestational age and should continue throughout pregnancy, breastfeeding, and thereafter for life. Additional intermittent preventive therapy (sulfadoxine-pyrimethamine (SP)) for malaria is not required in women already on CPT.

Cotrimoxazole can cause anaemia and neutropenia in some patients, as well as a skin rash.

Management of Patients with Cotrimoxazole Allergy

- A rash may occasionally develop, usually about 7-14 days following initiation of CPT. It is often a relatively mild maculopapular rash with or without pruritus. Infrequently, a more severe rash may develop with severe exfoliation of the skin and Stevens-Johnson syndrome. Rash severity should be assessed, with management based on severity (Table 4.4)
- Desensitization is effective in the majority of patients with moderate rash (Table 4.5). The rapid desensitization regimen (Table 4.6) can be used in situations where treatment for PCP is needed

Table 4.4: Management of Cotrimoxazole-Associated Allergy

Severity	Characteristics	Action
Mild	Dry; erythema +/- fine papules; pruritus; affecting < 50% of body surface area	Continue CTX; close monitoring; symptomatic treatment with antihistamines +/- topical steroids (NOT oral steroids)
Moderate	Dry; erythema +/- fine papules; pruritus; affecting ≥ 50% of body surface area	Stop CTX; symptomatic treatment with antihistamines +/- topical steroids (NOT oral steroids); trial of desensitization after symptoms completely resolved
Severe	Mucosal involvement; blistering; associated fever; any % of body surface area	Stop CTX; admission to hospital for supportive management (IV fluids, wound care, pain control, infection control, monitoring for superinfection); patient should NEVER be re-challenged with CTX or other sulfa-containing drugs

Cotrimoxazole Desensitization Protocols (for patients who have fully recovered from moderate reaction)

Table 4.5: Standard Cotrimoxazole Desensitization Regimen (8 days)

Day	Dose of TMP/SMX Suspension (40/200 mg per 5ml)
Day 1	0.5 ml
Day 2	1 ml
Day 3	2 ml
Day 4	3 ml
Day 5	4 ml
Day 6	5 ml
Day 7	1 SS tablet
Day 8	2 SS tablets/1 DS tablet per day

Table 4.6: Rapid Cotrimoxazole Desensitization Regimen (6 hours)

Hour	Dose of TMP/SMX Suspension (40/200 mg per 5ml)
Hour 0	0.5 ml
Hour 1	1 ml
Hour 2	2 ml
Hour 3	3 ml
Hour 4	4 ml
Hour 5	5 ml
Hour 6	1 SS tablet

Dapsone as a Substitute for CPT

In situations of severe allergy to cotrimoxazole or when desensitization is not successful, dapsone can be used instead of CTX. It is primarily effective as prophylaxis against PCP but does not have the other prophylactic benefits of cotrimoxazole.

Dapsone will contribute to anaemia in most patients, and causes haemolytic anaemia in some patients, so patients should have a baseline Hb before starting dapsone and Hb monitored every 1-2 weeks for the first couple of months.

When dapsone (as a substitute for CPT) is being used as PCP prophylaxis, it is only recommended for patients in WHO Stage 4 and/or absolute CD4 count < 200 cells/μL (or % CD4 count < 14%), and should be discontinued once a patient achieves a CD4 count of > 200 cells/μL for at least 6 months.

Dose of Dapsone

- Available as 25 mg and 100 mg tabs
- Children: 2 mg/kg once daily (maximum dose: 100 mg) OR 4 mg/kg once weekly (maximum dose: 200 mg)
- Adults: 100 mg once daily

4.3.2 Tuberculosis (TB) Prevention and Management for PLHIV

All PLHIV should be screened for TB at every visit using the Intensified Case Finding (ICF) tool.

All PLHIV older than 12 months of age who screen negative for TB should be provided with 6 months of Isoniazid Preventive Therapy (IPT) unless they have a specific contraindication. All patients who receive a full course of IPT should have this clearly documented in their file.

For PLHIV who have presumptive TB, Xpert MTB/Rif is the preferred testing platform to confirm the diagnosis. All PLHIV qualify for ART, including patients with HIV/TB co-infection.

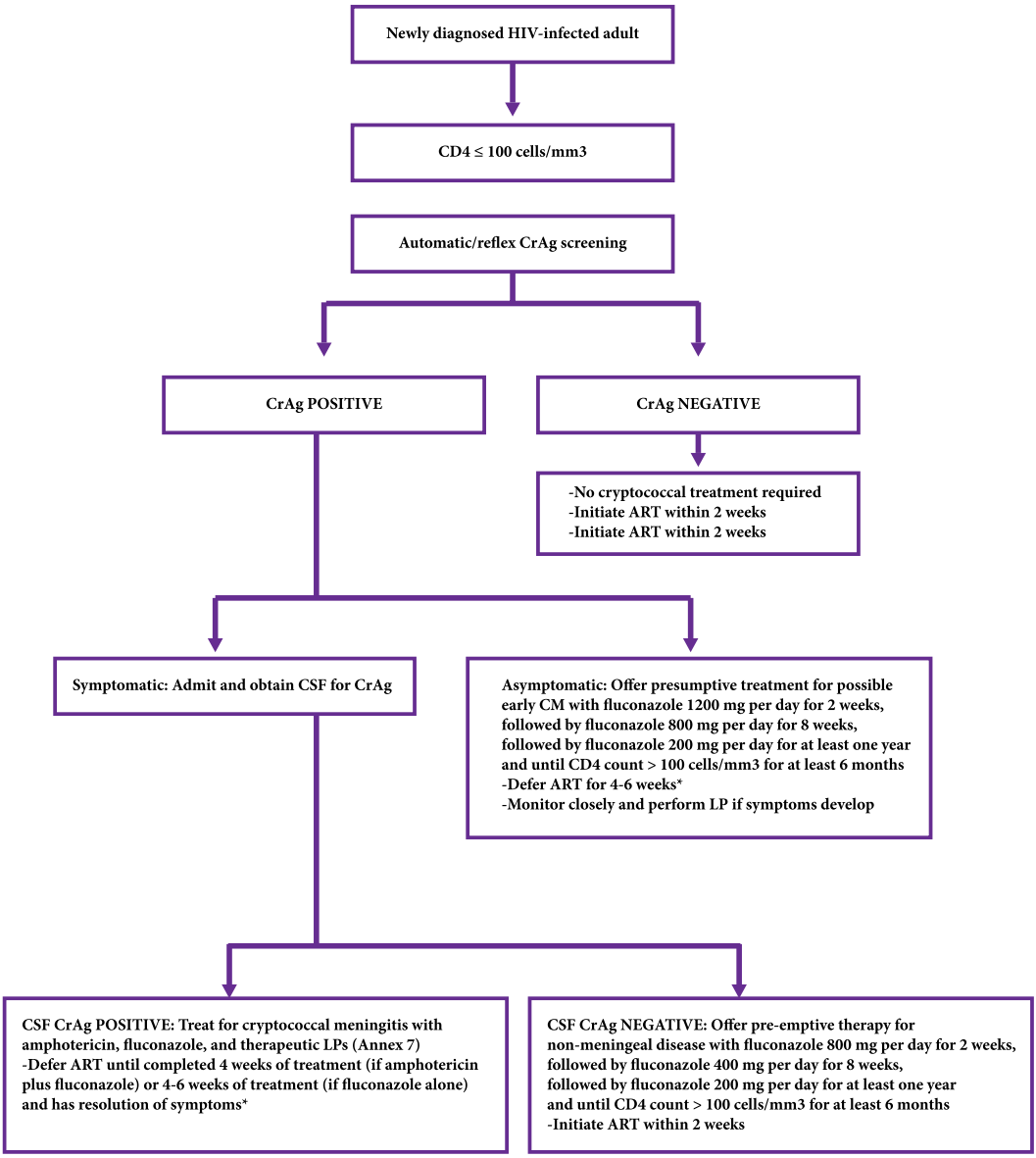
Section 8 provides specific guidelines for ICF, IPT, use of Xpert MTB/Rif, and ART for patients with TB/HIV co-infection.

4.3.3 Cryptococcal Meningitis (CM) Screening and Treatment

All adult PLHIV with a baseline CD4 count of ≤ 100 cells/ml should be screened for CM (Figure 4.1). This should preferably be a reflex test performed by the laboratory as soon as the low CD4 count is noted, rather than requiring the clinician to order a special test for screening. PLHIV, including children and adolescents, should receive CM screening if clinically suspected. For patients who are symptomatic for cryptococcal meningitis but screen serum CrAg negative, alternative diagnoses for sub-acute meningitis should be explored, such as TB meningitis.

Annex 7 provides detailed guidance on the use of amphotericin, fluconazole, and therapeutic lumbar punctures for the treatment of symptomatic cryptococcal meningitis.

Figure 4.1: Routine Screening for Cryptococcal Meningitis for HIV-infected Adults



**Patients with cryptococcal meningitis are at high risk of developing life-threatening IRIS; deferring ART has been shown to improve survival for these specific patients*

4.4 Reproductive Health Services

4.4.1 Sexually Transmitted Infections

Screening for syphilis using RPR should be performed as a baseline investigation for all PLHIV.

All PLHIV should be assessed for symptoms of STIs using the National Algorithms for Treating Common STI Syndromes 2015. Sexual partners should be treated as well (refer to corresponding guidelines).

Risk reduction counselling and provision of condoms is an integral part of STI treatment.

Patients who have persistent signs and symptoms of STIs after syndromic treatment should undergo diagnostic evaluation for definitive diagnosis and treatment.

At initial diagnosis of HIV, all sex workers should be treated for presumptive gonorrhoea and chlamydia (following treatment recommendations of vaginal/urethral discharge syndrome as per national guidelines), with on-going assessment for STIs at least quarterly

4.4.2 Family Planning and Pre-Conception Counselling

Pregnancy status should be determined for all women of reproductive age at every visit by asking about last menstrual period and, if indicated, performing a urine pregnancy test.

Pregnancy intention should be determined for all women of reproductive age and their partners so that appropriate family planning or pre-conception counselling can be provided.

For patients who do not have an immediate desire to become pregnant, dual contraception should be provided immediately, with follow-up appointments schedule to ensure no interruption in contraception provision. Table 4.7 outlines contraception options for PLHIV based on the ARVs they are using. Depo-Provera is efficacious, convenient for many women (as an injection every 3 months, which can be timed with clinic visits), and has no interactions with any ARVs. It should be used in combination with condoms to prevent STI/HIV transmission.

Table 4.7: Contraceptive Methods for PLHIV According to WHO 2015 Medical Eligibility Criteria

Contraceptive Method		ARVs Being Used					
		NRTIs (any)	NNRTIs		PIs (any)	INSTIs	
			EFV or NVP	ETR		RAL	DTG*
IM medroxyprogesterone (DMPA; Depo Provera)		1	1	1	1	1	-
Norethisterone enanthate (NET-EN; norethindrone)		1	2#	1	2	1	-
Implants		1	2#	1	2	1	-
Combined oral contraceptive (pill)		1	2#	1	2#	1	-
Intrauterine device (IUD)	Initiation	• Category 2 for asymptomatic or mild HIV disease (WHO Stage 1 or 2, or any WHO Stage once they are stable on ART) • Category 3 for women with advanced and symptomatic HIV disease UNTIL they are stable on ART and asymptomatic					
	Continuation	Category 2 for all women regardless of symptomatic HIV (do not require IUD to be removed)					
Condoms		No restrictions; use encouraged in combination with a hormonal contraception method or IUD as part of dual FP to prevent STI/HIV transmission					
Emergency contraceptive pill (ECP)		No restrictions; can be started up to 5 days after intercourse					
Sterilization		No reason to deny; delay in case of acute HIV-related infection					
Fertility awareness-based (FAB) methods		Can use if menstrual cycle is regular, although reliability is not as good as hormonal contraceptive methods or IUD. Encourage to use in combination with condoms to prevent STI/HIV transmission					
Lactational amenorrhoea method (LAM)		Effective for women who are less than 6 months post-partum, are exclusively breastfeeding, and have not resumed menses. Encourage to use in combination with condoms to prevent STI/HIV transmission					
Spermicides and diaphragm		Use is not recommended; may increase risk of HIV transmission					

Category 1: No restriction for the use of the contraceptive method
Category 2: Advantages of using the method generally outweigh the theoretical or proven risks
Category 3: The theoretical or proven risks usually outweigh the advantages of using the method
*DTG was not included in the WHO 2015 MEC Guidelines, however there are no known or anticipated drug interactions between DTG and hormonal contraception
#Contraceptive effectiveness might be significantly compromised (EFV>NVP>PIs); DMPA recommended as an alternative contraceptive method. Method does not present other health risks

For patients who intend to become pregnant, the key messages for preconception counselling are presented in Table 4.8.

Table 4.8: Pre-Conception Care Counselling Messages and Services for PLHIV

Scenario	Key Counselling Messages	Pre-conception Services (in addition to the Standard Package of Care for PLHIV)
All women/couples with intention to conceive	• All PLHIV qualify for ART, with initiation preferably within 2 weeks of HIV diagnosis • Deferring pregnancy until confirmed viral suppression reduces risk of vertical transmission to the baby, improves infant outcomes, and reduces risk of cross-transmission to the sexual partner • Unprotected sex should be limited to days when ovulation is expected (based on basal temperature monitoring, fertility calendar based on menstrual cycles, and/or on-line fertility calendar) • Routine ANC and delivery by a skilled birth attendant improves outcomes for mother and baby	• ART for all PLHIV, including those intending to become pregnant • Baseline investigations: - Hb (with management of anaemia) - RPR - Cervical cancer screening • STI symptom screening • Nutritional assessment, counselling, and support • Folic acid supplementation • Standard VL after 6 months on ART to confirm viral suppression
Additional messages for discordant couples: male partner HIV positive	• Defer unprotected sex until confirmed viral suppression in the HIV-positive partner • Discuss use of PrEP for the HIV-negative partner (see Section 11, Pre-Exposure Prophylaxis) • Consider specialist referral for additional options such as sperm washing and artificial insemination, particularly in situations where viral suppression is challenging	
Additional messages for discordant couples: female partner HIV positive	• Defer unprotected sex until confirmed viral suppression in the HIV-positive partner • Discuss use of PrEP for the HIV-negative partner (see Section 11, Pre-Exposure Prophylaxis) • Discuss self-insemination during the peri-ovulatory period, where appropriate/as preferred • Consider specialist referral for additional options such as artificial insemination, particularly in situations where viral suppression is challenging	

4.4.3 Maternal Healthcare

Maternal healthcare begins with preconception counselling (Table 4.8), and continues throughout pregnancy and breastfeeding. The standard package of antenatal and postnatal services in the context of HIV is described in Section 7 of these guidelines.

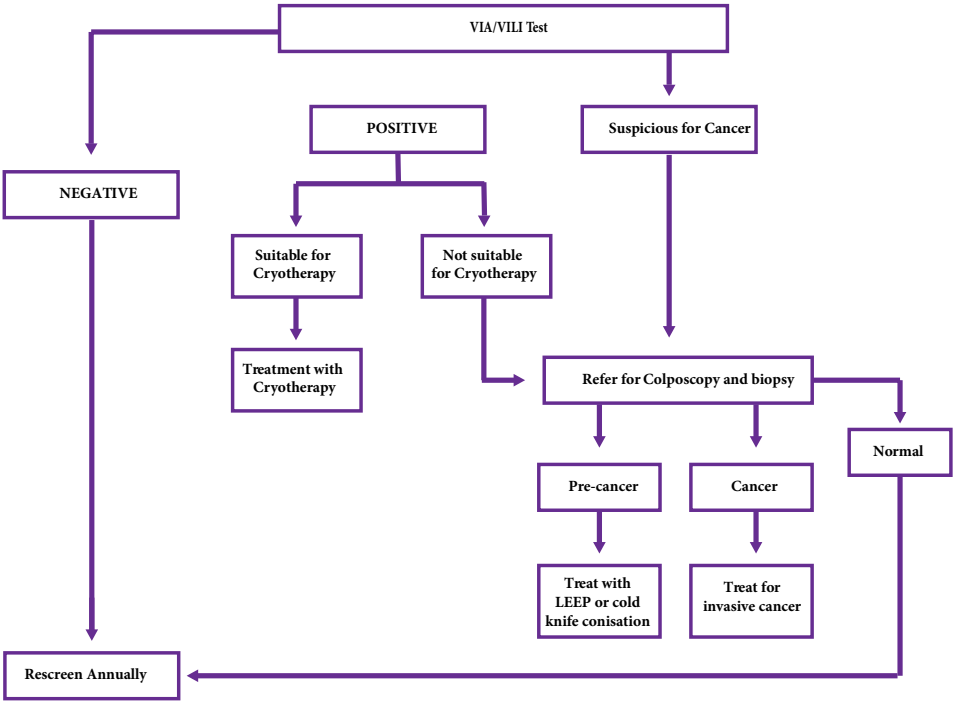
4.4.4 Cervical Cancer Screening

Cervical cancer is the leading cause of cancer death for women in Kenya. The risk of developing cervical cancer is greatly reduced with the use of HPV vaccination (see Section 4.8 on Immunizations). Even without the HPV vaccine, morbidity and mortality from cervical cancer can be prevented through early detection with routine screening.

- *All HIV positive women between the ages of 18 - 65 years who have ever been sexually active should be screened for cervical cancer*
- Screening should be every 6 months in the first year of screening, and then annually

Figure 4.2 shows the screening algorithm using Visual Inspection with Acetic Acid (VIA) or Visual Inspection with Lugol's Iodine (VILI)

Figure 4.2: Cervical Cancer Screening for HIV-Positive Women using VIA/VILI



4.5 Non-communicable Diseases Screening and Management

4.4.1 Sexually Transmitted Infections

Screening, prevention and management of specific non-communicable diseases are included in the standard package of care for PLHIV because of their associated high morbidity and mortality. PLHIV are at higher risk for cardiovascular, liver and kidney disease because of the chronic inflammatory state associated with HIV infection itself, and also as a side-effect of some of the ARVs used to treat HIV.

Risk factors for cardiovascular disease include: smoking, hypertension, dyslipidaemia, diabetes, obesity, sedentary lifestyle, family history of cardiovascular disease, age older than 45 years for men and 55 years for women.

Patients at higher risk for renal disease and for developing TDF-associated renal toxicity include: pre-existing renal disease, hypertension, diabetes, severe wasting (weight below 60 kg in adults), age > 45 years, WHO stage 3 or 4, and concomitant nephrotoxic agents.HIV and other chronic diseases require health systems that support chronic care and adherence; consideration should be given for integrating their management in the health facility.

HIV and other chronic diseases require health systems that support chronic care and adherence; consideration should be given for integrating their management in the health facility.

Lifestyle modifications are always the first line of prevention and management for hypertension, diabetes mellitus, and dyslipidaemia (Table 4.9). These are recommended for all patients to prevent cardiovascular disease and should be integrated into routine HIV care and treatment. Recommendations for screening, diagnosis, and initial management of hypertension, type 2 diabetes mellitus, dyslipidaemia, and chronic kidney disease are provided in Tables 4.10-4.13.

Table 4.9: Lifestyle Modifications to Prevent and Manage Cardiovascular Disease in PLHIV

Smoking Cessation
• Smoking cessation has multiple short-term and long-term benefits, including: - Skin does not age/wrinkle as quickly - Improved fitness and quicker recovery from common infections - Reduced risk of respiratory infections and chronic lung disease - Reduced risk of high blood pressure, diabetes, kidney disease, heart disease, and stroke - Improved infant outcomes (for pregnant women who smoke) - Reduced risk of cancers: lung, bladder, breast, mouth, throat, esophagus - Evidence of better response to ART (better viral suppression)
Dietary Changes and Weight Loss (refer to the National Nutritional and HIV Toolkit 2015 for more detailed recommendations)
• Weight loss to maintain a healthy BMI (nutritionists to be engaged in patient care) • Drink 8 glasses of water per day • Reduce/abstain from alcohol • Cut down sugar intake • Cut down red meat intake • Cut down consumption of fatty foods, fat for flavouring, and of fried foods • Increase intake of whole grains, vegetables, fruit, and beans • Increase intake of fish • Cut down salt intake to < 1.5 g/day (for patients with hypertension only)
Physical Activity
• Active lifestyle with moderate-intensity physical activity • 30 minutes of aerobic activity such as brisk walking, at least 5 days per week

Table 4.10: Hypertension Screening, Diagnosis, and Initial Management for Adult PLHIV

Screening
• BP should be measured and recorded for every adult at every visit
Diagnosis
• Hypertension requiring intervention is defined as BP ≥ 140/90 mmHg on at least 3 different occasions
Management (treatment target is BP < 140/90 mmHg)
If baseline BP is 140-159/90-99: • Lifestyle modifications for at least 6 months, along with monthly BP monitoring • If does not meet treatment target with lifestyle modifications then add drugs: - Introduce 1 drug at a time, and allow 2-3 weeks to achieve maximal effect before titrating up dosage; titrate to maximum dosage before adding an additional drug - In PLHIV without kidney disease or diabetes, first-line antihypertensive therapy is a thiazide diuretic such as hydrochlorothiazide starting at 12.5 mg OD (maximum dose 25 mg OD) **OR** a calcium channel antagonist such as amlodipine starting at 2.5 mg OD (maximum 10 mg OD) - In PLHIV **with** kidney disease or diabetes the first antihypertensive should be an ACE-I or ARB such as Enalapril 2.5-10 mg OD (maximum dose is 20 mg BD); Losartan 50 mg OD (maximum dose is 100 mg OD) - If inadequate response once dose has been titrated, an additional agent may be required e.g. hydrochlorothiazide starting at 12.5 mg OD (maximum dose 25 mg OD) - If inadequate response to two agents, consider consultation with or referral to a clinician experienced in the management of refractory hypertension. Note: Calcium-channel blockers have known drug interactions with PIs and NNRTIs and should be used with caution **If baseline BP ≥ 160/100 mmHg: initiate lifestyle modifications and introduce anti-hypertensive medications concurrently**

Table 4.11: Type 2 Diabetes Mellitus Screening, Diagnosis, and Initial Management for PLHIV

Screening

- Blood glucose (fasting or random) should be evaluated at baseline for all PLHIV, then annually if baseline screening is normal; urine dipstick for protein and glucose can be used if blood glucose testing is not available

Diagnosis

- Diabetes Mellitus is defined as fasting blood sugar ≥ 7.0 mmol/L, or random blood sugar ≥ 11.1 mmol/L, or HbA1C > 6.5%
- Abnormal results should be repeated to confirm the diagnosis

Management (treatment target is HgA1C ≤ 7.0% or FBS 4-7 mmol/L)

- Monitor HgA1c (or FBS if HgA1c not available) every 3 months for patients with confirmed diagnosis of diabetes mellitus
- Lifestyle modifications (weight loss, nutritional support to manage portion sizes and calculate glycaemic index of various foods to help with control of blood sugar) for 3-6 months
- If does not meet treatment target with lifestyle modifications then add drugs:
  - Metformin
    - Obtain baseline Creatinine; do NOT use metformin if creatinine clearance < 45 mL/min
    - Start with low dose (500 mg OD or BD) and titrate up every 1-2 weeks until reaches 1 g BD (or maximum tolerated dose if less than 1 g BD)
  - If does not meet treatment targets with metformin for 3-6 months at maximum tolerated dose then consider adding drug from another class (such as glyberide) and/or specialist consultation. Some patients may require insulin
- At every visit: A thorough history (to elicit features of hypoglycaemia, other cardiovascular disease risk factors, neuropathy, diabetic foot ulcers) and a physical exam (for BP, neuropathy, foot ulcers)
- Additional routine screening for patients with diabetes:
  - Annual ophthalmology examination for diabetic retinopathy
  - Annual urinalysis: start on an ACE-I/ARB if proteinuria develops (even if BP normal)

Table 4.12: Dyslipidaemia Screening, Diagnosis, and Initial Management for PLHIV

Screening

- Fasting lipid profile should be evaluated at baseline for all PLHIV, then annually if baseline screening is normal

Diagnosis

- Dyslipidaemia is defined as high fasting total cholesterol (>5.2 mmol/L), LDL (>3.4 mmol/L) or triglycerides (>2.2 mmol/L)

Management

- Lifestyle modifications for 3-6 months
- If the patient is on an ARV known to cause or exacerbate dyslipidaemia (primarily LPV/r) then consider a single-drug substitution to a more lipid-friendly drug (such as from LPV/r to ATV/r) as the treatment of choice before adding a lipid-lowering drug. Rule out treatment failure before making single-drug substitutions (Figure 6.2 in Section 6)
- If does not meet treatment target with lifestyle modifications then add drugs:
  - Atorvastatin: starting dose of 10 mg OD (maximum dose 20 mg if patient is on a PI/r; maximum dose 80 mg once daily if not on a PI/r)
  - Allow at least 3 months before repeating fasting lipids and titrating dose
- Once targets achieved can monitor lipids every 6-12 months

Table 4.13: Chronic Kidney Disease Screening, Diagnosis, and Initial Management for PLHIV

Screening
• Urinalysis (for protein) and serum creatinine should be evaluated at baseline for all PLHIV
Diagnosis
• Impaired renal function is defined as creatinine clearance < 60 ml/min, or dipstick proteinuria ≥ 1 • Abnormal results should be repeated to confirm diagnosis
Management
• Management depends on the cause of the renal impairment; additional investigations and/or specialist consultation may be required • Treat dehydration promptly and aggressively • If on TDF-containing regimen, substitute with another ARV (see Section 6.4), with the exception of patients with HBV/HIV co-infection (see Section 9) • Avoid nephrotoxic drugs • Evaluate for and treat hypertension • All NRTIs except ABC require dose adjustments for renal impairment, depending on the severity (see Figure 6.5 in Section 6 for specific dose adjustments). NNRTIs, PIs, and INSTIs do not require dose adjustments for impaired renal function

Other Non-communicable Diseases

PLHIV are at risk for a number of other non-communicable diseases, with increased risk compared to the general population for some of these. PLHIV are at increased risk for lymphoma compared to the general population, and females with HIV are also at increased risk for cervical cancer.

Cervical cancer is the most frequent cancer in women in Africa (see Section 4.4.4), followed by breast cancer, then liver cancer. Prostate cancer is the most frequent cancer experienced by men in Africa, followed by liver and oesophageal cancers. For screening, diagnosis, and management recommendations refer to the National Guidelines for Prevention and Management of Cervical, Breast and Prostate Cancers, 2012, and the National Guidelines for Cancer Management in Kenya, 2013. For individual patient management, referral to regional and national hospitals with capacity for comprehensive oncology services may be warranted.

4.6 Mental Health Screening and Management

PLHIV are susceptible to psychological disturbances due to HIV itself and perceptions regarding HIV in their environment. Some of the most common psychological disturbances include depression and suicide, anxiety, internalized stigma, post-traumatic stress disorder, cognitive difficulties such as dementia, and perceived lack of social support. Any of these can significantly interfere with a patient's sense of well-being and their adherence; however depression and alcohol/drug addiction are the most significant.

4.6.1 Depression

Depression is one of the most common psychiatric illnesses in the world, and chronic illness (including HIV) is a strong risk factor for depression. PLHIV are 3-6 times more likely to suffer from depression than the general population, with significant disability and poorer treatment outcomes if it is not identified and managed. Depression can be a significant contributing factor to poor adherence and HIV treatment failure.

All PLHIV should receive basic screening for depression before initiating ART and thereafter annually using the following two questions:

- During the past two weeks have you often been bothered by feeling down, depressed, or hopeless?
- During the past two weeks have you often been bothered by little interest or pleasure in doing things?

For all patients who answer yes to either of the questions above, and for all patients with a detectable viral load after 6 or more months on ART (whether or not they had achieved viral suppression in the past), should undergo a more thorough screening for depression using the PHQ-9 screening tool, with management guided by the PHQ-9 score (Table 4.14).

Table 4.14: Patient Health Questionnaire-9 (PHQ-9) for Depression Screening

PHQ-9 Depression Screening Name: _____ Date: _____

Ask the patient the questions below for each of the 9 symptoms and circle the response for each question. After asking all questions, add the points for each column at the bottom. The total score is the sum of the column totals. Interpretation and management recommendations are provided at the bottom of the table.

Question: "Over the last 2 weeks, how often have you been bothered by any of the following problems?"	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself, or that you are a failure, or that you have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things (linked with patient's usual activities, such as reading the newspaper or listening to a radio programme)	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Total ____ = (add the points from each column)	0	+___	+___	+___

Interpretation of PHQ-9 Score and Recommended Management

Total Score	Provisional Diagnosis	Recommended Management
0-4	Depression unlikely	Repeat screening in future if new concerns that depression has developed
5-9	Mild depression	• Provide counselling support and continue to monitor; refer to mental health team if available • If patient is on EFV, substitute with a different ARV after ruling out treatment failure (Figure 6.2 in Section 6)
10-14	Moderate depression*	• Provide supportive counselling (refer to a psychologist if available) • If patient is on EFV, substitute with a different ARV after ruling out treatment failure (Figure 6.2 in Section 6) **and** • Begin antidepressant medication (or, if unfamiliar with use of antidepressants then refer to an experienced clinician) **and** • Refer to a medical officer, psychiatrist, or mental health team if available
15-19	Moderate-severe depression*	
20-27	Severe depression*	

*Symptoms should ideally be present for at least 2 weeks for a diagnosis of depression and before considering treatment with antidepressant medication. Severe depression may require patients to start on anti-depressants immediately

Depression is a known adverse drug reaction with EFV although it is often mild and transitory. Patients on EFV who develop any persistent symptoms of depression should be switched to another ARV after ruling out treatment failure (Figure 6.2 in Section 6).

Supportive Counselling for Depression

Patients with mild depression should receive support counselling, which includes:

- Psycho-education on the following key messages:
  - Depression is common and can happen to anyone
  - Depressed people often have exaggerated negative opinions about themselves, their life and their future
  - Effective treatment is possible
  - Self-management includes:
    - Continue ART as prescribed
    - Continuing activities that they used to find interesting/pleasurable
    - Maintaining a regular sleep cycle
    - Keep physically active
    - Participate in community/social events
    - Return if any thoughts of self-harm
- Addressing psychosocial stressors
  - Explore potential stressors in the patient's life
  - Assist in problem-solving to reduce stressors
  - Assess for and manage gender-based violence
- Reactivation of or referral to social networks, including peer support groups
- Regular follow-up until symptoms improved and stable

Supportive Counselling for DepressionPharmacological Management of Depression

Patients with moderate depression or worse should be treated with supportive counselling plus an anti-depressant medication.

Fluoxetine is an antidepressant on the Kenya Essential Drug List. It does not have significant interactions with ARVs. Starting dose for an adult is usually 20 mg once daily taken in the morning (can start with a lower dose for patients who frequently have side-effects from medications. Dose can be titrated up by 20 mg every 2-4 weeks as needed, up to a maximum of 80 mg per day. Common side-effects include GI upset, headaches, insomnia, and disturbances of the menstrual cycle. These usually resolve after 1-2 weeks of continued use. As with all antidepressants, full effect is not achieved until around 4 weeks of continued use. Once symptoms of depression resolve, antidepressants should be continued for at least another 6 months and then slowly tapered, with close monitoring for recurrence of symptoms.

4.6.2 Alcohol and Drug Use/Addiction

Patients with mild depression should receive support counselling, which includes:
Alcohol and other drug use are common among the general population and among PLHIV. Alcohol and drug use can be a significant contributing factor to poor adherence and HIV treatment failure.

All adults and adolescents should be screened for alcohol and drug use before initiating ART and every 1-2 years using the following three questions:

- During the past 12 months, did you drink any alcohol (more than a few sips)?
- During the past 12 months, did you smoke any marijuana?
- During the past 12 months, did you use anything else to get high?

Patients who answer yes to any of the questions above, and all patients with a detectable viral load after 6 or more months on ART (whether or not they had achieved viral suppression in the past), should undergo a more thorough screening. For adolescents, use the CRAFFT Part B screening tool (Table 4.15). For adults, use the CAGE-AID screening tool (Table 4.16). Anyone who screens positive on these tools should have further assessment and management by clinical staff, ideally with some experience managing alcohol and drug use disorders.

Table 4.15: CRAFFT Screening Interview Part B for Adolescents

CRAFFT Screening for Alcohol and Drug Use Disorders for Adolescents (Part B)		
Ask the patient the six questions below. Each question requires a yes/no response. Answering Yes to two or more questions indicates an alcohol or drug use problem and requires further assessment and management.		
"I'm going to ask you a few questions that I ask all my patients. Please be honest. I will keep your answers confidential"		
Question	No	Yes
1. Have you ever ridden in a car driven by someone (including yourself) who was "high" or had been using alcohol or drugs?		
2. Do you ever use alcohol or drugs to relax, feel better about yourself, or fit in?		
3. Do you ever use alcohol or drugs while you are by yourself, or alone?		
4. Do you ever forget things you did while using alcohol or drugs?		
5. Do your family or friends ever tell you that you should cut down on your drinking or drug use?		
6. Have you ever gotten into trouble while you were using alcohol or drugs?		

Table 4.16: CAGE-AID Screening Questions for Adults

CAGE-AID Screening for Alcohol and Drug Use Disorders for Adults		
Ask the patient the four questions below. Each question requires a yes/no response. Answering Yes to two or more questions indicates an alcohol use problem and requires further assessment and management.		
"I'm going to ask you a few questions that I ask all my patients. Please be honest. I will keep your answers confidential"		
Question	No	Yes
1. Have you felt you should cut down on your drinking or drug use?		
2. Have people ever annoyed you by criticizing your drinking or drug use?		
3. Have you ever felt bad or guilty about your drinking or drug use?		
4. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?		

If referral to the mental health team is not immediately possible for those who screen positive, or as a starting point in supporting a patient while referral is being made, an assessment of whether the patient wants to quit and targeted messages/support based on their stage of quitting may be beneficial (Table 4.17). The WHO Alcohol, Smoking and Substance Involvement Screening Toolkit (ASSIST) provide additional resources for assessment, brief intervention guidance for clinicians, and self-help patient resources.

Table 4.17: Addiction Support Based on Stages of Change

Stage of Change	Counselling Approach
Pre-contemplation: not currently considering quitting; no immediate desire to quit	• Acknowledge that not everyone is ready to think about quitting • Clarify that it is their decision • Listen to them describe the benefits they get from their alcohol or drug use (their motivation for continuing to use) • Explore why other people might think it is a good idea to quit • Discuss the risks of continued alcohol or drug use
Contemplation: not sure if he/she wants to quit, or thinking about quitting but with no immediate plan to quit	• Acknowledge that not everyone is ready to quite immediately • Clarify that it is their decision • Listen to them describe the benefits they get from the alcohol or drug use (their motivation for continuing to use) • Listen to them describe the negative effects of their alcohol or drug use (their motivation for considering quitting) • Discuss any ideas they have on how they could go about quitting
Preparation: would like to quit within the next month	• Congratulate them on their decision to quit • Listen to them describe the benefits they expect to get from quitting • Discuss any plan they have to try quitting • Discuss the challenges they may face with quitting • Problem-solve with them on overcoming challenges, including identifying support systems • Encourage small steps towards quitting (e.g. avoiding situations that trigger use) • Acknowledge that they have the strength to succeed
Action: actively trying to quit, or has recently quit (within past 6 months)	• Listen to their experience with quitting • Congratulate them on the steps they have taken so far • Problem-solve with them on overcoming challenges, including identifying support systems • Review the long-term benefits of quitting
Maintenance: has quit (more than 6 months ago) and wants to remain abstinent	• Congratulate them on their success so far • Discuss potential for relapse and how to deal with it • Review the long-term benefits of maintaining abstinence from drug or alcohol use
Relapse:	• Acknowledge that relapse is common • Evaluate what triggered the relapse • Reassess motivation to quit and barriers to quitting • Problem-solve with them on overcoming challenges and what additional support systems and strategies can be used

4.7 Nutritional Services

Good nutrition is a critical component of management of HIV because it contributes to: reducing risk and frequency of other infections; delaying progression from HIV infection to AIDS; a healthy appearance and weight; gaining strength, maintaining and building muscle, and having energy to remain active, and; reducing side effects of ART.

4.7.1 Nutritional Assessment, Counselling and Support (NACS)

All PLHIV should receive nutritional assessment, counselling, and support

All PLHIV should receive nutritional assessment, counselling, and support tailored to the individual needs of the patients, including:

- Nutrition assessment and diagnosis
  - Anthropometric (Tables 4.18, 4.19 and 4.20 provide interpretation and required actions for anthropometric results for children and adults)
  - Biochemical (investigations as listed in Section 3, Table 3.2 for baseline and follow-up investigations)
  - Clinical (physical examination as described in Section 3, Table 3.1 for initial evaluation)
  - Dietary (24 hr recall for food type/frequency and household food security)
  - Environmental and psychosocial
  - Functional (ability to care for self, bedridden, etc.)
- Counselling and education
  - Benefits of maintaining good nutritional status for a person living with HIV
  - Mother infant and young child nutrition (MIYCN)
  - Reassuring the client that it is possible to
    - . Attain/maintain good nutritional status
    - · Look well and live a healthy life
  - Identifying locally available foods they can access given their own context, food safety and food preparation
  - Helping the client to plan meals and snacks with a variety of foods in order to meet their energy and nutrient needs and treatment plans
  - Identifying any constraints the client may face and find ways to minimize them
  - Helping the client to understand the potential side effects and food interactions of the medicines they are taking, and help the client identify ways to manage these side effects
  - Exploring with the client the cause(s) of poor appetite and appropriate responses (type of food, disease, pain, depression, anxiety, or side effects of medications)
  - Counselling on high levels of sanitation and food hygiene
- Support
  - Therapeutic and supplementary foods to treat clinical malnutrition (food by prescription, therapeutic feeds, fortified blended flour): Figures 4.3 and 4.4 provide malnutrition management recommendations for adults and children; Section 4.5 provides specific nutritional recommendations for patients with non-communicable diseases
  - Complementary foods for children aged 6 - 23 months to prevent malnutrition (Table 4.21 provides complementary feeding recommendations)
  - Micronutrient supplements to prevent vitamin and mineral deficiencies
  - Point-of-use water purification to prevent water-borne disease
  - Food security and linkage to community, such as household food support, home-based care, agricultural extension services, and economic strengthening and livelihood support

Some aspects of nutrition support (such as prescription of therapeutic and supplementary foods) should be provided by a trained healthcare professional, however all aspects should be promoted and supported at the community level.

Table 4.18: Interpretation of MUAC Results for Children and Pregnant/Lactating Women

MUAC Level by Age (cm)			Classification	Action to Take
6-59 mo	5-9 yrs.	10-17 yrs.		
< 11.5	< 13.5	< 14.5 cm	Severe acute malnutrition	Irrespective of clinical signs, admission (referral) for stabilization/therapeutic rehabilitation
11.5–12.5	13.5-14.5	14.5-18.5	Moderate acute malnutrition	Admission for supplementary feeding is recommended
12.6–13.5			Mild acute malnutrition	Nutritional education and counselling
> 13.5			Normal	Education and counselling of caregivers
Pregnant and Breastfeeding Women				
≤ 23			Malnourished	Provide nutritional support (Figure 4.4)
> 23			Normal	Education and counselling

Table 4.19: Interpretation of Z-scores for Children

Ratio	Indicator
Weight/Age	Underweight
Height/Age	Stunting
Weight/Height	Wasting*

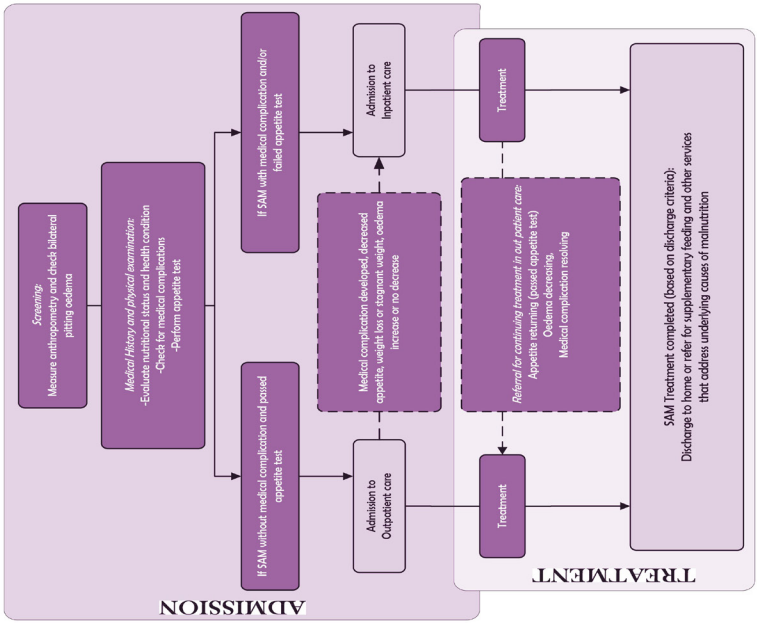
Z-score	Severity
< - 3	Severe
- 3 to - 2	Moderate
> - 2 to - 1	Mild
> - 1	Normal

Table 4.20: Interpretation of BMI Results for Adults

BMI Level	Classification	Action to Take
< 16	Severe malnutrition	Refer for facility-based therapeutic intervention; rehabilitation with therapeutic foods; counselling on intake issues and possible metabolic issues
16.0–18.4	Mild/moderate malnutrition	Nutritional counselling and supplementary feeding
18.5–25.0	Normal/ recommended	Nutritional counselling, consistent exercises to build muscles
25.1–30	Overweight	Nutritional counselling to reduce energy intake; aerobic physical activity to reduce weight
>30	Obese	Counselling to change lifestyle and reduce energy intake; aerobic physical activity to reduce weight

4.7.1 Nutritional Assessment, Counselling and Support (NACS)

Figure 4.3: Management of Severe Acute Malnutrition in Children



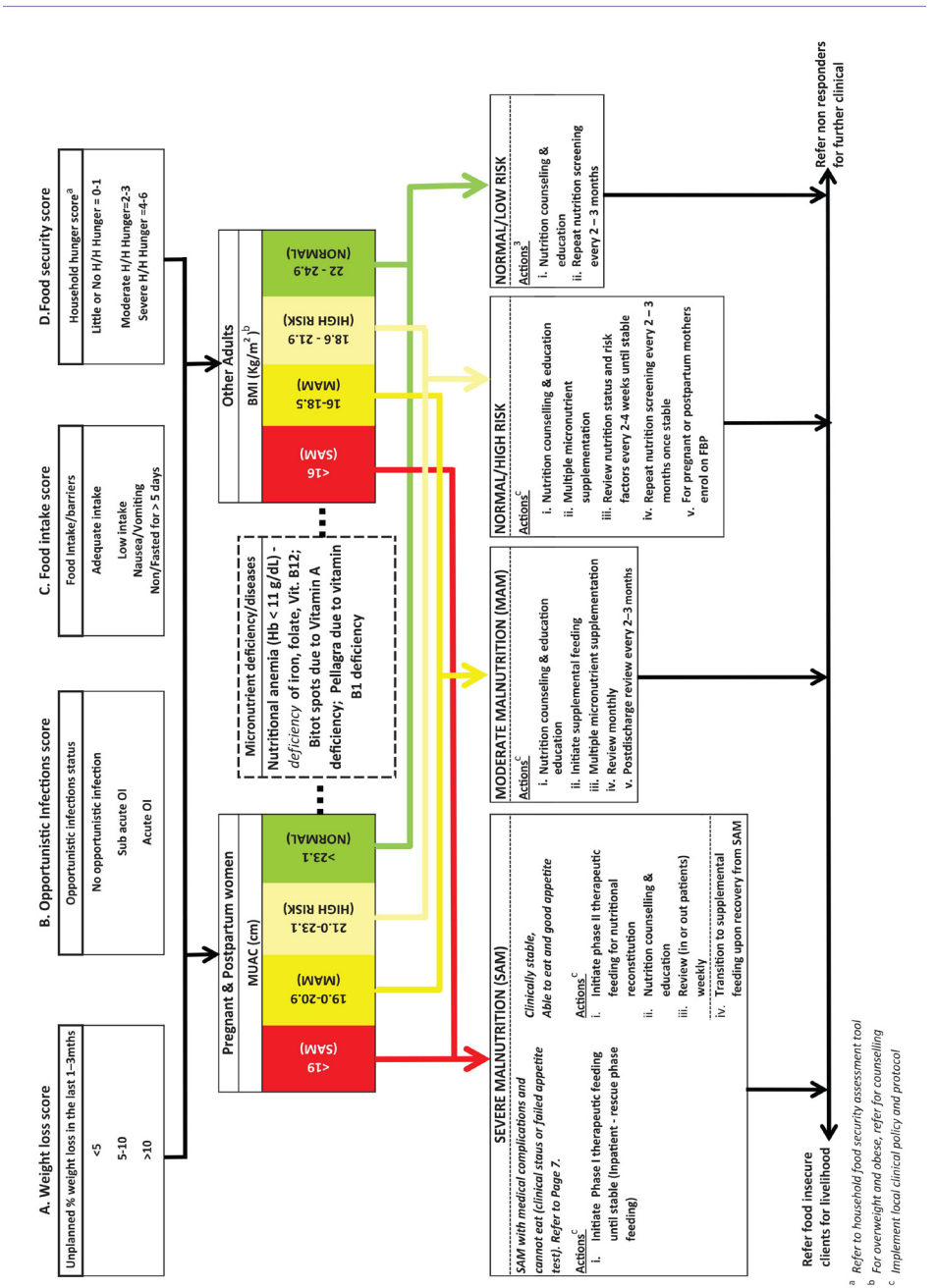
Other medical complications that necessitate hospitalization
In addition to severe bilateral pitting oedema (+++), marasmic kwashiorkor and poor appetite, the following complications necessitate inpatient care:

- ✓ Intractable vomiting
- ✓ Convulsions
- ✓ Lethargy, not alert
- ✓ Unconsciousness
- ✓ Lower respiratory tract infection
- ✓ High fever
- ✓ Severe dehydration
- ✓ Severe anaemia
- ✓ Hypoglycaemia
- ✓ Hypothermia
- ✓ Eye signs of vitamin A deficiency
- ✓ Skin lesions

The following complications require referral of patient for further medical evaluation:

- ✓ No appetite (failed appetite test)
- ✓ IMCI danger signs
- ✓ Increase in or newly developed bilateral pitting oedema
- ✓ Weight loss because of diarrhoea (re-feeding or other origin)
- ✓ Weight loss for three consecutive weeks
- ✓ Static weight (no weight gain) for five consecutive weeks
- ✓ Other signs of failure to respond to treatment

Figure 4.3: Management of Severe Acute Malnutrition in Children



4.21: Complementary Foods for Children 6-23 Months Old

Amount of Foods to Offer			
Age (months)	Texture	Frequency	Amount of food an average child will usually eat at each meal[1]
6-8	• Start with thick porridge, well mashed foods • Continue with mashed family foods	• 2-3 meals per day, plus frequent breastfeeds • Depending on the child's appetite, 1-2 snacks may be offered	• Start with 2-3 tablespoons per feed, increasing gradually to ½ of a 250mL cup
9-11	• Finely chopped or mashed foods, and foods that baby can pick up	• 3-4 meals per day, plus breastfeeds • Depending on the child's appetite, 1-2 snacks may be offered	• ½ of a 250mL cup/bowl
12-23	• Family foods, chopped or mashed if necessary	• 3-4 meals per day, plus breastfeeds • Depending on the child's appetite, 1-2 snacks may be offered	• ¾ to one 250mL cup/ bowl
[1]If baby is not breastfed, give an additional: 1-2 cups of milk per day, and 1-2 extra meals per day			

Note: HIV-positive mothers should be supported to exclusively breast feed for 6 months, with introduction of appropriate, adequate and safe complementary feeding from 6 months with continued breast-feeding until **at least** 12 months of age. Most infants will benefit from breastfeeding up to 23 months of age or beyond, irrespective of the mother's HIV status; infants should only be weaned from breast-feeding when adequate and safe foods are available. Risk of HIV transmission through breastfeeding is extremely low when the mother's viral load is undetectable.

4.8 Prevention of Other Infections

4.8.1 Immunizations

Childhood immunization

All children, regardless of HIV status, should be immunized following the full KEPI schedule (Table 4.22). For children with HIV, they should receive an earlier dose of measles vaccines at 6 months of age.

Table 4.22: Kenya Expanded Program on Immunizations 2016 Schedule

Age	Vaccines
Birth	OPV, BCG
6 weeks	OPV, Pentavalent (DPT-HepB-HiB), Pneumococcal, Rotavirus
10 weeks	OPV, Pentavalent (DPT-HepB-HiB), Pneumococcal, Rotavirus
14 weeks	IPV, Pentavalent (DPT-HepB-HiB), Pneumococcal
6 months	Measles (for PLHIV) and Vitamin A
9 months	Measles and Rubella
18 months	Measles and Rubella
11-12 years	Tdap (tetanus, diphtheria and pertussis)

PLHIV may have an inadequate response to immunizations, particularly before they achieve full viral suppression. The ideal timing, dose, and frequency of re-immunizations for children on ART are not well known. Providers will receive specific guidance or revaccination from the National Vaccines and Immunizations Programme and NASCOP.

Additional immunization recommendations for PLHIV include:

General considerations for immunization in adolescents and adults

- General guidance on vaccination in the general population applies
- Avoid live (replicating) vaccines if the CD4 < 200 cells/µl
- Suppressed VL (<1000 copies/ml) and high CD4 cell count (at least above 200 cells/µl; but best if >350 cells/µl) are associated with improved efficacy of vaccines and reduced risk of vaccine associated adverse reactions. Consider revaccination once the patient achieves CD4 > 200 cells/µl and/or suppressed VL < 1000 copies/ml
- Recommended vaccinations are listed in Table 4.23

Table 4.23: Vaccinations in Adolescents and Adults Living with HIV

Infection	Vaccine	Live (Y/N)	Course	Comments
Hepatitis B	Subunit	N	4 doses (at 0, 1, 2 and 6 months)	Engerix B/HBvaxPRO 40µg; Fendrix 20µg
Pneumococcus	Conjugate	N	1 dose (PCV 13)	Preferable to polysaccharide
	Polysaccharide	N	1 dose	Use if >65 years and with co-morbidity other than HIV
HPV	VLP	N	3 doses	Given over 6 months in girls 9 to 15 years (prior to sexual debut)
Influenza	Inactivated	N	1 dose	Annually
Yellow fever	Live attenuated	Y	1 dose	In those <60 yrs. of age and CD4 > 200 cells/µl
Typhoid	Polysaccharide	N	1 dose	Give the ViCPS parenteral. Repeat every 3 years
Cholera	Subunit	N	2 doses	As indicated (usually in epidemics). 2 oral doses of the non-replicating vaccine given 1-6 weeks apart with a single booster dose at 2 years from primary vaccination
Hepatitis A	Inactivated	N	2 - 3 doses	3 doses if CD4 count < 350 cells/µl at 0, 1 and 6 months. If CD4 count > 350 cells/µl, give 2 doses at 0 and 6 months. For those at continued risk, one booster dose every 10 years

4.8.2 Malaria

Children and adults living with HIV suffer heavier parasitaemia and more malaria morbidity with advanced HIV disease. Further, people with advanced immunosuppression are at risk of failure of anti-malarial treatment. In pregnancy, there is increased risk of placental malaria, severe anaemia, premature delivery and perinatal mortality. Drug interactions between ARVs and antimalarial drugs may further complicate management.

Recommendations for malaria prevention for PLHIV include:

- Offer cotrimoxazole preventive therapy to all PLHIV for protection against malaria infection (Section 4.3.1)
- In areas of stable malaria transmission, PLHIV should have access to insecticide treated mosquito nets (ITNs) or indoor residual spraying to reduce exposure to mosquito bites and therefore malaria transmission
- PLHIV travelling from non-malarious zones to malaria endemic areas should sleep under ITNs, and use effective anti-malarial prophylaxis according to the national guidelines (National Guidelines for the Diagnosis, Treatment and Prevention of Malaria in Kenya, Fourth Edition, 2014)

- Pregnant women with HIV living in areas of stable malaria transmission who are not able to take CPT should be given at least three doses of sulfadoxine-pyrimethamine (SP) intermittent preventive treatment for malaria as part of routine antenatal care; SP should not be given to women who are taking CPT
- PLHIV on CPT who develop fever should not be treated for a presumptive diagnosis of malaria. As far as possible, laboratory confirmation of malaria should be obtained prior to initiation of anti-malarial therapy
- PLHIV with malaria should receive standard antimalarial therapy according to national guidelines. However, those on CPT should not be given sulfa-containing anti-malarial drugs. Patients on ART receiving anti-malarial therapy should be monitored closely for adverse drug reactions

4.8.3 Safe Water, Sanitation and Hygiene

Diarrhoeal illnesses are common causes of morbidity and mortality among PLHIV. These diseases are often due to lack of access to safe drinking water, improper disposal of human and animal waste, and poor personal hygiene, leading to contamination of food and water.

Recommendations for prevention of faecal-orally spread illnesses include:

- Offer CPT to all PLHIV for protection against some GI infections (Section 4.3.1)
- PLHIV should be counselled to wash their hands with soap and water after handling human or animal faeces, after using the toilet, and before food preparation or eating
- Facilities for proper disposal of human waste should be available to PLHIV and their households
- PLHIV should be trained on, and provided with household-based water treatment methods and water storage containers that prevent direct hand contact with drinking water

5. Adherence Preparation, Monitoring and Support

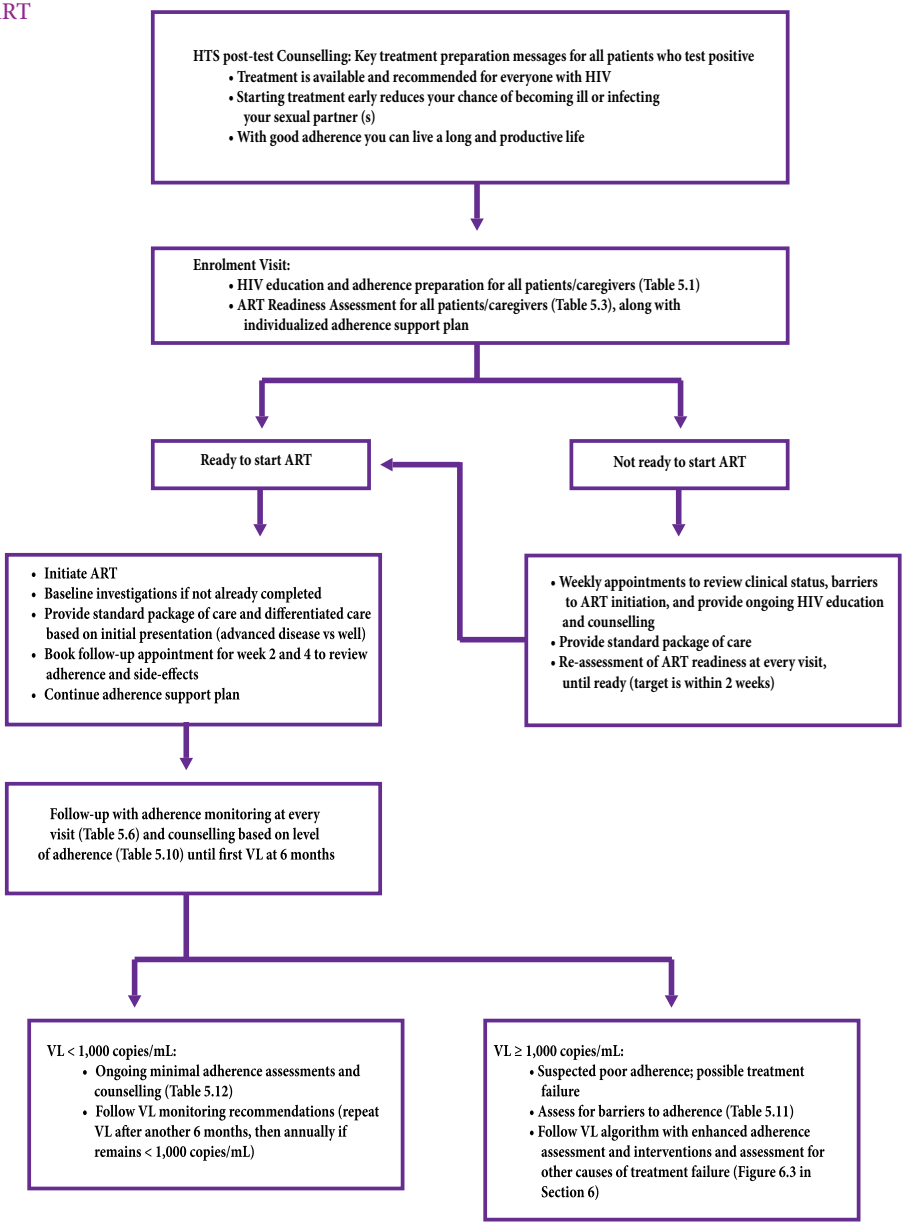
The individual benefits of ART (restoration and maintenance of health) and the population level impact (prevention of HIV transmission) are dependent on high levels of adherence to the prescribed medication, the accompanying medical advice and the follow-up plans. Adherence enhancing strategies should be implemented beginning at the point of HIV diagnosis (as part of post-test counselling and linkage), and continued during initial evaluation and follow-up for ART.

To avoid treatment failure and the need to switch patients to 2nd or 3rd line ART, it is key to have an adherence support strategy in place before ART initiation, anticipating common and individual barriers to good adherence. **Prevention of treatment failure starts before ART initiation.** This is particularly important with the new recommendation that all PLHIV qualify for ART, and ART should be initiated within 2 weeks of diagnosis. Adherence preparation must begin at time of HIV testing, and close follow-up is required after ART initiation.

The adherence preparation, monitoring, and support that a patient requires should be tailored to their level of adherence and the stage of ART initiation and follow-up that they are at (Figure 5.1).

Whenever possible, follow-up should be provided by the same care provider or team of care providers (e.g. same clinician and same counsellor) at every visit. This is particularly important during the first 6 months in care.

Figure 5.1: Adherence Preparation, Monitoring and Support until Viral Load after 6 Months on ART



Adherence is most difficult during the first few months of treatment: the patient is not yet in the habit of taking their medications every day, they are not familiar with common side-effects, and they have more challenges with disclosure and stigma, all of which can interfere with adherence. Poor adherence within the first few months of therapy is also the most risky period for development of resistant mutations, when the viral load is still high.

For these reasons, adherence preparation, monitoring and support must be emphasized during the first six months of ART, until the patient achieves full virological suppression.

Patient preparation and counselling should be a collaborative process between the provider and the patient or caregiver, to enable the patient to initiate and continue lifelong treatment. This is best done when the same adherence counsellor follows an individual patient throughout the preparation, initiation, and early ART period.

In some situations ART can be initiated concurrently with the first adherence counselling session, even during the enrolment visit, such as for neonates, infants, and for pregnant women. This may also apply to patients who enrol into care with a pre-existing good understanding of HIV and ART and strong motivation for immediate ART initiation. In these scenarios, even closer counselling and support must be continued during the early follow-up visits.

Every member in multidisciplinary team should provide treatment education and offer appropriate support to address potential barriers to adherence. Treatment preparation and support can be offered at triage, consultation, pharmacy or any other clinic station where confidentiality and privacy is assured and providers are adequately trained. It should also be incorporated into health talks, peer support group activities, and group counselling sessions.

Operational Guidance: Meaningful Involvement of People Living with HIV

For best patient outcomes, PLHIV themselves should be engaged to lead facility-based and community-based HIV education and support systems. They are often referred to as "peer educators", "mentor mothers", and "lay health workers" in these roles. PLHIV have successfully and significantly contributed to: improving identification of people at risk for HIV or infected with HIV; increasing linkage from testing to treatment; reducing onward transmission of HIV; providing psychosocial support, and; improving adherence and retention to care and ART.

Identifying PLHIV to engage in patient support systems:
- PLHIV on ART for ≥ 1 year
- Good adherence and undetectable VL
- Positive attitude and interest in supporting peers

Preparing and supporting PLHIV to play a role in patient support systems:
- Must be trained for the role they are expected to provide
- Must have job aids and IEC material appropriate for their role
- Must be supervised by healthcare professionals

Potential roles for PLHIV include:
- Providing HIV testing services
- Acting as peer linkage officers
- Leading or contributing to facility-based or community-based support groups
- Providing individual or group HIV education
- Providing individual or group adherence counselling
- Distribution of ART refills for stable patients

Compensation for PLHIV who contribute to patient support systems:
- Recognition (e.g. ID badges; certificates of service; acknowledgement at community forums)
- Training opportunities with certification
- Financial compensation (e.g. stipends; transportation allowances; salaries)
- First consideration for employment opportunities

5.1 ART Adherence Preparation

Preparation for ART begins at the time of HIV diagnosis and continues until initiation of ART.

5.1.1 Treatment Preparation as Part of HIV Testing Services

With the new treatment guidelines recommendation that all PLHIV qualify for ART, post-test counselling by the HTS provider should now include three key messages that begin the ART treatment preparation process for all PLHIV:

- Treatment (called antiretroviral therapy (ART)) is available and is recommended for everyone with HIV
- Starting treatment as soon as possible (preferably within two weeks of testing positive for HIV) reduces the chance of your illness getting worse or of passing HIV to others
- If you take your ART properly and do not miss pills you can expect to live a long and productive life

5.1.2 ART Treatment Preparation

ART treatment preparation involves HIV education and counselling, including a discussion of support systems to overcome possible barriers to adherence.

HIV Education and Counselling

HIV education and adherence preparation should be a standard component of the enrolment visit. Prior to ART initiation, all patients/caregivers must be provided with enough information to make an informed choice about ART initiation and adherence (Table 5.1), including for patients who initiate ART during the enrolment visit. A detailed content guide for HIV education and adherence counselling is provided in Annex 8. This information can be provided through group or individual counselling. The ART Readiness Assessment and the management plan should be completed individually.

Table 5.1: Components of HIV Education and Adherence Counselling (see Annex 8 for detailed content guide)

Component	Questions to be Covered
HIV	• What is HIV • How is HIV transmitted • Why should family members be tested for HIV
Viral load	• What is viral load • How often is viral load measured • What do viral load measurements mean
CD4 cells	• What are CD4 cells • How are CD4 cells affected by HIV • What happens when CD4 cells decrease • How often is CD4 cell count measured
Antiretroviral therapy (ART)	• What is ART • What are the benefits of ART • When is ART started • Does ART cure HIV • Can you still give HIV to others while taking ART • How long is ART taken
Treatment failure	• What happens if you stop taking ART • What happens if you do not take ART regularly • What happens if the viral load increases • What happens in treatment failure
ART side effects	• What are the side-effects of ART • What should you do if you notice any side effects
Adherence	• What is adherence • How should ART be taken • What usually interferes with good adherence • What might make it difficult for you individually to take your ART as prescribed • What can help you take ART as prescribed • What happens if you miss an appointment
Other medications	• What other medications will you take, in addition to ART (e.g. CPT, IPT)
Nutrition	• Why is nutrition important • What can you do to improve your nutrition
Follow-up	• How often will you need to come to clinic • What will we be checking for during your clinic visits
ART readiness assessment	• Are you ready to start ART today
Management plan	• Which investigations will you have today • Which medications will you start today • What else is required as you start or as you prepare to start ART • When should you return to the clinic

HIV education and counselling should be provided by a trained counsellor. This can be a peer educator, social worker, nurse, clinician, community health volunteer or any other healthcare worker who has completed training and mentorship on counselling for PLHIV. Completion of professional counsellor training is preferred.

Treatment preparation must be customized to the patient's needs and clinical status: for patients who present with advanced/symptomatic disease, the focus is on getting better; for patients who present clinically well, the focus is on staying healthy.

The ART HIV education and counselling session should be repeated at every visit (preferably with the same counsellor, peer educator, and/or clinician) until the patient is ready and willing to start ART, as determined using the ART Readiness Assessment Form (Table 5.3). Each repeat session should begin with a review of what the patient remembers from the previous session as well as any key issues the counsellor documented in the patient's chart, so the session can be customized to meet their needs. The ART preparation should not take more than 1-2 weeks except for special circumstances such as with uncontrolled mental health issues or untreated drug addictions.

Adherence Support

Psychosocial support for PLHIV and their families is essential for their well-being and good health outcomes. HIV affects virtually every aspect of one's life, as well as the lives of those close to them. PLHIV need psychological and social support to deal with various issues that are common to chronic illness as well as those that are unique to HIV. These include stigma, bereavement, self-image, loss of earning capacity, life skills, and chronic illness, among others. Providing psychosocial support entails identifying any needs that they may have and addressing them. In some cases, some of these needs can be anticipated and addressed even before they come to play in the individual's life.

The individualized patient management plan should include establishing appropriate adherence support interventions (Table 5.2).

Table 5.2: Adherence Support and Retention Interventions

Standard Adherence Support Interventions	
Structural interventions	• Conduct a baseline psychosocial assessment to explore the various aspects of the client's life that may influence their adherence to care and treatment, and their general well-being and tease out issues that need to be explored in detail during the counselling session e.g. disclosure, family planning, living circumstances • Use a multidisciplinary team approach to develop and implement treatment plans for each patient • Engage peer educators to lead HIV education and support services • Adequately prepare and assess the patients' readiness to initiate and continue with ART • Implement a system for identifying and taking action when patients miss an appointment • Formalize a system for providing health talks and treatment literacy classes for patients • Formalize a system for linking patients to community-based resources, including: community support groups, religious groups, CBOs, groups supporting income-generating activities, organizations providing food support, NEPHAK, child welfare societies, community health volunteers/ units, schools, children's homes
HIV education and counselling	• Remind the patient about HIV disease, how ART works, the importance of high level adherence and the consequences of non-adherence - Risk of ill health caused by HIV - Role of ART in restoring and maintaining good health - Link between adherence and viral load, CD4 and health - Side effects of medications and how to avoid, recognize and manage them. Manage side effects aggressively - Address misconceptions and beliefs about HIV and ART • Discuss and agree on a treatment plan with the patient. Gain commitment from the patient to follow through • Discuss use of alcohol and drugs and how to prevent these from affecting the treatment plan • For children it is important to maintain a non-judgemental attitude, establish trust with parents/caregivers, and involve the child as they mature
Disclosure and stigma	• Respect patient privacy and confidentiality • Discuss with the patient the role of disclosure to close family members/ trusted friend in promoting adherence • Offer to facilitate disclosure • For children/adolescents, discuss age-appropriate disclosure with the caregiver and offer to support the process (Annex 5) • Conduct stigma assessment and support appropriately
Treatment supporter	• Encourage the patient to identify a treatment supporter/buddy who will provide the patient with encouragement and social support and even remind the patient to take medication • Invite the treatment supporter to at least one of the adherence counselling sessions • Obtain consent from the patient to contact the treatment supporter if needed

Support group	• Link the patient to psychosocial support groups and other community-based support mechanisms (preferably through direct introduction) - Support groups give confidence and encouragement and promote positive attitude towards HIV status and may promote disclosure - Support groups offer opportunities for additional counselling and experience sharing, and are an avenue for developing/strengthening life skills - Some support groups engage in economic empowerment activities • Develop population-specific support groups when possible (e.g. youth groups with peer educators for adolescents; children's clubs; caregiver support groups) • MDT members should be patrons to the support groups, to guide activities in line with intended objectives *For more information, refer to the National Guidelines for the Formation and Management of Support Groups, 2013*
SMS reminder system	• Enrol patients into an automated SMS reminder system with their consent • Review the type of messages the patient may receive, the frequency of messages, and any actions the patient should take when receiving the message • Ensure the system and messages maintain patient privacy and confidentiality
Other reminder strategies	• Encourage patient/caregiver to set a specific time of day to take ART, and to associate ART time with a specific event/s in their daily schedule • Encourage patient/caregiver to set an alarm on their phone

5.1.3 ART Readiness Assessment

Table 5.3: ART Readiness Assessment Form

Criteria	Y/N*
A. Psychosocial/Knowledge Criteria (applies to patients and caregivers)	
1. Understands the nature of HIV infection and benefits of ART?	
2. Has screened negative for alcohol or other drug use disorder, or is stable on treatment (see Section 4.6)	
3. Has screened negative for depression or other psychiatric illness, or is stable on treatment (see Section 4.6)	
4. Is willing to disclose/has disclosed HIV status, ideally to a family member or close friend?	
5. Has received demonstration of how to take/administer ART and other prescribed medication?	
6. Has received information on predictable side effects of ART and understands what steps to take in case of these side effects?	
7. For patients dependent on a caregiver: caregiver is committed to long-term support of the patient, daily administration of ART, and meets the criteria above?	
8. Other likely barriers to adherence have been identified and there is a plan in place to address them (e.g. frequent travel for work, plan to deal with unexpected travel, distance from clinic, etc)?	
9. Patient/caregiver has provided accurate locator information and contact details?	
10. Patient/caregiver feels ready to start ART today?	
B. Support Systems Criteria (applies to patients and caregivers)	
1. Has identified convenient time/s of day for taking ART, and/or associated dose/s with daily event/s?	
2. Treatment supporter has been identified and engaged in HIV education, or will attend next counselling session?	
3. Is aware of support group meeting time/s?	
4. If facility has SMS reminder system: Has enrolled into SMS reminder system?	
5. Other support systems are in place or planned (e.g. setting phone alarm, pill box)?	
C. Medical Criteria (applies to patients)	
1. Newly diagnosed TB: **defer ART until patient tolerating anti-TB medications; initiate ART as soon as possible within the first 8 weeks of TB treatment (preferably within 2 weeks); monitor closely for IRIS**	
2. Newly diagnosed cryptococcal meningitis (CM), or symptoms consistent with CM (progressive headache, fever, malaise, neck pain, confusion): **defer ART until completed 4 weeks of CM treatment (if amphotericin plus fluconazole) or 4-6 weeks of CM treatment (if fluconazole alone) and symptoms resolved, or until ruling out CM as the cause of symptoms; monitor closely for IRIS**	

*If the response to any of the psychosocial criteria or support systems criteria is "No": develop a strategy to address the issue as quickly as possible, and consider assigning a case manager. ART may be initiated with adequate adherence support while the criteria is being addressed, or ART may be deferred until the criteria is met, on a case-by-case basis

At each visit up until ART initiation, every patient should be assessed for his or her readiness to start ART (Table 5.3); with each patient/caregiver allowed to make the final decision on whether and when to start ART.

5.1.4 Additional Considerations for Caregivers, Children and Adolescents

Children and adolescents depend on caregivers to support their adherence so there are special considerations for adherence preparation and support. All topics covered in the HIV Education and Adherence Counselling sessions (Table 5.1 and Annex 8) should be covered with the caregiver, with involvement of the child/adolescent as appropriate based on the stage of disclosure and their developmental stage (Table 5.4).

Table 5.4: Age-appropriate Involvement of Child/Adolescent in HIV Education and Adherence Counselling

Age	Counselling Approach
< 6 years old	The counselling sessions will focus on engaging all of the child's caregivers
6-12 years old	Both the caregiver and the child will be involved. The counselling will focus on the caregiver; younger children can be given a paper and pen and asked to draw their family, school, etc, and talk about their experiences. Disclosure of HIV status to the child should commence by 5 years of age and be completed by 10-12 years of age (Annex 5)
> 12 years old with caregiver present	Most of the counselling can focus on the adolescent, who is often fully responsible for medication administration. However, it is necessary to keep the caregiver coming and involved in supporting the adolescent. A recommended approach is to start with the caregiver alone, then see the caregiver and adolescent together, and then see the adolescent alone. Use the HEADSSS tool* to facilitate discussion
> 12 years old without the caregiver present	Use the HEADSSS tool* to facilitate discussion. Negotiate involvement of a treatment supporter

*HEADSSS assesses: Home; Education/Employment; Activities; Drugs; Sexuality; Suicide/depression/self-image; Safety. The HEADSSS tool is the in Paediatric Toolkit 2016 (A Guide for Caring for Children and Adolescents Living with HIV in Kenya)

In addition to the standard HIV Education and Adherence Counselling topics, unique issues need to be addressed for caregivers, children and adolescents (Table 5.5).

Table 5.5: Unique Considerations for Caregivers, Children and Adolescents

Caregiver Barriers to Adherence
• Frequently changing or multiple simultaneous caregivers
• Absent or sick caregiver
• Poor understanding of HIV management due to inadequate counselling, elderly, or illiterate caregiver
• Depression, alcohol and other drug use
• Living far from the health facility
• Economically unstable
• Lack of affection between caregiver and child
• Lack of support systems for the caregiver
Child/Adolescent Barriers to Adherence
• Level of disclosure (is the child/adolescent aware of their HIV status?)
• Lack of understanding of disease/treatment
• Developmental stages and emotional state
• Child refusal to swallow medicine (never allow dosing refusal: all activities should stop for the child until the dose is swallowed)
• Stigmatization and discrimination
• Low self-esteem
• Depression
• Defiance related to a troublesome caregiver-child relationship
• Inadequate structures at school (day or boarding) to support adherence
• Lack of support systems for the child/adolescent
Treatment Barriers to Adherence
• Large volumes of syrups
• Bad taste of syrups
• Pill burden
• Confusing regimens combining syrups and tablets
• Side effects
• Dose adjustment requirements as the child grows

For all children/adolescents, the level of disclosure should be assessed at first visit and the management plan should include a plan for age-appropriate disclosure (Annex 5).

5.2 Adherence Monitoring, Counselling and Support During the First 6 Months of ART

Once ART has been initiated, adherence should be assessed non-judgementally by a trained provider during each visit (Table 5.6). The objectives of this assessment are to evaluate and reinforce the patient's adherence to ART, to elicit any barriers to the same, and to develop a plan with the patient/caregiver to address any of the barriers identified. These may include incorrect knowledge of HIV infection and ART, unsupportive psychosocial factors, difficult home or school environment, substance use and poor motivation for taking medication. Patients/caregivers need to be counselled on the importance of being honest about their adherence in order for the healthcare team to serve them better.

Table 5.6: Adherence Monitoring Strategies

Adherence Monitoring Strategy	Technique	Frequency
Subjective (self-reported adherence)		
Morisky Medication Adherence Scale-4	Use Table 5.7 to assess adherence using a standardized questionnaire, and take action as required	Every patient, every visit
Morisky Medication Adherence Scale-8	Use Table 5.8 to assess adherence using a standardized questionnaire, and take action as required	Any time a healthcare worker suspects adherence problems (e.g. patients with suspected or confirmed treatment failure; patient who misses an appointment)
Objective		
Pill counts	Ask the patient to bring all their pills with them to follow-up visits. Calculate how many pills should be remaining based on the previous prescription date and amount prescribed, and compare to how many pills are actually remaining. Excess pills are assumed to be missed doses. Use Table 5.9 to calculate adherence rate and take action as required	• At every visit until confirmed viral suppression • Any time a healthcare worker suspects adherence problems
Pharmacy refill records	Compare drug pick-up date with expected date of pick-up (based on number of pills dispensed at last visit). If drug pick-up date is later than expected, it is assumed the patient is missing doses equivalent to the number of days late	• At every drug pick-up • Any time a healthcare worker suspects adherence problems
Viral load	Follow the VL monitoring algorithm (Figure 6.3 in Section 6). VL < 1,000 copies/mL is the best available confirmation of adequate adherence	• After starting ART: at months 6, 12, and then annually • For pregnant and breastfeeding women: every 6 months (and at 1st ANC visit if already on ART)
Home visit	Observe where and how a patient stores and takes their medications, and assess if they have extra medications because of missed doses. Home visits may also provide a better understanding of a patient's living situation and specific barriers to adherence. Unscheduled home visits may be more revealing, but should only be conducted if the patient consented to home visits previously (preferably at the time of enrolment or initiation)	For patients with suspected or confirmed treatment failure, patients who default from care, or any time the MDT feels a home visit will contribute to patient management

Accurately assessing adherence requires clinicians to develop a collaborative and non-judgmental relationship with patients. This is best done when one provider follows an individual patient longitudinally. The key to asking patients about their adherence is not in the specifics of the tool used but in taking the time to ask about adherence regularly, and doing so in an open and truly inquisitive manner. Otherwise, many patients will simply state what they believe the clinician wants to hear: perfectly adherent.

Every provider in each ART service delivery point should receive training and gain confidence in assessing adherence and providing adherence support and counselling to the majority of patients who do not have significant barriers to adherence. However, patients with significant adherence challenges and multiple barriers to adherence should be referred to providers with additional training and time to offer dedicated and enhanced adherence support and counselling. Involving experienced colleagues at the same health facility should be done as soon as a concern is identified, and the patient should be discussed by the MDT to generate as many solutions as possible. Consultation with Mental Health Teams or regional or national mentors may be required for complex situations.

Table 5.7: Morisky Medication Adherence Scale (MMAS-4)

MMAS-4: Ask the patient each question below. Circle the corresponding score for each response. After completion of all questions, add up all the points that you have circled for the total score.		
Question	Yes	No
1. Do you ever forget to take your medicine?	1	0
2. Are you careless at times about taking your medicine?	1	0
3. Sometimes if you feel worse when you take the medicine, do you stop taking it?	1	0
4. When you feel better do you sometimes stop taking your medicine?	1	0
Total Score (sum of all items)		

Interpretation of MMAS-4 Score		
MMAS-4 Score	Adherence Rating	Action Required
0	Good	Continue with routine monitoring, counselling and support
1-2	Inadequate	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 5.11) • Engage treatment supporter in adherence counselling sessions • Follow up in 2-4 weeks
3-4	Poor	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 5.11) • Engage treatment supporter in adherence counselling sessions • Implement DOTs • Follow up in 1-2 weeks

Table 5.8: Morisky Medication Adherence Scale (MMAS-8)

MMAS-8: Ask the patient each question below. Circle the corresponding score for each response. After completion of all questions, add up all the points that you have circled for the total score.		
Question	Yes	No
1. Do you ever forget to take your medicine?	1	0
2. Are you careless at times about taking your medicine?	1	0
3. Sometimes if you feel worse when you take the medicine, do you stop taking it?	1	0
4. When you feel better do you sometimes stop taking your medicine?	1	0
5. Did you take your medicine yesterday?	0	1
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicine?	1	0
7. Taking medication every day is a real inconvenience for some people. Do you ever feel under pressure about sticking to your treatment plan?	1	0
8. How often do you have difficulty remembering to take all your medications? (Please circle the correct number) ___A. Never/Rarely ___B. Once in a while ___C. Sometimes ___D. Usually ___E. All the time	Points: A. 0 B. ¼ C. ½ D. ¾ E. 1	
Total Score (sum of all items)		

Interpretation of MMAS-8 Score		
MMAS-8 Score	Adherence Rating	Action Required
0	Good	Continue with routine monitoring, counselling and support
1-2	Inadequate	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 5.11) • Engage treatment supporter in adherence counselling sessions • Follow up in 2-4 weeks
3-8	Poor	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 5.11) • Engage treatment supporter in adherence counselling sessions • Implement DOTs • Follow up in 1-2 weeks

Table 5.9: Adherence Rate Based on Pill Counts

Missed Doses per Month		**% of Medications Taken**	**Adherence Rating**	**Action Required (see Table 5.10 for more details)**
For once-daily regimen	For BD regimen			
1 dose	1-3 doses	≥ 95%	Good	• Continue with routine monitoring, counselling and support
2-4 doses	4-8 doses	85-94%	Inadequate	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 5.11) • Engage treatment supporter in adherence counselling sessions • Follow up in 2-4 weeks
≥ 5 doses	≥ 9 doses	< 85%	Poor	• Discuss as an MDT • Assign a case manager • Assess for and address barriers to adherence (Table 5.11) • Engage treatment supporter in adherence counselling sessions • Implement DOTs • Follow up in 1-2 weeks

5.2.2 Adherence Counselling and Support During the First 6 Months of ART

All patients recently initiated on ART need careful adherence monitoring and support to ensure they achieve virological suppression. This is particularly important given the brief pre-initiation preparation phase. The intensity of counselling and support are dependent on the patients' level of adherence as assessed by the methods described in section 5.2.1.

Table 5.10 summarizes adherence counselling and support for patients from the time of ART initiation until the 6-month viral load results are available. For patients who have inadequate or poor adherence, Table 5.11 describes the assessment for barriers to adherence.

Table 5.10: Adherence Counselling and Support During the First 6 Months of ART

No adherence concerns (based on adherence assessment and healthcare team opinion)	
Counselling: Group or Individual, at every visit (can be done by any member of the healthcare team, including the clinician)	• Review patient/caregiver HIV knowledge (Table 5.1, Annex 8) and address any gaps • Review patient/caregiver understanding of ART administration (dosing, timing, frequency) and address any gaps • Elicit any concerns the patient/caregiver has about ART, other medications, visit schedule, or health. Address any concerns or engage another care team member who can address them • Explore any major recent or expected changes in the patient's/ caregiver's life or daily routine that could disrupt adherence • Update patient locator and contact information
Support	• Encourage the patient/caregiver to continue with the support systems discussed and implemented pre-ART • Encourage introduction of additional standard support systems (Table 5.2), including supporting disclosure as needed
Inadequate or poor adherence (based on adherence assessment or healthcare team opinion)	
Counselling: Individual, at every visit until adherence is good (preferably by someone trained on adherence counselling)	• **Assess for and address potential barriers to adherence (Table 5.11)** • Review patient/caregiver HIV knowledge (Table 5.1, Annex 8) and address any gaps • Review patient/caregiver understanding of ART administration (dosing, timing, frequency) and address any gaps • Elicit any concerns the patient/caregiver has about ART, other medications, visit schedule, or health. Address any concerns or engage another care team member who can address them • Explore any major recent or expected changes in the patient's/ caregiver's life or daily routine that could disrupt adherence • Update patient locator and contact information
Support	• Review effectiveness of support systems they already have in place • Encourage introduction of additional standard and enhanced support systems (Table 5.2), including supporting disclosure as needed, assigning a case manager and considering DOTs

Table 5.11: Assessing Barriers to Adherence

Theme	Assessment
Awareness of HIV status	• Has the patient/caregiver accepted HIV status? • For children/adolescents: is age-appropriate disclosure underway/complete?
Understanding of HIV infection and ART?	• How HIV affects the body and risk of transmission to sexual partners and children • ART and how it works • Understanding of side effects and what to do in case of side effects - "Have you experienced any side effect since your last visit? Has this affected the way you take your medicine?" • Benefits of adherence • Consequences of non-adherence including drug resistance and treatment failure
Daily routine	• Review the patient's/caregiver's daily routine: "Tell me about your typical day" • Review how the patient takes medicine or how the caregiver administers it: - "Please tell me how you take each of your medicines?" - "How does taking your medicine fit into your daily routine?" • If the patient's/caregiver's daily routine conflicts with medication schedule, work with them to find a new medication schedule that will be more appropriate • Remind the patient/caregiver to take/give missed or delayed doses as soon as he/she remembers (up to 12 hours late if on a once-daily regimen, or up to 6 hours late if on a twice-daily regimen). The next dose should be taken at the usual time • "What do you do in case of visits, and travel?" • Remind the patient/caregiver to plan travel well, pack sufficient medicine; but should their medication get finished before they return, advise them to visit the closest ART centre and show their appointment card to get a refill • For orphans it is critical to assess who the primary caregiver is and their commitment
Psychosocial circumstances	Home environment: • "Who do you live with?" • "Who is aware of your HIV status? Are there people in your life with whom you've discussed your HIV status and ART use?" - Discuss the usefulness of enlisting the support of family members, friends or a treatment supporter/buddy in reminding them to take medication (for children/adolescents, this includes teachers and/or supportive peers at school); offer assisted disclosure - Encourage the patient to identify and bring a treatment supporter during the next visit • Support system (treatment buddy, psychosocial support groups, etc) • Changes in relationships with family members/friends • Screen the patient/caregiver for alcohol and substance abuse (Tables 4.15 and 4.16 in Section 4) - Discuss impact on ability to remember to take medication - Explore motivation to stop and offer support/referral - Encourage limiting use and planning ahead so as not to forget to take medication • Screen for gender-based violence (Section 4.2.2) • Stigma and discrimination - "Does it bother you people might find out about your HIV status?" - "Do you feel that people treat you differently when they know your HIV status?" • Discuss if stigma is interfering with taking medication on time, or with keeping clinic appointments • Beliefs: has the patient tried faith healing? Has the patient ever stopped using medication because of religious beliefs?
Mental Health Screening	• Screen patient/caregiver for depression using the PHQ-9 (Table 4.14 in Section 4) and manage/refer as required
Referrals	• Establish if the patient has been referred to other services (including nutrition, psychosocial support services, other medical clinics, substance use treatment, etc) • Did he/she attend the appointments? What was his/her experience? Do the referrals need to be re-organized?

5.3 Adherence Monitoring, Counselling and Support for Patients with Viral Load < 1,000 copies/mL

Once a patient has confirmed viral suppression (with VL < 1,000) this is confirmation of adequate adherence to ART. The patient can be reassured that they will do well if they continue to adhere. However, *all patients are at risk of new or worsening barriers to adherence, so adherence monitoring, counselling and support should continue despite viral suppression, but at a lower intensity and frequency unless concerns are identified (Table 5.12).*

Table 5.12: Adherence Counselling and Support for Patients with Viral Load < 1,000 copies/mL

No adherence concerns (based on adherence assessment and healthcare team opinion)	
Counselling: Group or Individual, every visit	• Elicit any concerns the patient/caregiver has about ART, other medications, visit schedule, or health. Address any concerns or engage another care team member who can address them • Explore any major recent or expected changes in the patient's/caregiver's life or daily routine that could disrupt adherence • Update patient locator and contact information
Support	• Encourage the patient/caregiver to continue with the support systems that are in place already
Inadequate or poor adherence (based on adherence assessment or healthcare team opinion)	
Counselling: Individual, at every visit until adherence is good	• **Assess for and address potential barriers to adherence (Table 5.11)** • Review patient/caregiver HIV knowledge (Table 5.1, Annex 6) and address any gaps • Review patient/caregiver understanding of ART administration (dosing, timing, frequency) and address any gaps • Elicit any concerns the patient/caregiver has about ART, other medications, visit schedule, or health. Address any concerns or engage another care team member who can address them • Explore any major recent or expected changes in the patient's/caregiver's life or daily routine that could disrupt adherence • Update patient locator and contact information
Support	• Review effectiveness of support systems the patient already has in place • Encourage introduction of additional standard and enhanced support systems (Table 5.2), including supporting disclosure as needed, assigning a case manager and considering DOTs

5.4 Enhanced Adherence Assessment and Interventions for Patients with Suspected or Confirmed Treatment Failure

Treatment failure should be suspected whenever a patient has been on ART for at least 6 months and has: a detectable viral load; a decline in CD4 count, or; any new or worsening clinical condition. Treatment failure is confirmed as per the viral load monitoring algorithm (Figure 6.3 in Section 6). Poor adherence is often the most important factor in developing treatment failure, through there can be other causes. Adherence must be thoroughly assessed and all issues must be addressed before switching patients to the next line of ART. ***Do not change regimens until the reason/s for treatment failure have been identified and addressed, and a repeat VL is still >1,000 copies/mL after 3 months of good adherence.***

5.4.1 Enhanced Adherence Assessments

As soon as treatment failure is suspected the patient/caregiver should be discussed by the facility multi-disciplinary team to develop a plan for assessing barriers to adherence (including scheduling a home visit), and assessing other potential causes of treatment failure (e.g. inadequate dosing/dose adjustments, drug-drug interactions, drug-food interactions, impaired absorption (e.g. chronic severe diarrhoea)).

Patients with suspected or confirmed treatment failure should undergo adherence assessments as described in Table 5.7, including the MMAS-8 and the home visit. If the patient has a caregiver, treatment buddy, and/or spouse/partner who is enrolled in HIV care, that person's file should also be reviewed to confirm their most recent viral load results and adherence.

All patients with suspected or confirmed treatment failure should have a thorough assessment of potential barriers to adherence (Table 5.11).

5.4.2. Enhanced Adherence Counselling

The goal of Enhanced Adherence Counselling is to assess possible barriers to adherence in a non-judgmental way and to help the patient construct an adherence plan with concrete objectives. It is important not to focus solely on knowledge of HIV and ART but also to review psychological, emotional, and socio-economic factors that may contribute to poor adherence. In addition, exploring the patient's motivation for taking medication often highlights reasons for poor adherence.

Three sessions of Enhanced Adherence Counselling are recommended as the minimum number of sessions, but additional sessions can be added as needed (Table 5.13). If the adherence is evaluated as adequate, a repeat viral load is done after three months of good adherence, and another Enhanced Adherence Counselling session is conducted to discuss the viral load results. A detailed content guide for Enhanced Adherence Counselling is provided in Annex 9.
It is preferable to have the patient go through all adherence counselling sessions with the same counsellor in order to provide continuity, and that the session is documented to ensure follow-up of all issues identified.

Table 5.13: Components of Enhanced Adherence Counselling Sessions (Annex 9 for detailed content guide)

Enhanced Adherence Counselling Sessions: Overview	
Session 1	• Review understanding of viral load (VL) and discuss why the patient's VL is high • Review cognitive, behavioural, emotional and socio-economic barriers to adherence: - Treatment literacy - Medications: dosage, timing, storage - Side effects - Discuss risk reduction (e.g. for substance abuse) - Motivation - Mental health screening (screen for depression using PHQ-9, Table 4.14) - Discuss patient's support systems • Referrals and networking • Assist patient to develop adherence plan to address the identified issues
Session 2	• Review adherence plan from the first session and discuss any challenges • Identify other possible gaps and issues emerging • Referrals and networking • Assist patient to modify the adherence plan to address the identified issues
Session 3	• Review adherence plan from the first and second session and discuss any challenges • Identify other possible gaps and issues emerging • Assist patient to modify the adherence plan to address the identified issues • Decision on repeat VL based on current adherence: - If the adherence is good: plan repeat VL testing after three months of good adherence and explain possible ways forward, emphasizing role of the patient and the health facility • If adherence challenges persist: plan further Enhanced Adherence Counselling sessions before repeating the VL
Session to Discuss Repeat Viral Load Results	• Discuss result of the second VL test • Plan the way forward: - If VL now < 1,000: continue current regimen with enhanced adherence, repeat VL after 6 months - If VL ≥ 1,000: prepare patient for change of regimen (Figure 5.2)
Enhanced Adherence Support Interventions (for patients failing or at high-risk of failing treatment)	
Case management	• Assign a case manager to all children and adolescents (those not achieving optimum treatment outcomes); pregnant women, orphans, patients with alcohol and substance abuse, patients with mental illness, patients with suspected or confirmed treatment failure, and any patients who the healthcare team feels has poor adherence or is at high risk of defaulting from care • The case manager is the link between the patient and the MDT • Roles of the case managers include: - Coordinating multidisciplinary management for patients under case management - Following up on appointment-keeping for their patients - Organizing patient reminders (SMS, calling the day before) and other support systems - Ensuring appropriate defaulter tracing - Coordinating home visits to their patients
Directly observed therapy	• Patients with suspected treatment failure should have DOTs to ensure good adherence before a viral load is repeated to confirm treatment failure • DOTs involves a healthcare provider, family member, treatment supporter or any trained peer observing the patient ingesting their prescribed ART on a daily basis • DOTs can be tapered off once the patient adopts consistent adherence-enhancing behaviours and barriers to adherence are overcome

5.4.3 Enhanced Adherence Support Systems

Adherence support systems will need to be adapted to patients' specific needs and the context (Table 5.13). Special attention needs to be given to children, adolescents, patients with mental health disorders and substance users.

Case Manager

All patients with suspected or confirmed treatment failure should be assigned a case manager. The case manager is the link between the patient and the MDT, and can coordinate other adherence support systems that may best serve the patient (Table 5.13).

Directly Observed Therapy/ Daily Witnessed Ingestion

For patients with an initial VL ≥ 1,000 copies/mL, the patient should have DOTs (somebody watching the patient actually swallow their medicine every day) to confirm good adherence for 3 months before repeating the viral load. DOTs can be provided by: healthcare workers, CHVs, peer educators, caregivers, or family members.

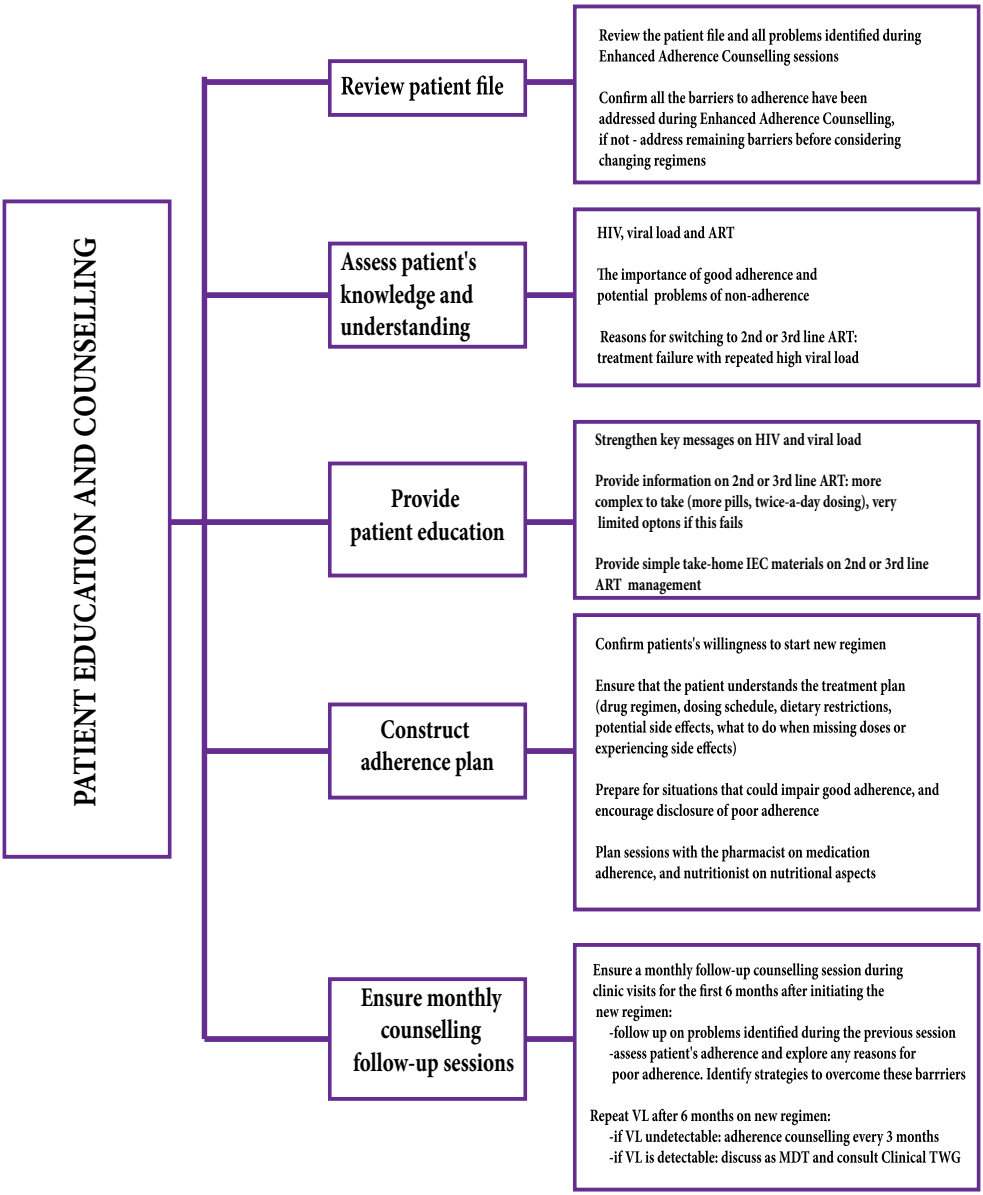
Support Groups

For health facilities with several patients who are failing treatment or who are on 2nd line ART, special support groups can be established so these patients can work through their adherence challenges together. Community support groups can also be engaged and linked to the facility for supporting patients with adherence challenges.

5.5 Treatment Preparation for 2nd Line or 3rd Line ART

After confirming treatment failure and making the decision to start 2nd line or 3rd line ART (based on discussion as an MDT, and in consultation with the Regional or National HIV Clinical TWG), the patient requires targeted counselling and education to prepare them for the new regimen and to support ongoing adherence (Figure 5.2). If the health facility has several patients on 2nd or 3rd line ART then consideration should be given to having the patients booked on the same day for a dedicated clinic with full MDT support.

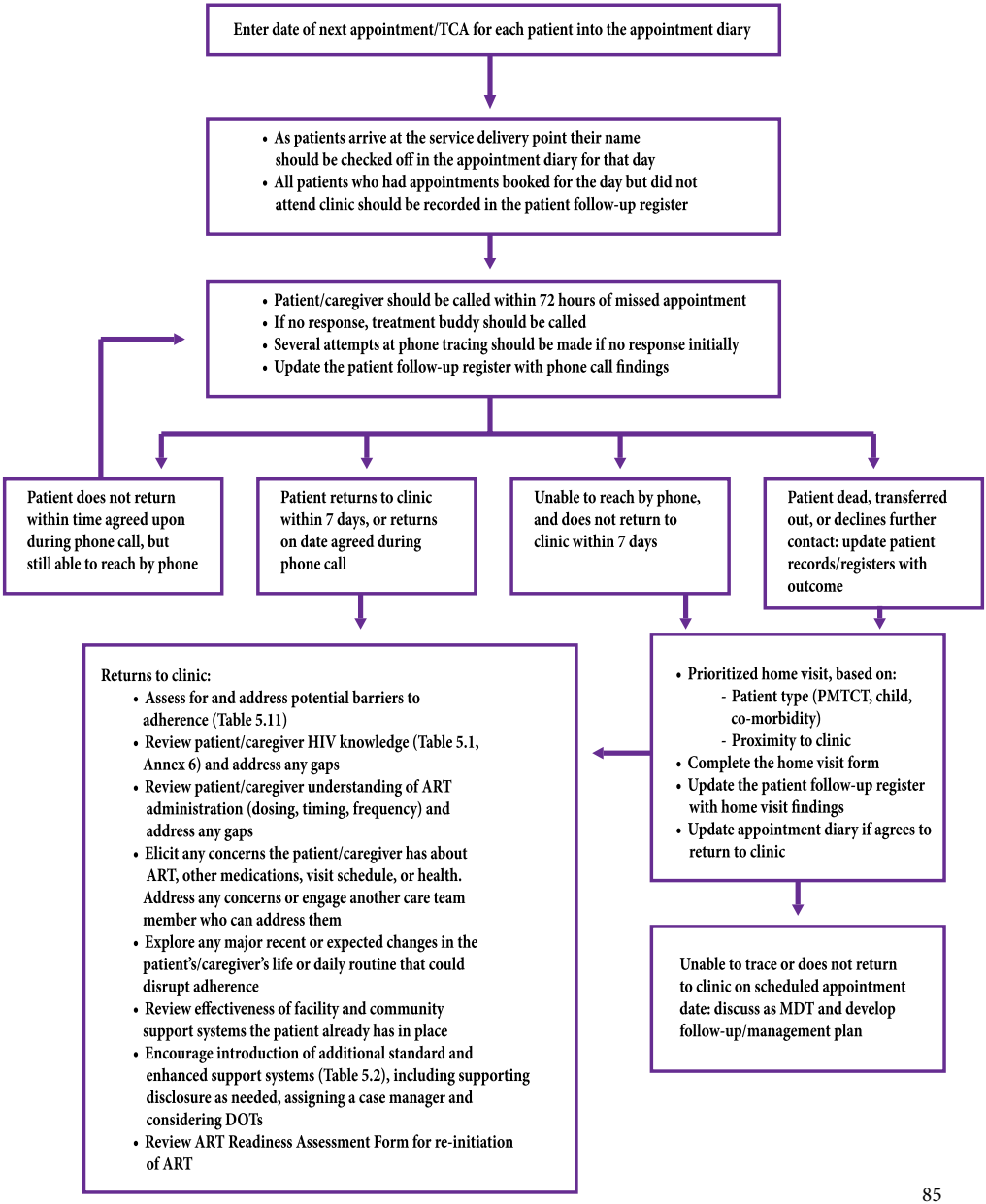
Figure 5.2: Adherence Counselling and Education for Patients Preparing to Initiate 2nd Line or 3rd Line ART



5.6 Identifying, Tracing, and Supporting Patients who Default from Care

Every service delivery point that is providing ARVs for patients (whether ART, PEP, or PrEP) must have a functional system for identifying patients who miss appointments and for taking action within 24 hours of a missed appointment (Figure 5.3).

Figure 5.3: Identifying, Tracing and Supporting Patients who Default from Care



6. Antiretroviral Therapy in Infants, Children, Adolescents, and Adults

Available ARVs, while very effective in managing HIV disease, cannot cure HIV infection. The goal of ART is to suppress viral replication with the aim of reducing the patient's VL to undetectable levels. Uninterrupted ART with ongoing strict adherence will help maintain undetectable VL levels thereby preventing damage to the body's immune system and restoring and maintaining healthy living, as well as reducing the risk of sexual and vertical transmission of HIV. Effective ART consists of a minimum of 3 agents from at least 2 different classes of ARVs.

6.1 Eligibility for ART

All individuals with confirmed HIV infection are eligible for ART, irrespective of CD4 cell levels, WHO clinical stage, age, pregnancy or breastfeeding status, co-infection status, risk group, or any other criteria.

6.2 Timing of ART Initiation

ART should be started in all patients as soon as possible (preferably within 2 weeks of confirmation of HIV status).

ART can be initiated as soon as patients meet the ART Readiness Criteria (see Section 5), even if it is the same day as enrolment into care. ART initiation on the same day as enrolment into care has additional benefits for HIV prevention (e.g. for pregnant and breastfeeding women, and the HIV positive partner in a discordant relationship), and may have additional mortality benefits for infants less than 12 months of age. Special considerations for timing of ART initiation are listed in Table 6.1.

Table 6.1: Special Considerations for Timing of ART Initiation

Enhanced Adherence Counselling Sessions: Overview	Timing of ART Initiation	Comments
Pregnant and breastfeeding	Consider ART initiation on the same day as enrolment	Intensive adherence counselling and close follow-up required because of limited time for patient preparation
Infants < 12 months	Consider ART initiation on the same day as enrolment	Intensive adherence counselling and close follow-up required because of limited time for patient preparation
Patients with strong motivation to start ART immediately	Consider ART initiation as soon as they meet ART Readiness Assessment criteria, even if on the same day as enrolment	Intensive adherence counselling and close follow-up required because of limited time for patient preparation
Patients with newly diagnosed TB	Defer ART until tolerating anti-TB medication; initiate ART within 8 weeks of starting TB treatment (preferably within 2 weeks)	Monitor closely for IRIS
Patients with cryptococcal meningitis	If treating CM with amphotericin and fluconazole: defer ART until after completing 4 weeks of CM treatment and symptoms have resolved If treating CM with fluconazole alone: defer ART until after completing 4-6 weeks of CM treatment and symptoms have resolved	Monitor closely for IRIS
Patients for whom adherence will be particularly challenging	Start ART as soon as adequate support systems are in place for adherence (e.g. enrolling a PWIDs into a methadone program; psychiatric treatment for a patient with mental illness; caregiver identified for an orphan)	A case manager should be assigned to all patients with complex adherence challenges
All other patients	Start ART within 2 weeks of HIV diagnosis, once they meet ART Readiness Assessment criteria	Adequate ART preparation, and continued adherence monitoring and support is recommended after ART initiation for all patients

6.3 First-Line ART for Infants, Children, Adolescents and Adults (including Pregnant and Breastfeeding Women)

The recommendations below apply to patients who are starting ART for the first time. Preferred and alternative first line regimens are shown in Tables 6.2 and 6.3. ARVs for infant prophylaxis are presented in Tables 7.4 to 7.6. As additional drugs become available through the national program, such as fixed-dose combinations with dolutegravir (DTG), wider access to raltegravir (RAL), lower-dose EFV, LPV/r pellets, and paediatric formulations of TDF, ATV/r and rifabutin, guidance on their use will be provided by NASCOP.

All patients must have weight taken and documented at every visit, and children and adolescents must have correct weight-based dosing of ARV confirmed at every visit.

Infants and children depend on their caregivers for adherence to medication. Palatability can also occasionally cause children to refuse medication. Caregivers should be adequately prepared for the role of administering ARVs to infants and children, including anticipated challenges and possible solutions.

Table 6.2: Preferred First-line ART Regimens and Dosing for Children, Adolescent and Adults[1]

Age	Preferred Regimen	Dosing[2] (correct weight-based dosing must be confirmed at every visit)
< 2 weeks	AZT + 3TC + NVP[3]	**AZT 4 mg/kg BD, 3TC 3 mg/kg BD, NVP 4 mg/kg BD** AZT/3TC/NVP 60/30/50 mg: (0.25 tab BD) **This regimen should only be continued until 2 weeks of age, then the infant should be switched to ABC+3TC+LPV/r**
2 weeks - < 4 weeks	ABC + 3TC + LPV/r	**2-2.9kg**: ABC/3TC (60/30mg): 0.5 tab BD, **plus** LPV/r (80/20mg/ml): 1.0 ml BD
		3-5kg: ABC/3TC (60/30mg): 0.5 tab in AM, and 1.0 tab in PM, **plus** LPV/r (80/20mg/ml): 1.0 ml BD
4 weeks - < 3 years	ABC + 3TC + LPV/r[4]	**3-5.9kg**: ABC/3TC (60/30mg): 1 tab BD, **plus** LPV/r (80/20mg/ml): 1.5 ml BD
		6-9.9kg: ABC/3TC (60/30mg): 1.5 tabs BD, **plus** LPV/r (80/20mg/ml): 1.5 ml BD
		10-13.9kg: ABC/3TC (60/30mg): 2 tabs BD, **plus** LPV/r (80/20mg/ml): 2 ml BD
		14-19.9kg: ABC/3TC (60/30mg): 2.5 tabs BD, **plus** LPV/r (80/20mg/ml): 2.5 ml BD, or LPV/r (200/50mg) 1 tab BID
3 - 15 years (< 35 kg body weight)	ABC + 3TC + EFV[5]	**10-13.9kg**: ABC/3TC (60/30mg): 2 tabs BD**, plus** EFV (200mg): 1 tab once daily
		14-19.9kg: ABC/3TC (60/30mg): 2.5 tabs BD, **plus** EFV (200mg): 1.5 tabs once daily
		20-24.9kg: ABC/3TC (60/30mg): 3 tabs BD, **plus** EFV (200mg): 1.5 tabs once daily
		25-34.9kg: ABC/3TC (300/150mg): 1 tab BD, **plus** EFV (200mg): 2 tabs once daily
3 - 15 years (≥ 35 kg body weight)	TDF + 3TC + EFV	TDF/3TC/EFV (300/300/600mg): 1 tab once daily
> 15 years	TDF + 3TC + EFV[6,7]	TDF/3TC/EFV (300/300/600mg): 1 tab once daily
PWID > 15 years	TDF + 3TC + ATV/r	TDF/3TC (300/300mg): 1 tab once daily, plus ATV/r (300/100mg): 1 tab once daily with food

1. Patients currently on regimens that are not included in the indicated preferred (Table 6.2) or alternative (Table 6.3) regimens should be continued on their current regimen together with routine monitoring until guidance is provided to phase-out specific drugs or regimens, or until the patient has a specific indication to change the regimen or a single agent
2. See Annex 10 for weight-based dosing of all single-drug and fixed-dose combination formulations
3. Infants who initiate ART at less than 2 weeks of age should initiate on AZT+3TC+NVP irrespective of previous NVP exposure; metabolism of other ARVs is not well known for this age group. As soon as these infants become 2 weeks old, they should switch to ABC + 3TC + LPV/r
4. LPV/r pellets, which have better acceptability for children, may replace or be an alternative to LPV/r suspension once available through the national program.

Weight-based dosing of LPV/r 40mg/10mg per capsule pellets:

Weight band (kg)	No of capsules of LPV40mg/r10mg oral pellets	
	AM	PM
3-5.9	2	2
6-9.9	3	3
10 - 13.9	4	4
14 - 19.9	5	5
20 - 24.9	6	6
25 - 29.9	7	7
30 - 34.9	8	8
≥ 35 kg	10	10

Additional guidance will be provided as soon as the pellets become available.

5. Consider transitioning children/adolescents from ABC+3TC+EFV to TDF+3TC+EFV once they reach a sustained weight above 35 kg (at least 2 readings 1 month apart) for decreased pill burden. Confirm undetectable VL before making any single-drug substitution (Figure 6.2)
6. This is the recommended first line regimen for all adults including: pregnant women (at any gestational age), breastfeeding women, patients with TB/HIV co-infection, and patients with HBV/HIV co-infection. This regimen is recommended irrespective of previous exposure to single-dose NVP
7. In adults not on anti-TB therapy, lower dose EFV (at 400 mg/day) is as effective as EFV at 600 mg/day but with fewer side effects. When EFV 400 FDCs becomes available, providers will receive official guidance on when and how to transition patients on regular dose EFV to the lower dose form

Table 6.3: Special Circumstances to Use Alternative ARVs in First-Line Regimens[1]

Age	Scenario and ARV Affected	Alternative ARV to Use
< 2 weeks	AZT: Infant Hb < 9.5 g/dL	Defer ART until 2 weeks age, then start ABC+3TC+LPV/r
2 weeks - < 3 years	ABC: Develops ABC hypersensitivity reaction[2]	Use AZT (if Hb ≥ 9.5 g/dL) or RAL (if Hb < 9.5 g/dL)
	LPV/r: Unable to tolerate LPV/r because of GI side-effects	Use NVP (if no previous NVP exposure from PMTCT) or RAL (if previous exposure to NVP)
	LPV/r: Currently on anti-TB medications[3]	Use LPV/r+ RTV If not able to tolerate super-boosted LPV/r+ RTV then use AZT+ABC+3TC for duration of TB treatment
	Mother on PI-based regimen at time of suspected transmission	Consult Regional or National Clinical HIV TWG (ulizanascop@gmail.com)
3 - 15 years (< 35 kg body weight)	ABC: Develops ABC hypersensitivity reaction[2]	Use AZT (if Hb ≥ 9.5 g/dL) or RAL (if Hb < 9.5 g/dL)
	EFV: Unable to tolerate EFV (severe CNS side effects or moderate-severe rash)	Use LPV/r
3 - 15 years (≥ 35 kg body weight)	TDF: Impaired renal function (CrCl ≤ 50 mL/min)	Use ABC
	EFV: Unable to tolerate EFV (severe CNS side effects or moderate to severe rash)	Use ATV/r (if ≥ 40 kg) or LPV/r (if < 40 kg)
> 15 years	TDF: Impaired renal function (CrCl ≤ 50 mL/min)	Use ABC
	EFV: Unable to tolerate EFV (severe CNS side effects or moderate-severe rash)	Use ATV/r
PWID > 15 years	TDF: Impaired renal function (CrCl ≤ 50 mL/min)	Use ABC
	ATV/r: Unable to tolerate ATV/r	Use RAL

1. For other scenarios that are not covered in this table, discuss as an MDT and consult the Regional or National Clinical HIV TWG (ulizanascop@gmail.com)
2. ABC hypersensitivity reaction (AHR) is rare in the Kenyan population. Table 6.9 provides the definition and management of AHR
3. Use "super-boosted" LPV/r by adding additional ritonavir suspension to manage the drug interaction between LPV/r and rifampicin (see Table 8.7 in Section 8 for dosing recommendations). **As soon as TB treatment is completed the child should go back to standard LPV/r dosing**. For children who cannot tolerate LPV/r + RTV (usually because of GI side-effects), the alternative regimen is AZT+ABC+3TC; **as soon as TB treatment is completed the child should go back to ABC+3TC+LPV/r**, because of the increased risk of developing treatment failure while on a triple-NRTI regimen

6.4 Monitoring and Changing ART

The objectives of clinical and laboratory monitoring during ART are to identify and treat inter-current illnesses, assess for and manage adverse drug reactions, and evaluate response to treatment. Routine laboratory monitoring recommendations are described in Table 3.4 in Section 3, however, additional investigations should be ordered whenever there is clinical suspicion for which a laboratory test result may alter patient management.

Indications for changing ART include adverse drug reactions or toxicity, drug-drug interactions, co-morbidity and treatment failure.

6.4.1 Changing ARVs Due to Adverse Drug Reactions

Patients starting ART should be educated as to potential side effects of ART and all other prescribed medication. Once patients have been on ART for several months, ADRs are unlikely.

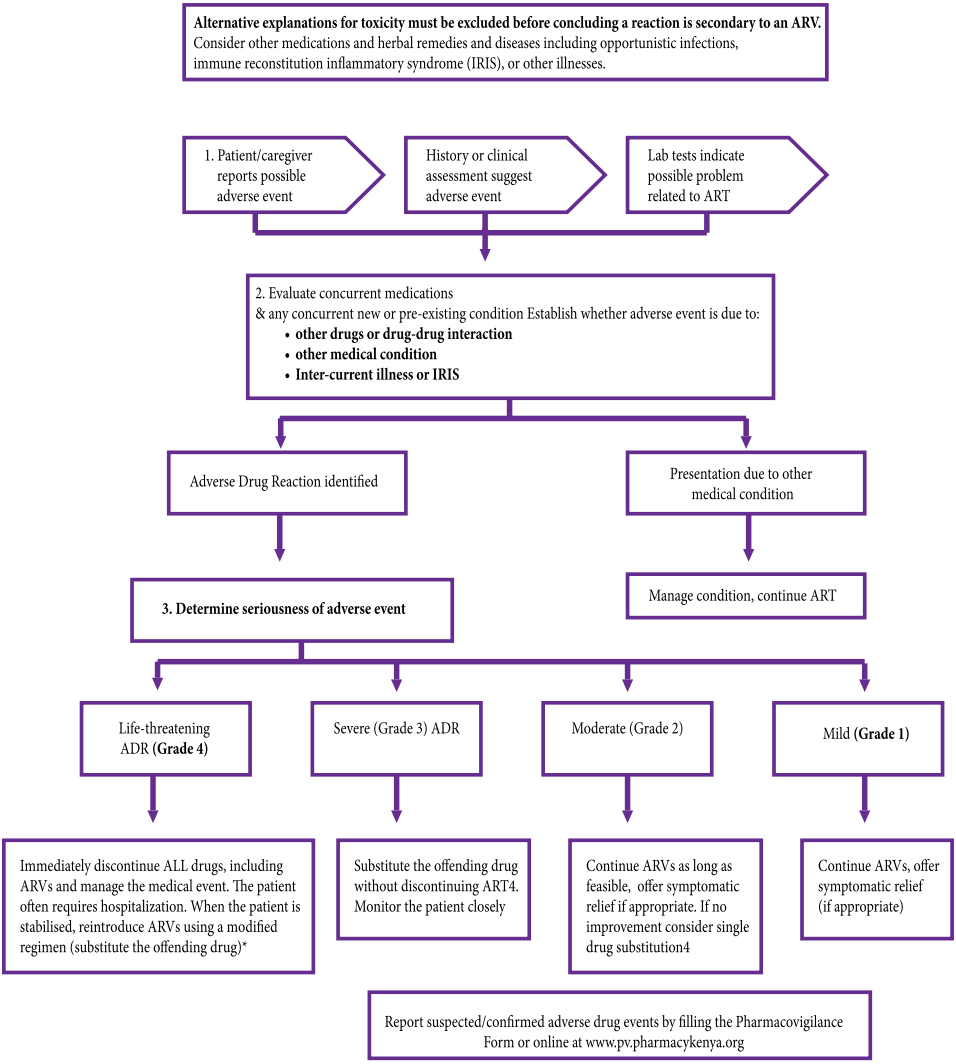
ADRs can have a significant impact on patient adherence and must be identified early and managed aggressively. All ADRs should be reported to the Pharmacy and Poisons Board using existing pharmacovigilance tools.

The most common significant ADRs associated with ARVs that may require a drug substitution are summarized in Table 6.4. General principles for managing ADRs are outlined in Figure 6.1. Managing specific ADRs is described in Tables 6.6-6.9.

Table 6.4: Common Significant Adverse Drug Reactions

ARV Agent	Adverse Drug Reaction	High Risk Situations/Comments
NRTIs		
ABC	ABC hypersensitivity reaction	Do not re-challenge
AZT	Anaemia, neutropenia	CD4 count < 200 cells/mL; BMI < 18.5 (or body weight < 50kg); anaemia at baseline
	Lactic acidosis	Pregnancy; obesity
	Lipoatrophy	Low CD4 count
TDF	Renal Dysfunction	Underlying renal disease; Age > 40 years; BMI < 18.5 (or body weight < 50kg); diabetes; hypertension; concomitant PI use or nephrotoxic drug
NNRTIs		
All NNRTIs	Rash/hypersensitivity (NVP>>EFV>ETR)	For NVP: women with CD4 count > 250 cells/mL; men with CD4 count > 400 cells/mL
EFV	CNS side-effects	Pre-existing psychiatric disorder
	Gynaecomastia	Consult
NVP	Hepatotoxicity	HBV or HCV co-infection; concomitant use of hepatotoxic drugs; women with CD4 count > 250 cells/mL; men with CD4 count > 400 cells/mL
PIs		
All PIs boosted with RTV	GI intolerance (LPV/r>DRV/r>ATV/r	Consult
	Dyslipidaemia (LPV/r>DRV/r>ATV/r)	Obesity; sedentary lifestyle; diet high in saturated fats and cholesterol
ATV/r	Hyperbilirubinemia	Note: this only requires drug substitution if cosmetic effect of jaundice is likely to interfere with patient adherence
DRV/r	Rash/hypersensitivity	Sulfa allergy
INSTIs		
All INSTIs	Rash/hypersensitivity	Consult

Figure 6.1: General Principles for Managing Adverse Drug Reactions



1. At every clinic visit the patient on ART should be monitored clinically for toxicities using appropriate history (history of symptoms that suggest toxicity) and physical examination (relevant signs). Targeted laboratory assessment may be used to confirm specific toxicities
2. Evaluate concurrent medications and establish whether the toxicity is attributable to an ARV drug (or drugs), or to a non-ARV medication taken at the same time. Consider other disease processes (e.g. concurrent infectious processes or IRIS)
3. All toxicities should be graded. Manage the adverse event according to severity

* Follow single-drug substitution algorithm (Figure 6.2)

Figure 6.2: Managing Single Drug Substitutions for ART

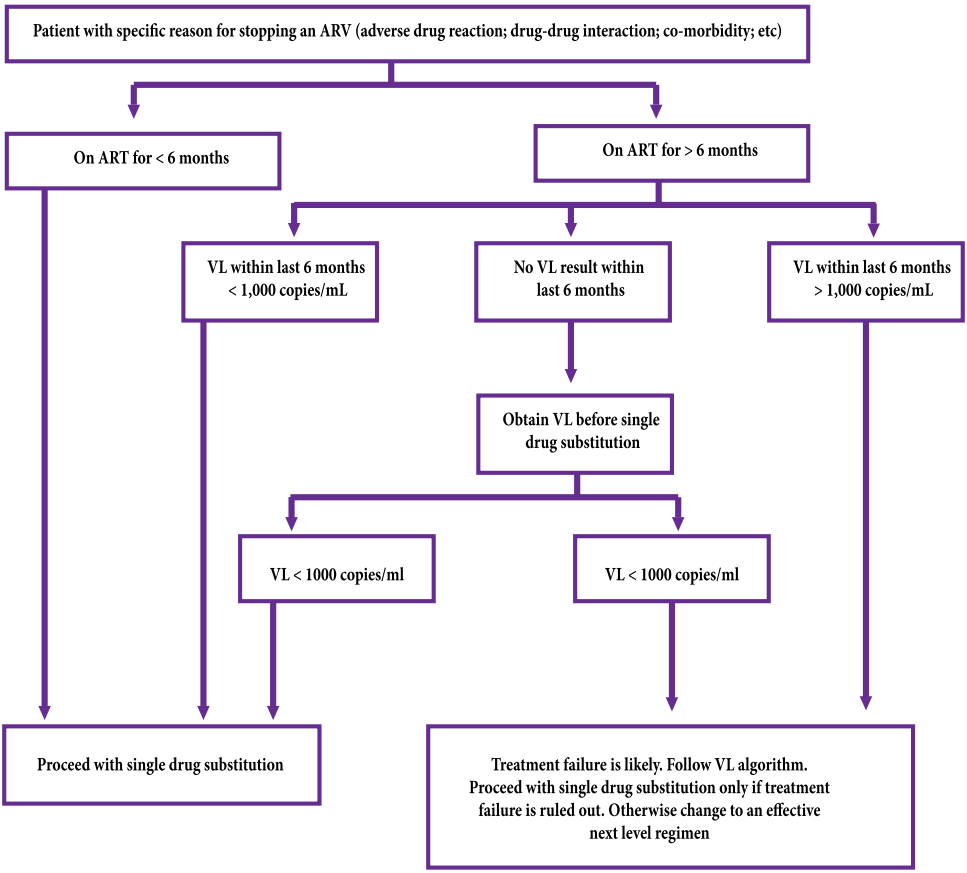


Table 6.5: ARV Dose Adjustments with Renal Impairement[1]

Drug	CrCl (mL/min)		Haemodialysis (dose after dialysis)	Peritoneal dialysis
	10-50	<10		
TDF[2]	AVOID[2]	AVOID[2]	300 mg once weekly	Unknown
ABC	Unchanged	Unchanged	Unchanged	Unchanged
AZT	Unchanged	300 mg once daily	300 mg once daily	300 mg once daily
3TC	150 mg once daily	50 mg once daily	50 mg first dose, then 25 mg once daily	50 mg first dose, then 25 mg once daily
NNRTIs (all)	Unchanged	Unchanged	Unchanged	Unchanged
PIs (all)	Unchanged	Unchanged	Unchanged	Unchanged
INSTIs (all)	Unchanged	Unchanged	Unchanged	Unchanged

1. Patients with baseline CrCl of ≤ 50 mL/min should not be initiated on TDF; patients who develop renal impairment (CrCL ≤ 50 mL/min) while on TDF should be switched to an alternate ARV (preferably ABC) following the single drug substitution algorithm, (Figure 6.2)
2. For patients with HBV co-infection, the benefit of TDF for treating HBV often outweighs the renal impairment, so more severe levels of renal impairment are tolerated. See Table 9.3 in Section 9 for TDF dose adjustments for patients with HBV/HIV co-infection

Table 6.6: Management of AZT-Associated Bone Marrow Suppression

Test	Result	Action
Hb (g/dL)	> 8.5 (but decrease from pre-AZT baseline)	300 mg once weekly
	≤ 8.5	Switch from AZT to an alternative ARV
Neutrophils (x 109/L)	1.0 – 1.5 (and decrease from pre-AZT baseline, if available)	Retain AZT, repeat in 1 week (if accessing follow-up Hb is difficult then consider switching to an alternative ARV immediately)
	≤ 1.0	Switch from AZT to an alternative ARV

Note:

1. Patients with baseline Hb of < 9.5 g/dL should not be initiated on AZT; patients who develop anaemia while on AZT should be managed as per this table
2. AZT-associated bone marrow suppression occurs early in the course of treatment, usually within 3 months of initiating ART
3. All patients with anaemia and/or neutropenia, whether on AZT or not, should be evaluated for other likely causes of anaemia/neutropenia and managed appropriately

Table 6.7: Management of Drug-Related Hepatotoxicity

ALT	**<2.5 x Upper Limit of Normal (ULN)**		**2.5 – 5 x ULN**	**> 5 x ULN**
Action	Retain regimen, repeat in 2 weeks	Retain regimen, repeat in 1 week	Discontinue offending drug/s	Unknown

Note: All patients with acute increase in liver enzymes should be evaluated for other likely causes of hepatitis/ hepatotoxicity and managed appropriately

Table 6.8: Management of Abacavir Hypersensitivity Reaction

Diagnosis
Within 8 weeks of initiating an ABC-containing regimen, patient develops any 2 of the following symptom groups concurrently: • Fever • Erythematous and/or pruritic rash • Respiratory symptoms (shortness of breath and/or sore throat and/or cough) • GI symptoms: nausea and/or vomiting and/or diarrhoea • Extreme fatigue and/or body pain preventing normal activities AND: there is no likely alternative explanation for the symptoms
Management
• Stop ABC immediately and substitute with an alternative ARV • Patient must NEVER be re-challenged with ABC – a single dose could result in a fatal hypersensitivity reaction • Clearly mark file and educate patient about avoiding ABC in future

Note:
ABC hypersensitivity reaction is rare in our population: always consider other more likely possible diagnoses
Symptoms generally get worse within hours after each dose of ABC

6.4.2 Changing ARVs Due to Drug-Drug Interactions

Patients must be asked about other medications (including non-prescription and herbal medicine) they are taking at every visit. Some common drugs have specific drug-drug interactions that may require dose adjustment or substitution of the ARV or the other interacting drugs. Common medications that interact with specific ARVs include: rifampicin, rifabutin, several anti-fungals, anti-convulsants, calcium-channel blockers, some anti-depressants, some statins, methadone, and some anti-malarials. Annex 13 provides common drug-drug interactions and recommendations of actions to take in case of co-administration.

6.4.3 Changing ARVs Due to Treatment Failure

Routine viral load is the test of choice for monitoring response to ART and identifying treatment failure. It should be carried out at 6 and 12 months after initiating or changing ART and every 12 months thereafter if below 1000 copies/ml.

Defining Treatment Failure

Clinical

Treatment failure should be suspected when a new or recurrent HIV associated condition indicating severe immunodeficiency (WHO stage III/IV condition) develops after at least 6 months on ART. Exclude IRIS occurring after initiation of ART. Treatment failure should always be confirmed by a viral load test.

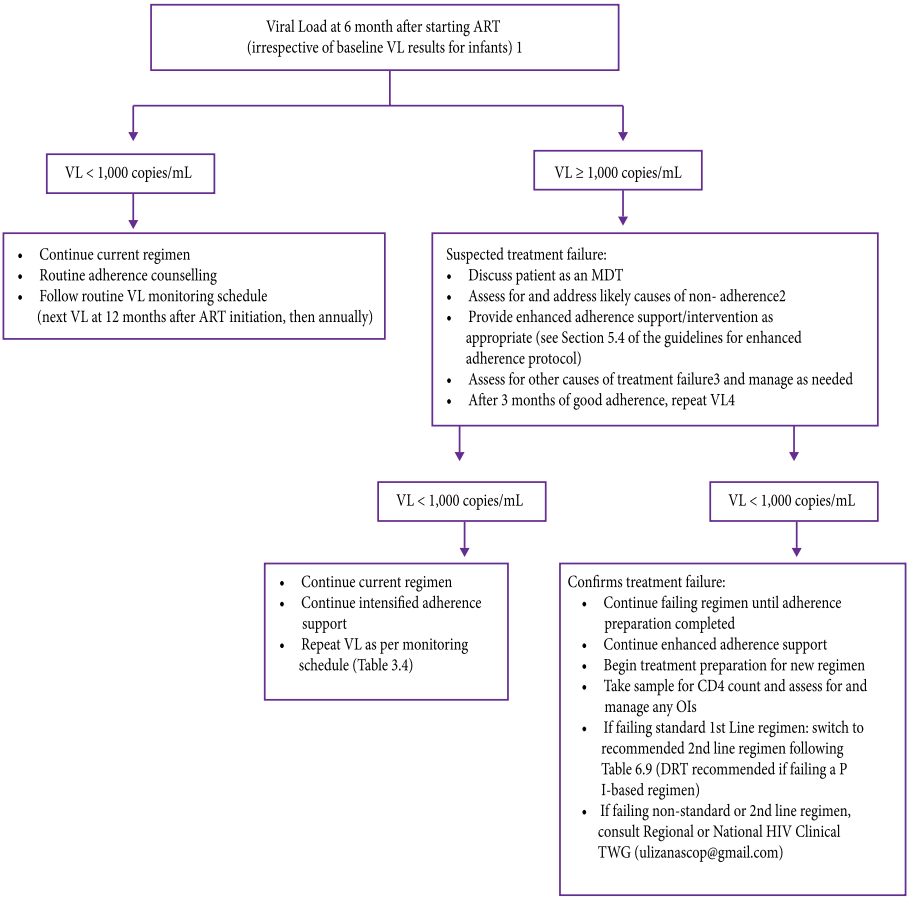
Virologic (recommended)

Treatment failure is defined by a persistently high viral load ≥ 1000 copies/mL (two viral loads measured within a 3-month interval with adherence support between measurements) after at least 6 months of using ART.

However, for pregnant and breastfeeding women, persistently high viral load ≥ 1000 copies/mL (two viral load tests measured after 1-month interval with adherence support between measurements) should be considered treatment failure.

Clinical and immunological criteria for identifying treatment failure have low sensitivity and specificity for diagnosing treatment failure. Every effort should be made to obtain a routine viral load test.

Figure 6.3: Viral Load Monitoring of Patients on ART (1st Line or 2nd Line)



1. As part of treatment preparation, patients should be informed that viral load (VL) is the recommended means of monitoring ART. VL results should always be discussed with patients, even when they are undetectable. The goals of treatment and definition of success should be discussed and adherence messaging reinforced.
2. Common causes of poor adherence include: stigma, non-disclosure, travel, toxicities, alcohol or drugs, mental health disorder, religious beliefs, inadequate treatment preparation, chaotic lifestyle, lack of support systems, and poor patient-provider relationship
3. Common causes of treatment failure include: inadequate dosing/dose adjustments, drug-drug interactions, drug-food interactions, impaired absorption (e.g. chronic severe diarrhoea)
4. For pregnant or breastfeeding women, repeat VL after 1 month instead of waiting for 3 months of good adherence

Non-adherence is the most frequent cause of treatment failure. As per the VL algorithm (Figure 6.3), **adherence issues must be addressed BEFORE confirming treatment failure**. All adherence issues must be resolved before switching to a new regimen otherwise the patient will quickly fail the new regimen as well, and soon run out of viable ART options. Section 5 provides detailed guidelines on adherence preparation, assessment, and support.

Table 6.9: Recommended Second-line ART Regimens in infants, children, adolescents and adults including pregnant and breastfeeding women[1]

Age/Scenario	First-line ART	Second-line ART
2 weeks - < 3 years	ABC (or AZT) + 3TC + LPV/r	DRT-based 2nd line[2]
	ABC + 3TC + NVP (or RAL)	AZT + 3TC + LPV/r
3 - 15 years (< 35 kg body weight)	ABC + 3TC + EFV (or RAL)	AZT + 3TC + LPV/r
	ABC (or AZT) + 3TC + LPV/r	DRT-based 2nd line[2]
	AZT + 3TC + EFV (or RAL)	ABC + 3TC + LPV/r
3 - 15 years (≥ 35 kg body weight)	TDF (or ABC) + 3TC + EFV (or NVP)	AZT + 3TC + ATV/r (or LPV/r)[3]
	TDF (or ABC or AZT) + 3TC + LPV/r (or ATV/r)	DRT-based 2nd line[2]
	AZT + 3TC + EFV (or NVP)	TDF + 3TC + ATV/r (or LPV/r)[3]
> 15 years including adults	TDF (or ABC) + 3TC + EFV (or NVP)	AZT + 3TC + ATV/r
	AZT + 3TC + EFV (or NVP)	TDF + 3TC + ATV/r
	TDF (or ABC or AZT) + 3TC + ATV/r (or LPV/r)	DRT-based 2nd line[2]
HIV/HBV co-infection	Maintain both 3TC and TDF in second line (to treat the HBV), even if the patient failed a TDF-containing first-line regime (i.e. follow the preferred second-line as per the table above, but if it does not contain TDF then add TDF as a fourth drug in the regimen)	

1. If there were previous single-drug substitutions during 1st line ART, or any drug in the recommended 2nd line regimen is contraindicated or not tolerated, consult the Regional or National Clinical HIV TWG (ulizanascop@gmail.com). Such patients may require DRT to select agents for the second-line ART. Additional drugs may be available on a case-by-case basis, including RAL, DTG, ETR, or DRV/r
2. Patients failing PI-based first-line regimens should have a Drug Resistance Test (DRT) ordered as soon as treatment failure is confirmed. The patient summary and DRT results should be sent to the Regional or National Clinical HIV TWG to determine the most suitable second-line regimen for the patient (ulizanascop@gmail.com). The DRT results will be used to determine if a PI will still be effective in 2nd line
3. ATV/r can be used as the preferred PI in adults (any weight) and in adolescents who are ≥ 40 kg (with available formulations). For adolescents < 40 kg, LPV/r should be used until paediatric formulations of ATV/r become available

Important Considerations for First-line Treatment Failure in Children

- Second-line ART in infants and children is more complex to manage. These children should undergo thorough clinical and psychosocial assessment to rule out inter-current illness or non-adherence as the reason for a high viral load
- All children failing first-line should be discussed in the MDT and preferably with an experienced ART provider prior to change of ART to second-line. **However, this should not cause undue delay in switching a failing regimen.**
- The choices for infants and children failing an alternative first-line regimen are limited and may need to be discussed with a R/NHCSC. Some of these children will require HIV DRT to determine the most suitable second-line regimen

Second-line ART Treatment Failure

Providers are encouraged to refer to the 'Toolkit for Third Line Antiretroviral Therapy for Service Providers in Kenya 2016' for comprehensive information on managing patients failing second-line ART.

The following general rules apply:

- Patients failing second-line ART have limited options left. Agents used to construct a third-line regimen are often more expensive, will have increased pill burden and more side effects. These factors will exacerbate pre-existing poor adherence.
- Second-line treatment failure should be confirmed by viral load testing following the VL algorithm (Figure 6.3): after the first VL above ≥ 1,000 copies/ml), assess for and address all causes of poor adherence, assess for all other possible causes of treatment failure. These patients should be discussed at an MDT session. Repeat the VL after 3 months of good adherence (preferably with daily witnessed ingestion of the ARVs by a treatment buddy, relative, CHV, etc). If the second VL is still is ≥ 1,000 then continue the failing second-line regimen and consult the R/NHCSC (ulizanascop@gmail.com) using the standard Case Summary Form. These patients will require DRT in order for the TWG to design the most suitable third-line regimen.
- Patients failing second-line ART require thorough assessment for barriers to adherence and ongoing enhanced adherence support including
  - Assignment to a case manager
  - More frequent adherence counselling by a trained counsellor
  - Assessment and treatment of mental health and substance use disorders
  - Provision of adherence support such as modified directly observed therapy, a treatment supporter, home visits etc.

Table 6.10: Possible Third-line ART in Children, Adolescents and Adults

	Regimen	Comment
Children	RAL (or DTG) + 3TC + DRV + RTV	In children weighing ≥ 30 kg and aged 6-12 years, DTG can be substituted for RAL National HIV Clinical TWG may recommend recycling of first and second-line ARVs with partial or complete activity
	AZT + RAL (or DTG) + 3TC + DRV + RTV	
	ABC/TDF + RAL (or DTG) + 3TC + DRV + RTV	
	ETV + 3TC + DRV + RTV	
Adults	RAL (or DTG) + 3TC + DRV + RTV	
	AZT + RAL (or DTG) + 3TC + DRV + RTV	
	TDF + RAL (or DTG) + 3TC + DRV + RTV	
	ETV + 3TC + DRV/r	

Table 6.11: Dosing of third-line ARVs in Children and Adults

Drug	Weight band (kg)	
Raltegravir (RAL) (chewable tabs)	3 to <6	25 mg BID
	6 to <10	50 mg BID
	10 to < 14	75 mg BID
	14 to < 20	100 mg BID
	20 to < 25	150 mg BID
RAL (adult and adolescent) 400 mg film coated tab	≥25	400 mg BID
Dolutegravir (DTG for children ≥ 6 to < 12 years of age	30-40	35 mg OD
Dolutegravir (DTG) adolescents ≥ 12 years and > 40 kg, adult	≥40	50 mg OD, if co-administered with rifampicin, give DTG 50 mg BID
Etravirine children and adolescents at least 6 to 18 kg	16 - <20	100 mg BID
	20 - < 25	125 mg BID
	25 - <30	150 mg BID
	≥30	200 mg BID
Etravirine (Adult)	≥30	200 mg BID
Darunavir 100 mg/ml OR 75 mg tabs*	10-13.9	2.5 ml BD or 3 tabs (with 40 mg RTV) BID
	14-19.9	3.5 ml BD or 5 tabs (with 40 mg RTV) BID
Darunavir tabs (150 mg, 600 mg, 800 mg)	20 - < 30	375 mg (with 50 mg RTV) BID
	30 - < 40	450 mg (with 100 mg RTV) BID
	≥ 40	600 mg (with 100 mg RTV) BID

7. Prevention of Mother to Child Transmission of HIV

Routine antenatal care (ANC) offers an important opportunity to provide high quality combined HIV prevention through targeted health education and counselling, HIV testing, couple and family testing, and linkage to HIV prevention and treatment. Prevention of mother-to-child transmission of HIV (PMTCT) should be offered as part of a comprehensive package of fully integrated, routine antenatal care interventions (Table 7.1).

Table 7.1: Essential Package of Antenatal Care

Intervention	Recommendation/Description
Group & Individual Education	• Include information on at least 4 ANC visits, details of ANC services (including health check and treatment of any illness, medical tests including HIV testing, monitoring of maternal and foetal wellbeing etc.), nutrition, personal care, recognizing and responding to danger signs during pregnancy, birth preparedness including skilled birth attendance, post-natal care including immunization, family planning and maternal and infant nutrition; HIV prevention and treatment (HTS, preventing new infections during pregnancy, ART for those who are HIV positive, monitoring of ART; and ARV prophylaxis and follow-up for HEIs)
Counselling	• Birth preparedness: support the pregnant woman and her partner to develop an individual birth plan that includes place of delivery with skilled attendance, emergency transport, birth companionship and readiness for infant care. • Pregnancy danger signs: offer information on returning to ANC as soon as possible in case they develop fever, low abdominal pain, fever, severe headache, swollen feet, convulsions • Maternal and infant nutrition and feeding: All pregnant women should receive information on proper nutrition during pregnancy and breastfeeding; and safe infant feeding options and nutrition practices. Promote exclusive breastfeeding for 6 months irrespective of HIV status. During pregnancy, provide iron, folate and multivitamins; monitor for anaemia, advise on adequate caloric intake (HIV positive women require an additional 10% of RDA) • HIV Testing services: - All pregnant women (unless known HIV positive) should be counselled and tested for HIV during their first ANC visit and repeat testing conducted in the third trimester for all women who test HIV negative at the first ANC visit. The test (if negative) should be repeated at labour and delivery. - All breastfeeding mothers (unless known HIV positive) should be counselled and tested at 6 weeks postnatal visit. The HIV test (if negative)should be repeated 6 months and thereafter follow testing recommendations as per the risk categories - Mothers should be counselled about the schedule for repeat HIV testing in pregnancy and postnatal as part of routine ANC and postnatal education - All pregnant and breastfeeding women who are not tested, opt-out or decline HIV testing during the first contact should be offered HIV counselling and testing in subsequent visits with appropriate linkage and referral for prevention, care and support services - All HIV positive and breastfeeding women enrolled into care should receive counselling and support (assisted disclosure), case managed linkage and follow-up including comprehensive care and treatment (lifelong ART) - All spouses/partners of pregnant and breastfeeding women should be offered HIV testing and counselling and to all children if the mother is HIV positive • All pregnant women should receive information on risk reduction • Post-partum contraception: counsel on contraception methods. Emphasise dual protection to avoid new/re-infection and unplanned pregnancies

Table 7.1: Essential Package of Antenatal Care (Continued)

Intervention	Recommendation/Description
PHDP	• For HIV positive women, encourage and support disclosure of HIV status, partner/ family testing, condom use, post-partum contraception, STI screening, prevention, and treatment, adherence counselling and support, assessment for and prevention of Gender-based violence and continued HIV education/counselling
Clinical Evaluation	• History - including medical, obstetric and psychosocial history. Use of medication including herbal remedies, drug allergies • TB screening: All women presenting to ANC should be screened for TB infection using the symptom-based TB screening tool (refer to section 8) • Reproductive tract infections: screen for RTI (abnormal genital discharge, genital ulcers, and history of pelvic inflammatory disease). Manage a positive screen as recommended for syndromic management of STIs (section) • Physical examination - perform general and obstetric examination including vital signs, systemic and breast examination; and obstetric examination (abdominal and foetal examination, speculum and bimanual examination, cervical cancer screening, STI screening) • For HIV positive women, obtain and record additional information using MOH 257
Antenatal Profile	• Obtain syphilis serology, HB, blood group and rhesus, urinalysis, rapid HIV test for the pregnant woman and her partner, and if TB screening positive, sputum for nucleic acid test or smear microscopy (refer to section 4)
Additional tests for HIV positive	• Refer to sections 3
Offer appropriate preventive and treatment	• Maternal immunization • Iron, folate and multivitamins • Syndromic STI treatment if indicated • Antimalarial and ITNs • For HIV positive pregnant women: Start or continue lifelong ART (see section 6), IPT (isoniazid 300 mg once daily for 6 months) and CPT. For women starting ANC while on ART, rule out treatment failure (refer to section 6)

7.1 Antiretroviral Therapy for HIV-positive Pregnant Women and Infant Prophylaxis

The goal of ART for HIV positive pregnant women is two-fold; to restore and maintain the mother's immune function and therefore general health, and secondly, to prevent transmission of HIV in utero, at labour and delivery and during breastfeeding. To achieve this goal, the mother must take effective antiretroviral therapy to achieve viral suppression, ideally below 1000 copies/ml. Table 7.2 below summarizes recommendations for use of ART for HIV positive pregnant women.

Table 7.2: Summary for Use of ART for HIV Positive Pregnant and Breastfeeding Women

Overall recommendations	
When to start	Same as for non-pregnant adults (section 6): ART should be initiated in all pregnant and breastfeeding women living with HIV, regardless of gestation, WHO clinical stage and at any CD4 cell count and continued lifelong. ART should be started, ideally, on same day as HIV diagnosis with ongoing enhanced adherence support including community-based case management and support.
What to start with (first-line ART)	• Start on TDF/3TC/EFV (300/300/600 mg), as FDC, 1 tab once daily regardless of prior NVP exposure • For patients already on ART, continue ART unless the regimen or part of the regimen is contraindicated because of the pregnancy
Infant prophylaxis	• Refer to Table 7.3 below
Monitoring	Review monthly until after delivery. Offer adherence support **Viral load** **General guidance for VL monitoring during pregnancy and breast-feeding** • For newly initiated ART in pregnant and breastfeeding women, obtain VL 6 months after initiation, if ≥1000 copies/ml, intensify adherence, repeat the VL after 1 month and if still ≥ 1000 copies/ml, change to an effective regimen. If < 1000 copies/ml, repeat viral load every 6 months until end of breastfeeding then follow-up as for general population • For HIV positive women on ART for > 6 months, obtain a VL as soon as pregnancy is confirmed. If the VL ≥ 1000 copies/ml, intensify adherence, repeat the VL after 1 month and if still ≥ 1000 copies/ml, change to an effective regimen. If < 1000 copies/ml, repeat viral load every 6 months until end of breastfeeding then follow-up as for general population
Scenario	
Pre-conception planning for women already on ART	Maintain ART unless using a regimen or part of the regimen contraindicated in pregnancy; in which case, the ART regimen should be switched following the recommendations in section 6. Ensure effective ART (viral suppression, undetectable to less than 1000 copies/ml). Refer to section 4 for pre-conception care for women on ART who desire pregnancy.
Pregnant women starting ANC from care and treatment and ART	Maintain ART, unless using a regimen or part of a regimen contraindicated in pregnancy. Carry out a VL to ascertain viral suppression and exclude treatment failure (refer to VL algorithm in section 6)
HIV positive, ART naïve (known positive or identified during ANC and late pregnancy)	Prepare the patient and start ART as soon as possible, preferably on the same day HIV infection is confirmed.
Known HIV positive but not on ART during pregnancy, presents in labour/ identified HIV positive during L&D	Start on ART during labour After delivery, continue treatment preparation and support and continue ART
Not on ART, presents post-partum and breastfeeding	Prepare and start on appropriate ART as soon as possible, preferably on the same day HIV infection is confirmed. Manage the baby as HEI (refer to section 2 and 6)
Managing labour and delivery	Minimize vaginal examinations, use aseptic techniques to conduct delivery, **avoid artificial rupture of membranes**, monitor labour and avoid prolonged labour by use of the partograph, avoid unnecessary genital tract trauma. Where available, consider elective Caesarean section prior to onset of labour if the VL in late pregnancy (after 36 weeks gestation) is ≥ 1000 copies/ml.

Table 7.3: ARV Prophylaxis for HIV-Exposed Infants

	Infant Prophylaxis	Maternal ART
HIV exposed Infant	• 12 weeks of infant prophylaxis: - AZT+NVP for 6 weeks, followed by NVP for 6 weeks • DBS for PCR at first contact, following EID algorithm	If mother not on ART, initiate ART as soon as possible (preferably same day)[1]
1. If a breastfeeding mother refuses to start ART but agrees to provide infant ARV prophylaxis, provide 6 weeks of AZT+NVP, followed by daily NVP until 6 weeks after complete cessation of breastfeeding. Perform DBS for PCR at first contact with the infant and follow the EID algorithm Note: If child has contraindication or unable to tolerate NVP or AZT then continue the other drug to complete a total of 12 weeks of infant prophylaxis		

Table 7.4: Dosing of ARVs for Infant Prophylaxis from Birth to 12 Weeks of Age

Age/Weight	Dosing of NVP (10mg/mL) OD	Dosing of AZT (10mg/mL) BD
Birth to 6 weeks		
Birth weight < 2000 g	2 mg/kg per dose	4 mg/kg per dose
Birth weight 2000-2499 g	10 mg (1 ml of syrup)	10 mg (1 ml of syrup)
Birth weight ≥2500 g	15 mg (1.5 ml of syrup)	15 mg (1.5 ml of syrup)
> 6 weeks to 12 weeks		
Any weight	20 mg (2 ml of syrup)	60 mg (6 ml of syrup)
> 12 weeks (Table 7.5 and 7.6)		

Table 7.5: NVP Dosing for Infant Prophylaxis beyond 12 Weeks of Age*

Age	Dosing of NVP (10mg/mL) Once Daily
12 weeks – 14 weeks	20 mg (2 ml of syrup)
15 weeks – 6 months	25 mg (2 ml of syrup)
7 months – 9 months	30 mg (2 ml of syrup)
10 months – 12 months	40 mg (2 ml of syrup)
> 12 months	50 mg (2 ml of syrup)

Table 7.6: AZT Dosing for Infant Prophylaxis beyond 12 Weeks of Age*

Weight	Dosing of AZT: (10mg/mL syrup) Twice Daily
3.0-5.9 kg	6 ml of syrup
6.0-9.9 kg	9 ml of syrup
10.0-13.9 kg	12 ml of syrup
14.0-19.9 kg	15 ml of syrup

* Child presents to facility late and has to be on AZT and NVP beyond 12 weeks of age

7.2 Infants and Young Children Nutrition the Context of HIV

- All mothers who are HIV negative or are of unknown status should be encouraged and supported to exclusively breastfeed for the first 6 months and continue breastfeeding with appropriate complementary feeding at 6 months for a period of 24 months and beyond
    - Retest HIV negative mother as per national guidelines
    - Encourage women of unknown HIV status to take the HIV test and manage accordingly
- All HIV positive mothers should be given information on the government guidance on BF in the context of HIV and counselled on benefits and challenges of breastfeeding
- All HIV positive mothers should be encouraged and supported to exclusively breastfeed for the first six months of life, introducing appropriate complementary foods at six months and continue BF up to AT LEAST 12 months of the infant's life and preferably up to 24 months. Breastfeeding should ONLY stop once a nutritionally adequate and safe diet with¬out breast milk can be provided and supported for all and especially for those categorized as food insecure
- Mothers whose infants are HIV infected should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods at 6 months, and continue breastfeeding 24 months and beyond. Infant's treatment be initiated in line with Kenya ART guidelines. Mothers who decide to stop breastfeeding at any time should stop gradually within one month and both should continue with ART treatment according to national guidelines

8. TB/HIV Co-infection Prevention and Management

TB is a leading cause of morbidity and mortality for PLHIV. Reducing this burden of illness requires identifying TB early, providing pre-emptive and preventive treatment for TB, and providing optimal treatment for both HIV and TB. Timely initiation of ART is an effective way to reduce the burden of TB in PLHIV.

All PLHIV should receive counselling about the risk of acquiring TB, strategies for reducing exposure to TB, recognizing clinical manifestations of TB and seeking care promptly, the risk of transmission of TB to others and TB preventive therapy to prevent TB disease.

Healthcare settings present suitable conditions for transmission of TB; particularly among vulnerable individuals like PLHIV. All healthcare settings should develop and implement TB infection control guidelines to reduce the risk of transmission of TB between patients, visitors and staff.

8.1 TB Screening for PLHIV: Intensified Case Finding (ICF)

TB screening and prevention services should be offered to ALL PLHIV at every clinical visit and to all household contacts of active TB patients. Symptom-based TB screening using the ICF tool MUST be performed for all PLHIV at every clinic visit to rule out active TB (Tables 8.1 and 8.2); patients who screen positive (presumptive TB cases) must complete definitive diagnostic pathways and patients who screen negative should be evaluated for isoniazid preventive therapy (IPT) (Figure 8.1).

Table 8.1: Paediatric and Adult Intensified Case Finding Screening Tool

Screening Questions	Y/N
1. Cough of any duration (Y/N)	
2. Fever (Y/N)	
3. Failure to thrive or poor weight gain (Y/N)	
4. Lethargy, less playful than usual (Y/N)	
5. Contact with a TB case (Y/N)	

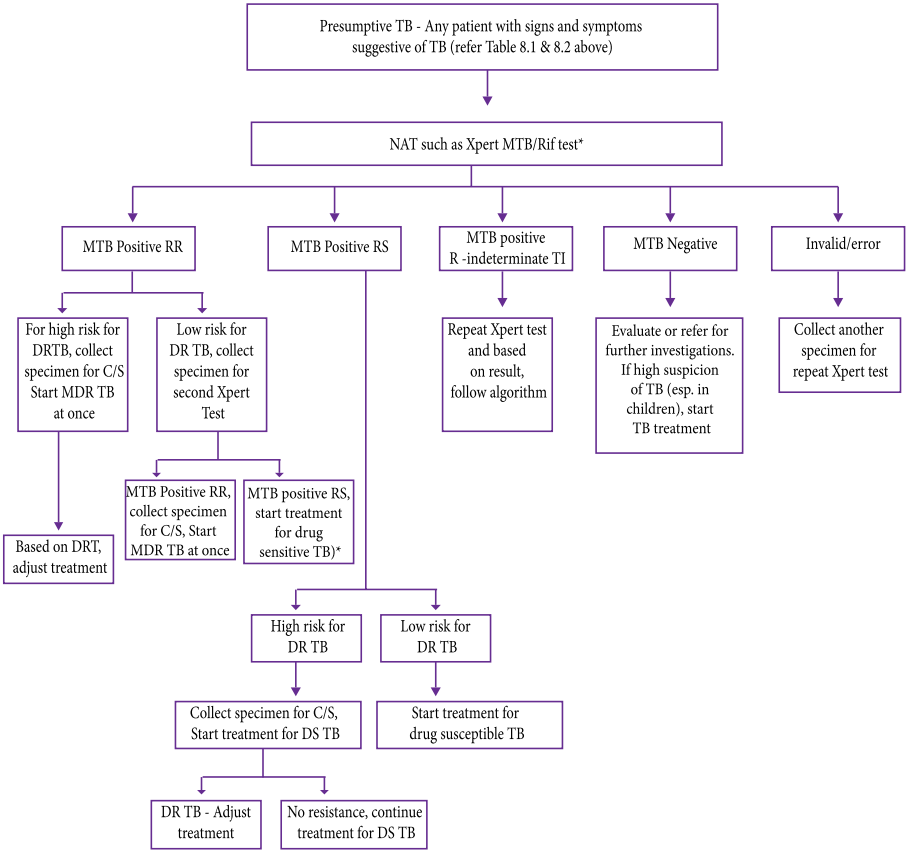
- If "Yes" to any of the above questions, suspect TB, examine the child and use the pediatric TB diagnostic algorithm to evaluate for active disease. Rule out underlying conditions, refer if necessary.
- If "No" to all questions, initiate workup for IPT and repeat screening on subsequent visits

Table 8.2: Adolescent and Adult Intensified Case finding Screening Tool

Screening Questions	Y/N
1. Cough of any duration	
2. Fever	
3. Noticeable weight loss	
4. Night sweats	

- If "Yes" to any question; take a detailed history, examine the patient and do sputum examination if coughing (sputum smear or GeneXpert). Exclude underlying illnesses
- If "No" to all questions, initiate workup for IPT and repeat screening on subsequent visits

Figure 8.1: Management of Presumptive TB Cases



*Evidence has shown that the patient is more likely to have TB which will respond to 1st line TB treatment

The Xpert MTB/Rif test is the recommended first test for diagnosis of TB and rifampicin resistance in all presumptive TB cases.

- Suitable specimen for Xpert MTB/Rif include sputum, CSF, gastric and nasopharyngeal aspirates, pleural, pericardial and ascetic fluid, fine needle aspirates and tissue biopsies.

For bacteriologically confirmed PTB, sputum smear microscopy test at months 2, 4 and 6 is used for follow-up monitoring of treatment.

8.2 Isoniazid Preventive Therapy (IPT)

Refer to the National Isoniazid Preventive Therapy Standard Operating Procedure March 2015

8.2.1 Indications for IPT

IPT should be provided to those patients in whom TB is excluded (using the ICF tool) and meet the eligibility criteria to initiate IPT. The following client categories are eligible for IPT:

- HIV-infected children less than 12 months of age who have had recent close contact with sputum positive TB disease with no evidence of active TB
- All PLHIV above 12 months of age (children and adults including pregnant and breastfeeding women) who screen negative for active TB
- All children under 5 years old, irrespective of HIV status, who have had recent close contact with sputum positive TB disease with no evidence of active TB
- Prisoners who screen negative for active TB (irrespective of their HIV status)

8.2.2 Contraindications to IPT

Patients with the following should not receive IPT until the underlying issue/s are addressed:

- Active tuberculosis disease
- Active hepatitis
- Active substance abuse and/or regular and heavy alcohol consumption
- Symptoms of peripheral neuropathy
- Poor adherence to CPT, ART or clinic appointments
- Poor understanding of IPT by parent/caregiver
- Infants < 1 year who do not have direct exposure to TB contacts
- Note: past history of TB and/or current pregnancy are not contraindications for starting isoniazid preventive therapy

8.2.3 Dose and Duration of IPT

IPT should be administered at a dose of 10 mg/kg/day (maximum dose 300 mg) for at least 6 months as part of a comprehensive package of HIV care. Table 8.3 provides weight-based dosing of isoniazid.

Table 8.3: Dose of INH for Isoniazid Preventive Therapy

Weight (kg)	Dose in mg	Number of 100mg INH tablets
<5	50	½ tablet
5.1-9.9	100	1 tablet
10-13.9	150	1½ tablet (or ½ adult 300mg tablet)
14-19.9	200	2 tablets
20-24.9	250	2½ tablets
>25	300	3 tablets (or 1 adult 300mg tablet)

Patients taking INH should also be given pyridoxine daily to reduce the risk of developing peripheral neuropathy. Table 8.4 provides the weight-based dosing for prophylactic pyridoxine.

Table 8.4: Dose of Prophylactic Pyridoxine for Patients on INH

Weight (kg)	Number of tablets of pyridoxine (50mg)
5-7	(1/4) quarter tablet daily
8-14	(1/2) half tablet daily
≥ 15	(1) one full tablet daily

8.2.4 Follow-up of Patients on INH

- Review patients on IPT monthly and review/reinforce adherence
- Screen for active TB during each clinic visit using intensive case finding (ICF) form
- Update ICF cards and IPT register record at every visit and document outcome on completion of therapy
- Monitor for INH adverse effects (co-administer with pyridoxine to minimize adverse events)
  - IPT should be discontinued in symptomatic patients with ALT/AST more than three times the upper limits of normal
- The facility should maintain a TB contact register

8.3 ART for TB/HIV Co-infection

As with all PLHIV, those who are diagnosed with TB/HIV co-infection should be on ART and CPT as part of the comprehensive package of care for PLHIV.

Timing of ART for TB/HIV Co-infection

- Patients who are not yet on ART
  - Start anti-TB immediately
  - Initiate ART as soon as anti-TB medications are tolerated, preferably within 8 weeks
- Patients who are already on ART
  - Start anti-TB immediately
  - Continue ART, making any required adjustments to the ART regimen based on predicted drug interactions (Table 8.6)

ART Regimen Selection for TB/HIV Co-infection

Preferred ART regimens for patients with TB/HIV co-infection are summarized in Tables 8.5 and 8.6.

Table 8.5: Preferred ART Regimens for TB/HIV Co-infection for Patients Newly Initiating 1st Line ART

Age	**1st Line if TB/HIV Co-infection**
< 2 weeks	Start anti-TB treatment immediately; start ART after 2 weeks of age, once tolerating anti-TB drugs (follow the regimen recommendations children 2 weeks to < 3 years of age)
2 weeks - < 3 years	• ABC + 3TC + LPV/r + RTV[1,2] • If not able to tolerate super-boosted LPV/r+RTV then use AZT + ABC + 3TC for duration of TB treatment • After completion of TB treatment revert back to the recommended 1st line regimen (ABC + 3TC + LPV/r)
3-15 years (< 35 kg body weight)	ABC + 3TC + EFV
3-15 years (≥ 35 kg body weight)	TDF + 3TC + EFV
>15 years	TDF + 3TC + EFV
PWID >15 years	TDF + 3TC + ATV/r (using rifabutin-based anti-TB treatment)

1. Use "super-boosted" LPV/r by adding additional ritonavir suspension to manage the drug interaction between LPV/r and rifampicin (see Table 8.7 for dosing recommendations). As soon as TB treatment is completed the child should go back to standard LPV/r dosing. For children who cannot tolerate LPV/r + RTV (usually because of GI side-effects), the alternative regimen is AZT+ABC+3TC; as soon as TB treatment is completed the child should go back to ABC+3TC+LPV/r, because of the increased risk of developing treatment failure while on a triple-NRTI regimen
2. EFV is no longer being recommended for children < 3 years old because of highly variable EFV metabolism at that age

Table 8.6: Preferred ART Regimens for TB/HIV Co-infection for Patients Currently on 1st Line ART[1, 2]

Current Regimen[3]	Age	Recommended Substitution
PI/r-based	< 3 years old	• Super-boost LPV/r with additional RTV[4] • If not able to tolerate super-boosted LPV/r + RTV then use AZT + ABC + 3TC for duration of TB treatment • **After completion of TB treatment revert back to the original regimen**
	3 years – 15 years (weight < 35kg)	Switch to EFV. If EFV cannot be used, super-boost LPV/r with additional RTV to a ration of 1:1
	Child < 15 years and ≥ 35 kg	
3-15 years (≥ 35 kg body weight)	> 15 years (any weight)	Continue PI/r; use rifabutin for anti-TB treatment
EFV-based	Any age	Continue same regimen
NVP-based*	< 3 years old	Switch to AZT + ABC + 3TC **(as soon as TB treatment is completed switch back or original regimen)**
	≥ 3 years old	Switch to EFV

***Guidelines recommend LPV/r for children < 3 years, however some children < 3 years maybe on NVP due to LPV/r toxicity**

1. Always assess for HIV treatment failure in patients who develop TB after being on ART for ≥ 6 months
2. For patients on 2nd line ART, subsequent regimens, or nonstandard drugs such at RAL or DTG who require regimen change because of TB treatment, consult the Regional or National HIV Clinical TWG (ulizanascop@gmail.com)
3. NRTIs in the patient's current regimen do not require any adjustments with anti-TB treatment
4. Use "super-boosted" LPV/r by adding additional ritonavir suspension to manage the drug interaction between LPV/r and rifampicin (see Table 8.7 for dosing recommendations). As soon as TB treatment is completed the child should go back to standard LPV/r dosing. For children who cannot tolerate LPV/r+RTV (usually because of GI side-effects), the alternative regimen is AZT+ABC+3TC; as soon as TB treatment is completed the child should go back to ABC+3TC+LPV/r, because of the increased risk of developing treatment failure while on a triple-NRTI regimen

Table 8.7: Ritonavir Dosing for Super-Boosting LPV/r in Children Taking Rifampin

Weight Range (kg)	**Lopinavir/ritonavir (LPV/r)**		**Additional dosing of ritonavir for children taking rifampin**
	Twice Daily	Twice Daily	Twice Daily
	Lopinavir/ ritonavir 80/20mg/ml solution	Lopinavir/ ritonavir 200/50mg tablets	Ritonavir liquid (80mg/ml, in 90 ml bottle) Ritonavir dose is adjusted to nearest mark for the ease of measurement
3 - 5.9	1 ml	-	1 ml
6 - 9.9	1.5 ml	-	1 ml
10 - 14.9	2 ml	-	1.5 ml
14 - 19.9	2.5 ml	1 tab twice daily	2 ml
20 - 24.9	3 ml	1 tab twice daily	2.5 ml
25 - 34.9	4 ml	2 tab in am & 1 tab in pm	4 ml in am & 2 ml in pm

9. HBV/HIV and HCV/HIV Co-infection Prevention and Management

9.1 Hepatitis B/HIV co-infection

HIV and HBV have shared transmission routes. Acute HBV infection in HIV positive people is associated with increased risk of chronicity, reduced chances of spontaneous clearance, higher rates of replication and reactivation and therefore increased incidence of chronic liver disease, cirrhosis and hepatocellular carcinoma (HCC). Additionally, HIV/HBV co-infection has been associated with rapid HIV disease progression and poorer HIV treatment outcomes. Other complications of HIV/HBV co-infection include increased incidence of direct hepatotoxicity, drug-toxin interactions and ART-related immune reconstitution hepatitis.

9.1.1 Screening

All HIV positive persons should be screed for HBV infection, using HBsAg, as part of initial evaluation. To promote towards population-wide prevention, hepatitis B prevention should be integrated into routine HIV prevention and care programmes. In this setting, other indications for HBsAg screening could include:

- Household and sexual contacts of HBsAg positive individuals
- Persons who inject drugs (PWID)
- Men who have sex with men
- Sex workers
- Prisoners
- Blood donors
- Unvaccinated healthcare providers

HIV positive persons on follow-up who present with signs of liver disease (jaundice, ascites, abnormal liver on palpation, other signs of cirrhosis) or unexplained and persistent ALT elevation should also be screened for HBV as part of their work-up.

9.1.2 Prevention

A. Vaccination: HBV vaccination reduces the risk of new (incident) HBV infection in HIV positive persons; and also reduces the risk of new infections becoming chronic. Therefore,

- HIV positive infants, children, adolescents and adults without evidence of hepatitis B infection (HBsAg negative) should be vaccinated against hepatitis B with the standard vaccination regimen.
- HIV exposed infants (HEI) should also receive hepatitis B vaccination as part of childhood immunization as recommended by National Vaccines and Immunizations Programme.
- As a strategy to reduce the population level burden of HBV infection, HIV prevention and treatment settings should integrate HBV prevention through vaccination. Thus, HBV vaccination is recommended for the following groups:
    - Babies and young children (through EPI and catch-up immunization for those who missed EPI vaccination)
    - Household contacts of people who are HBsAg positive
    - Sexual contacts of HBsAg positive people
    - People on haemodialysis,
    - PWID
    - Individuals with chronic liver disease and/or hepatitis C
    - Inmates and prison personnel
    - Healthcare workers

Table 9.1: Hepatitis B vaccination schedule for HIV-positive adolescents and adults

Vaccine	Dose (intramuscular)	Schedule
Engerix™	40 mcg	0, 1, 2,and 6 months
HBvaxPRO™	40 mcg	
Fendrix™ (adjuvanted)	20 mcg	

B. General preventive measures: General measures for infection prevention adopted by HIV positive persons and in healthcare settings are effective in preventing HBV transmission. These include:

- Hand hygiene
- Use of personal protective equipment
- Medical waste management including safe disposal of used sharps
- Disinfection and sterilization
- General health advice against sharing of personal effects like towels, tooth-brushes, combs and other grooming equipment.
- Harm reduction counselling and services for PWID as outlined in section 12.
- Safer sex practices

9.1.3 Treatment

A. When to start ART

All HIV infected patients who are co-infected with hepatitis B should be started on ART irrespective of CD4 cell count, WHO clinical state or activity and stage of liver disease.

The general recommendations for treatment preparation, adherence counselling and support and monitoring of therapy for PLHIV apply. However, because HBV positive patients are at higher risk of hepatotoxicity, closer monitoring of liver function (with ALT) is advised. Table 9.2 below provides a summary of areas of focus during initial evaluation for HIV/HBV co-infected patients initiating therapy.

B. Recommended first-line ART in HIV/HBV co-infection

The recommended first-line ART in HIV/HBV co-infection is TDF + 3TC + EFV.

Treatment with both TDF and 3TC is recommended as 3TC alone will result in rapid emergence of resistance. In case of renal impairment (as assessed by creatinine clearance), the dose of TDF should be adjusted (refer to Table 9.3).

Table 9.2: Summary of Initial Clinical and Laboratory Evaluation in HIV/HBV co-infection

	Findings	Action
History	Alcohol use, cigarette smoking, intravenous drug use, risky sexual practices, anorexia, right upper quadrant pain, jaundice, early satiety, haematemesis, dark stool, bleeding, pruritus	Assess, counsel and support to stop taking alcohol; counsel and support smoking cessation; counsel and provide or refer for harm reduction interventions
Physical examination	Enlarged liver, enlarged spleen, ascites, scratch marks	Evidence of established chronic liver disease, closer follow-up due to increased risk of hepatotoxicity, discuss or refer to a consultant for additional evaluation and management
ALT	If elevated, may point to active liver disease. Exclude other causes of elevation of liver enzymes.	Every effort should be made to assess for liver function (albumin and INR); especially in symptomatic patients. However, this should not delay initiation of ART
Creatinine	Calculate creatinine clearance	In HIV/HBV co-infection, TDF is indicated even in patients with CrCl below 50 mL/min. In such patients, avoid FDCs. Instead administer the ART as single drugs to allow for dosage adjustment as shown below
Comorbidities	HCV antibody, HDV, random blood sugar, lipid profile, alcoholic and non-alcoholic liver disease, hepatocellular carcinoma (family history)	Refer the patient for additional investigations where these are suspected

Table 9.3: Dose adjustment of TDF in patients with impaired renal function*

Creatinine clearance (mL/min)***	50 - 80	30-49 mL	10-29	Haemodialysis
TDF 33 mg/g granules	245 mg (7.5 scoops of granules or 245mg film-coated tablet) once daily	132 mg (4 scoops of granules) once daily	65 mg (2 scoops of granules once daily	16.5 mg (0.5 scoop) after each 4 hr session of dialysis
TDF 300 mg	300 mg once daily	300 mg every 48 hrs	300 mg every 72 to 96 hours (twice weekly). For patients getting HD, administer 300 mg once weekly after completion of dialysis sessions **	

*Patients with impaired renal function in whom the continued use of TDF outweighs the risks (such as in the management of HIV/HBV co-infection) should be managed with input from a specialist in internal/paediatric or renal medicine

** Assuming 3 haemodialysis sessions per week, each of approximately 4 hours duration or after 12 hours cumulative haemodialysis

***For dosing of other ARVs refer Table 6.5

C. Follow-up, Monitoring

Follow-up of HIV/HBV con-infected patients should be as for all other patients on ART. However, consider more frequent monitoring (using ALT) for patients with active liver disease (jaundice, liver cirrhosis and features of portal hypertension at baseline. The presence of co-infection also increases the risk of drug-related hepatotoxicity from all ARV drugs by 3-5 times, especially when anti-TB and HAART are given simultaneously. Also, hepatic flare (AST > 5 times normal value) can occur, often in the initial 3 months. ALT elevations 5-10 times normal can be tolerated in the first 3 months of HAART as long as the patient is not severely symptomatic, remains stable without progression; and there is no evidence of synthetic dysfunction (INR normal, glucose normal, albumin normal).

Subsequent laboratory monitoring after baseline should be conducted every 6 months. Patients should be counselled and supported to abstain from consuming alcohol.

D. Stopping treatment, treatment interruptions

TDF-based ART should not be stopped abruptly in a patient with HIV/HBV co-infection as this may result in a flare-up of the hepatitis. If the regimen must be stopped and another alternative for suppressing hepatitis B cannot be found, liver enzymes should be monitored and treatment re-instated as soon as possible.

E. Second line for HIV/ HBV co-infected

Maintain TDF + 3TC (or FTC) in the ART regime for patients switching from TDF-based-therapy.

The recommended second-line ART regimen in HIV/HBV co-infection is AZT + TDF + 3TC (or FTC) + ATV/r (or LPV/r or DTG or RAL)

HIV/HBV co-infected patients failing second-line ART should be discussed in the MDT and referred to a regional or national clinical support centre.

9.2 Hepatitis C/HIV co-infection

In Kenya, the prevalence of HCV infection is high in PWID (estimated to be between 10 and 30 %). The prevalence in the general population and among PLHIV is low (estimated to be below 3%); but likely to be higher in HIV infected PWID due to shared routes of transmission. HIV/HCV infection is associated with:

- Rapid progression of liver fibrosis
- Higher risk of deteriorating liver disease even in the presence of controlled HIV disease
- Worsened hepatotoxicity as a result of ART and other drugs used in the treatment of comorbidities

Thus, HIV-positive persons at risk of HCV co-infection should be identified and offered HCV treatment. The recent introduction of direct acting antiviral therapies (DAAs) for treatment of HCV has simplified the management of HIV/HCV co-infection; making it possible to uncomplicated HIV/HCV infection safely even in primary care settings.

However, treatment for HCV is a rapidly evolving field of therapeutics. Providers are encouraged to seek regular updates on the subject and, when in doubt, to discuss individual cases with experienced providers or consult a national or regional clinical support centre.

9.1.1 Screening

HCV serology should be offered to individuals at risk of HCV infection. These include

- People who inject or use intranasal drugs
- Persons who have had tattoos, body piercing or scarification procedures from settings of doubtful infection prevention precautions
- Children born to HCV positive mothers
- Household and sexual contacts of HBsAg positive individuals
- Persons who inject drugs (PWID)
- Men who have sex with men
- Sex workers
- Prisoners
- Blood donors
- Unvaccinated healthcare providers

Up to 45% of individuals who are infected with HCV spontaneously clear the infection. To confirm chronic HCV infection, HCV positive individuals should be offered nucleic acid HCV RNA testing to establish presence of chronic HCV infection.

9.2.2 Prevention

General preventive measures: General measures for infection prevention for prevention of blood-borne infections are effective in preventing HCV transmission. These include:• People who inject or use intranasal drugs

- Recommendations for healthcare settings
  - Hand hygiene: including surgical hand preparation, hand-washing and use of gloves
  - Safe handling and disposal of sharps and waste
  - Effective disinfection and sterilization
  - Provision of safe blood and blood products
  - Training of healthcare providers
- Recommendations for PWID
  - Harm reduction counselling and support (refer section 12)
- Recommendations for prevention of sexual transmission
  - Correct and consistent condom use
  - Access to prevention services for sex workers and other people at risk (including screening and treatment STIs, frequent testing for HIV and HCV testing)

9.2.3 Treatment of HIV/HCV co-infection

A. Initial evaluation

Table 9.4: Summary of Initial Clinical and Laboratory Evaluation in HIV/HCV co-infection

	Findings	Action
History	Alcohol use, cigarette smoking, intravenous drug use, risky sexual practices, anorexia, right upper quadrant pain, jaundice, early satiety, haematemesis, dark stool, bleeding, pruritus	Assess, counsel and support to stop taking alcohol, counsel and support smoking cessation; counsel provide and refer for harm reduction interventions
Physical examination	Enlarged liver, enlarged spleen, ascites, scratch marks	Evidence of established chronic liver disease, closer follow-up due to increased risk of hepatotoxicity, discuss or refer to a consultant for additional evaluation and management
HCV RNA PCR	For confirmation of chronic HCV infection.	If available, a baseline
HCV genotype		Important for selecting appropriate DAA regimen
ALT	If elevated, may point to active liver disease. Exclude other causes of elevation of liver enzymes.	Every effort should be made to assess for liver function (albumin and INR); especially in symptomatic patients. However, this should not delay initiation of ART
Comorbidities	HBV, HDV, random blood sugar, lipid profile, alcoholic and non-alcoholic liver disease, hepatocellular carcinoma (family history)	Refer the patient for additional investigations where these are suspected

Table 9.5: Recommended DAA for the treatment of HCV without cirrhosis

Genotype	DAA Regimen	Duration of treatment	ART considerations
1, 2 & 3	Daclatasvir (60 mg) + Sofosbuvir (400 mg)	12 weeks	If the ART regimen contains EFV, increase the dose of Daclatasvir to 90 mg once daily. When used concomitantly with boosted Atazanavir, the dose of Daclatasvir should be reduced to 30 mg once daily
	Daclatasvir (60 mg) + Sofosbuvir (400 mg)	12 weeks*	
	Daclatasvir (60 mg) + Sofosbuvir (400 mg)	12 weeks*	
4	Elbasvir (50 mg + Grazoprevir (100 mg)	12 weeks	Use with ARVs with minimal interactions with these: TDF, ABC, 3TC, FTC, RAL and DTG
5 & 6	Ledipasvir (90 mg) + Sofosbuvir (400 mg)	12 weeks	Avoid concomitant use of TDF and Ledipasvir if the CrCl is < 50 ml/min

*Treatment duration is extended to 16 to 24 weeks in patients with compensated cirrhosis. Patients with compensated and decompensated cirrhosis should be started on DAA HCV therapy under specialist supervision.

10. ARVs for Post-exposure Prophylaxis (PEP)

Post Exposure Prophylixs should always be offered as soon as possible (if possible < 72 hours) after a high-risk exposure (as defined in Table 10.1). Three-drug regimens are preferred for PEP, however if the patient is unable to tolerate a drug (usually the PI/r), then 2 drugs can be used. Patients should be counselled and strongly encouraged to complete the full 28-day course of PEP once a decision has been made to initiate PEP.

For occupational exposure, immediate care of the exposure site includes: wash the site with soap and water; encourage bleeding from the site but do not increase the tissue damage in any way (e.g. do not scrub or cut the site).

Table 10.1: Post-exposure Prophylaxis

Considerations	Recommendation	
Eligibility: Must meet all of the following criteria	• Exposed individual is HIV negative at baseline • Exposure must have occurred within the past 72 hours • Exposure must be high-risk (high-risk type AND source AND material): - Type: mucous membrane; non-intact skin, or; percutaneous injury - Source: HIV positive or of unknown HIV status - Material: blood or bloody body fluids; breast milk; semen; vaginal secretions; synovial, pleural, pericardial, amniotic fluids; CSF, or; HIV cultures in lab	
Management at initial contact	• Counsel on risks and benefits of PEP and obtain verbal consent for HIV testing • Voluntary testing for both exposed and source individuals • Offer PEP as soon as high-risk exposure is established and exposed individual tests HIV-negative at baseline (if HIV testing not available, can provide 1-2 days of PEP to cover until HIV test performed) • Pregnancy testing • Cr (if TDF-containing regimen) and Hb (if AZT-containing regimen), however PEP should be offered even when lab tests are not available. Do not delay administration of PEP while waiting for lab results • Hepatitis B vaccination (if not previously immunized & not known HBV positive)	
ARV regimen for PEP	Adult: TDF* + 3TC + ATV/r Children: ABC* + 3TC + LPV/r	*AZT can be used as an alternative when TDF or ABC cannot be used
Time of initiation	As soon as possible after exposure, but no later than after 72 hours	
Duration of PEP	28 days (dispense all 28 days of treatment at the first visit)	
Dose of PEP	Same as indicated for ART; use weight-based dosing for children	
Follow-up	• Follow up client at 7 days, 14 days, and 28 days after starting PEP • Follow-up HIV testing at 3 and 6 months after exposure • Assess for and manage side effects due to PEP	
Counselling	Adherence counselling, risk reduction, trauma and mental health counselling, social support and safety, safe sex practices	
Other services for sexual assault	• STI prophylactic treatment to all (treat for vaginal/urethral discharge syndrome following the national STI algorithms) • Emergency contraception for non-pregnant women • Tetanus toxoid for any physical injury of skin or mucous membranes • Documentation of clinic evidence of assault and collection of forensic evidence • Refer to post-rape care guidelines for additional details	

11. Oral Pre-Exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis (PrEP) against HIV involves taking daily antiretroviral agents by HIV negative individuals to reduce the risk of acquiring HIV infection.

Oral PrEP containing TDF should be offered to individuals at substantial ongoing risk of HIV infection, as part of a package of combination prevention tailored to individual choice and risk profile as determined during initial and follow-up assessment and risk reduction counselling.

PrEP may be offered to the HIV seronegative partner in a sero-discordant relationship during attempts to conceive.

11.1 Recommended ARVs for PrEP

The recommended ARV regimen for use as PrEP is: TDF 300 mg and Emtricitabine 200 mg once daily (given as a FDC). Alternatively, TDF 300 mg once daily can be used if TDF/FTC is not available. If neither of these options is available, TDF 300 mg/ 3TC 300 mg may be used.

Table 11.1: Recommended Antiretroviral Agents for Oral PrEP

Preferred	Alternative
TDF/FTC (300 mg/200 mg) as FDC once daily	TDF 300 mg once daily
	TDF/3TC 300 mg/300 mg as FDC once daily

PrEP should only be offered after thorough assessment to establish eligibility, readiness for effective use, required follow-up and absence of contraindications to TDF +/- FTC/3TC.

11.2 Indications for PrEP

PrEP is offered to sexually active HIV-negative individuals who are at significant risk of acquiring HIV infection. Clients must meet ALL of the following criteria before initiating PrEP:

1. At high risk for acquiring HIV, by meeting ANY of the following indications
   - Sexual partner is known HIV positive and: not on ART, or on ART < 6 months, or suspected poor adherence to ART, or most recent VL is detectable
   - Sexual partner/s are of unknown HIV status and are at high-risk for HIV infection (has multiple sexual partners, has had STIs, engages in transactional sex, injects drugs, from high HIV burden settings)
   - Engaging in transactional sex
   - History of recent sexually transmitted infection
   - Recurrent use of post-exposure prophylaxis
   - History of sex whilst under the influence of alcohol or recreational drugs as a habit
   - Inconsistent or no condom use or unable to negotiate condom use during intercourse with persons of unknown HIV status
   - Injection drug use where needles and syringes are shared
   - Sero-discordant couples trying to conceive

2. AND meet ALL of the following criteria
   - Confirmed HIV negative (rapid antibody testing following the HTS algorithm on the day of PrEP initiation is adequate confirmation of HIV-negative status)
   - Does not have a current or recent (within past one month) illness consistent with acute HIV infection (fever, sore throat, muscle or joint pains, swollen glands, diarrhoea or headache) in combination with a preceding high-risk exposure for HIV
   - Assessed as ready to adhere to PrEP and willing to attend follow-up evaluations including repeat HIV testing and monitoring for side effects
   - No contraindication to use of TDF +/- FTC/3TC

PrEP does not eliminate the risk of HIV infection; also it does not prevent STIs or unintended pregnancies. It should, therefore, be offered as part of a combination prevention package that includes risk reduction counselling, HIV testing, condoms and lubricants, STI screening and treatment, contraception, needle exchange and opioid replacement therapy.

11.3 Risk Behaviour Assessment

Providers should make every effort to establish rapport with potential PrEP clients, provide adequate privacy and offer assurances of confidentiality. A non-judgemental attitude will contribute towards open conversation where clients will be free to share accurate information on risk (for risk assessment, Table 11.2) and concerns about PrEP. PrEP should only be offered after thorough assessment to establish eligibility, readiness for effective use, commitment to adhere to required follow-up and absence of contraindications to TDF and/or FTC.

Table 11.2: Risk Behaviour Assessment

In the last 6 months:
Have you been sexually active?
Have you had more than one sexual partner?
Have you had sexual contact where neither you nor your sexual partner was wearing a condom?
How many of your sexual partners were HIV-positive or unknown HIV status?
Have you had sex with HIV-positive partners or persons of unknown HIV status without a condom? Have you been treated for a sexually transmitted infection?
Have you injected drugs that were not prescribed by healthcare provider? If yes, did you use syringes, needles or other drug preparation equipment that had already been used by another person?
Have you had sex while you or your partner was under the influence of alcohol or drugs?
History of GBV?
Are you in a HIV discordant relationship newly diagnosed?

11.4 Minimum Required Laboratory Evaluation for PrEP

Before initiating PrEP, the following investigations should be performed:

- Rapid HIV test as per HTS guidelines
- Baseline creatinine is recommended but should not delay initiation of PrEP. For clients with pre-existing risk factor for renal impairment (such as age > 65 years, diabetes, uncontrolled hypertension, glomerulonephritis, HBV and HCV infection), every effort should be made to obtain a serum creatinine prior to initiation of PrEP
- Where available: HBsAg and HCV serology; if HBsAg is negative, offer HBV vaccination

The following investigations should be done for monitoring patients on PrEP

- Rapid HIV antibody test every 3 months
- Annual serum creatinine and CrCl

Table 11.3: Summary of Initial and Follow-up Assessment

Visit	Action
First (Screening Visit) Clinician Visit	• HIV testing and counselling • Evaluate for eligibility & willingness and readiness to take oral PrEP • Educate about the risks, benefits and limitations of PrEP • Educate client about recognizing symptoms of acute HIV infection and what to do if such symptoms occur (i.e. urgently return for HIV testing) • Behaviour risk assessment • STI screening, contraceptive counselling and services • LMP and contraceptive use (for women); if pregnancy suspected, obtain a pregnancy test. However, pregnancy in not a contraindication to PrEP • Adherence counselling • Discuss combination prevention • Laboratory Evaluation - CrCl, HBsAg, pregnancy test (baseline investigations should not delay initiation of PrEP) If no contraindication to TDF and the client is eligible and ready, prescribe TDF/FTC one tablet once daily for 30 days (alternative TDF/3TC one tablet once daily for 30 days, or TDF 300 mg once daily for 30 days); agree on a follow-up date before the prescription is finished
Visit 2 (Month 1) Counsellor/Clinician Visit	• Counsellor/ Clinician visit • Safety monitoring clinical assessment • HIV testing • Adherence and risk reduction counselling • Offer HBV vaccination if available and HBsAg negative
Visits Months 3, 9, 15, 18 Counsellor-led visits	• HIV testing and counselling • HIV risk review and assessment for PrEP continuation • Support adherence counselling
Visits for months 6, 12, 18, 24, 36 Clinician-led visit	• HIV test • Creatinine and creatinine clearance annual (earlier, if indicated) • Risk assessment review • Adherence support • Review for continuation or discontinuation of PrEP

During every visit,

- Reassess risk of HIV infection and offer risk reduction counselling. HIV testing should be repeated every 3 months
- Assess for adverse effects and adherence

Remind PrEP users that it takes 7 doses of PrEP to achieve adequate levels of the ARVs in tissues to be effective. During these days, safer sex practices should be encouraged (including abstinence and condoms).

11.5 Contra-indications to Oral PrEP

- HIV infection or suspected acute HIV infection (i.e. flu-like symptoms in the last 4 weeks in combination with a preceding high-risk exposure for HIV)
- Adolescents < 35 kg or age < 15 years
- Impaired renal function (estimated creatinine clearance of <50 mL/min)
- Unable or unwilling to adhere to prescribed PrEP or follow-up schedule

Table 11.4: Managing Clinical and Laboratory Results on Initial and Follow-up Assessment

Screening	Action
HIV-positive at initial evaluation	Do not start PrEP, counsel and link to care and treatment
HIV-positive after initiation of PrEP	Discontinue PrEP, counsel and link to care and treatment
Positive STI Screen	Thorough genitourinary and anorectal examination, urine dipstix for urethritis, serological testing for syphilis, full STI evaluation of resources available. (Refer to STI algorithm). Refer to guidelines on syndromic management of STIs
HBsAg-negative	Offer HBV vaccination
HBsAg-positive	This is not a contraindication to PrEP. However, will require monitoring of liver function and referral for management of liver disease
Flu-like illness after initiating PrEP	Continue PrEP, test for HIV at first contact and after 28 days, and if negative, continue with usual follow-up
Side effects of PrEP	GIT - nausea, vomiting, weight loss: these are often mild, self-limiting and occur during the first 1-2 months. Provide supportive counselling, offer symptomatic treatment e.g. anti-emetics like Metoclopramide 10 mg 8 hourly for 3 to 5 days Renal - transient increase in creatinine, and rarely proteinuria and Fanconi's syndrome (presenting as polyuria, bone pain and weakness). Measure creatinine (and calculate estimated creatinine clearance) at initiation of ART, at 1 and 4 months and annually thereafter (or whenever indicated (symptom directed)). If creatinine clearance (eGFR) < 50 mL/min; Do not start PrEP, recheck after 2 weeks. Refer for evaluation of underlying renal disease. If the renal function returns to normal, reassess for PrEP and initiate/ continue PrEP. When restarting PrEP, optimum protection is reached after 7 doses of PrEP. PrEP should not be prescribed for individuals using nephrotoxic drugs like acyclovir, aminoglycosides, retinoids, instead, offer alternative HIV prevention services
Pregnancy or breastfeeding	Pregnancy and breastfeeding are not contraindications to provision of PrEP. Pregnant or breastfeeding women whose sex partners are HIV positive or are at high risk of HIV infection may benefit from PrEP as part of combination prevention of HIV infection. PrEP is also indicated for HIV-negative in discordant partnerships who wish to conceive. PrEP in these situations can be prescribed during the pre-conception period and throughout pregnancy to reduce risk of sexual HIV infection

11.6 Criteria for Discontinuing PrEP

PrEP should be discontinued if ANY of the following criteria are met:

- HIV positive
- Change in risk status (low risk)
- Renal dysfunction with creatinine clearance below 50mL/min
- Client request to stop
- Sustained non-adherence
- Sustained viral suppression of the HIV positive partner in a discordant relationship. But the couple should continue consistent condom use

Users discontinuing PrEP due to low risk or requesting to stop should continue PrEP for at least 28 days after the last potential exposure to HIV. Reasons for discontinuation should be documented in the client's record.

Table 11.5: Pre-Initiation Education Check-list

How PrEP works as part of combination prevention	**Explain the need for baseline and follow-up tests including HIV testing**
Limitations of PrEP • Link efficacy to adherence • PrEP reduces but does not eliminate the risk of acquiring HIV • PrEP does not prevent pregnancies and STIs	Discuss when and how PrEP may be discontinued
PrEP use • The medications used (show the client the pills) • How the medications are used (daily) • Number of daily doses required to achieve efficacy (7 doses) • What to do when doses are missed (continue daily doses) • Discontinuation of PrEP (need to continue for 28 days from last potential exposure to HIV) • Side effects and what to do in case these are experienced (Consult the clinician)	Discuss what to do in case of client experiences symptoms of seroconversion (acute HIV infection)
Long-term use and safety of PrEP	**Risk reduction counselling and Support** Education (risk and safer sex practices) Managing mental health needs Couple counselling Access to, and consistent use of condoms and lubricants Access to and need for frequent HIV testing Early access to ART VMMC STI screening and treatment Harm reduction for PWID

Table 11.6: Pre-Initiation Assessment Check-list

Item	Y/N	Item	Y/N
HIV testing and counselling, HIV-negative		STI screening and treatment	
Symptoms of acute viral infection in last 6 weeks		For Women	
		Pregnancy test	
		Pregnancy and pregnancy intention	
		• Is the client currently using any contraception?	
		• If not, is she interested in using long-term hormonal contraception in addition to condoms?	
		• Is the client trying to conceive?	
		• Is the client pregnant or breastfeeding?	
Behaviour risk assessment		Plans for accessing PrEP	
Substance use and mental health screening		Serum creatinine and creatinine clearance > 50 mL/min	
Partner information		HBsAg	
Pre-initiation education and understanding of PrEP		HCV serology	
Readiness and willingness to adhere to prescribed PrEP and follow-up schedule		Medication history	

11.7 Who Should Provide PrEP and Where

PrEP must be prescribed by a healthcare professional who has completed training on the national guidelines for the use of ARVs as PrEP.

PrEP can potentially be offered in any setting that has trained healthcare professionals who have been trained on the national guidelines for use of ARVs as PrEP, and with systems and tools in place for the monitoring, documentation, and reporting of PrEP use.

PrEP implementation can be integrated in any setting that meets the conditions for initial evaluation and initiation including:

- Drop-in Centers (DICEs) for key populations (including community and facility settings)
- HIV clinics (for HIV-negative partners before the HIV-positive partner achieves viral suppression)
- ANC/MNCH/RH and STI clinics
- Community settings meeting the criteria for initial client assessment and evaluation eg Integrated prevention centers and youth friendly outlets
- Resupply of PrEP can be done in both community and facility settings

Documentation of PrEP must include completion of the following tools:

[e.g. PrEP enrolment register, appointment diary, follow-up register, initial and follow-up clinical assessment forms, etc]

12. People Who Inject Drugs (PWID) and HIV

A. Introduction

People who inject drugs (PWID) are at increased risk of HIV infection. In Kenya, the HIV prevalence among PWID is up to 4 times that of the general population. PWID also suffer a higher burden of viral hepatitis (HBV and HCV), TB and sexually transmitted infections irrespective of HIV status. Despite these, PWID have limited access to HIV prevention, care and treatment services.

Every effort should be made to implement provide evidence-informed interventions in the comprehensive package of measures targeting PWID; either in combination or (depending on site capacity) singly, with linkage to comprehensive care, Table 12.1).

PWID have complex needs related drug dependency, psychosocial and medical complications of injection and other substance use. When they require ART, anti-TB or any other therapy, they are at increased risk of adverse drug reactions and drug interactions; and non-adherence. These patients are best, comprehensively, managed by providers who have received specific training in the management of injection drug use. Once identified, PWID should be counselled and linked to programs with the capacity to offer comprehensive care for such patients.

Table 12.1: Comprehensive Package of Harm Reduction for PWID

Intervention	Comment/Recommendations
HIV testing services	PWID are at high risk of HIV infection, are diagnosed late and therefore have poorer treatment outcomes following ART initiation • PWID should be offered regular HIV testing and counselling and be linked to comprehensive HIV prevention, care and treatment services including harm reduction counselling and support • Retest for HIV every 3 months if there is ongoing risk
Targeted information, education and communication for PWID and their sexual partners	PWID and sexual partners should be provided with information and counselling on risks related to drug use and risky sexual behaviour; and where and what harm-reduction services are available. Peer-based networks are effective in improving access and retention to harm reduction care
Condom provision	The correct and consistent use of condoms with condom-compatible lubricants is recommended for all PWID to prevent pregnancy and sexual transmission of HIV and STIs
Prevention and treatment of sexually transmitted infections	PWID may be at higher risk of STIs due to sex work or other risky sex practices. STIs, especially GUDs increase the risk of HIV infection and transmission, and are often a sign of unsafe sexual behaviour or risk of HIV transmission. Screening, diagnosis, treatment and prevention of STIs should be offered routinely as part of comprehensive HIV prevention and care for PWID

Table 12.1: Comprehensive Package of Harm Reduction for PWID (continued)

Intervention	Comment/Recommendations
Prevention, diagnosis and treatment of TB	Independent of HIV infection, PWID have an increased risk of TB. HIV infection further increases this risk. All PWID should be screened regularly for active TB using the symptom-based screening algorithm at each contact with healthcare worker. Once active TB is ruled out, IPT should be provided to PWID living with HIV for 6 months with support provided to ensure adherence. PWID with active TB should receive standard TB treatment as per the national guidelines and supported to complete treatment. Anticipate and manage complications due to viral hepatitis or renal impairment. • PWID should have the same access to TB prevention, screening and treatment services as other populations at risk of or living with HIV
Prevention, vaccination, diagnosis and treatment for viral hepatitis	Hepatitis B and C disproportionately affect PWID due to overlapping risk factors of sexual transmission and sharing needles, syringes and other drug use items. Harm reduction and behavioural interventions are also effective in reducing risk of infection/transmission of HBV and HCV. • PWID should be screened for HBV (by HBsAg) and HCV (by HBV serology) at first contact. - Hepatitis B · Hepatitis B vaccination is recommended for those who are HBsAg negative. A higher-dose HBV vaccine should be used with the rapid regimen. If the rapid regimen is not available, the standard regimen should be offered · HBV/HIV co-infected PWID should be started on ART containing TDF + 3TC or FTC in addition to harm-reduction interventions to optimize adherence and treatment outcomes - Hepatitis C · HCV/HIV co-infected PWID should be initiated on ART. Specific HCV antiviral therapy is recommended in consultation with expertise in the management of HCV infection
Needle and syringe programmes (NSPs)	NSPs help decrease drug-related risk behaviours, reduce quantity of contaminated needles in circulation, reduce risk of new HIV infections and improve referrals and linkages to HTS and HIV care and treatment services. NSPs are effective means for introducing combination prevention to PWID including HTS, STI screening and treatment, condoms provision, OST, and HIV care and treatment • **All PWID should be linked to NSPs to access sterile injecting equipment.**
Opioid substitution therapy (OST)	OST using methadone or other suitable alternative is effective in • the treatment of opioid dependency, • reducing risk behaviours related to drug use and • reducing HIV transmission • improving PWIDs' adherence to ART Identify and link all PWID for opioid substitution therapy.

Table 12.1: Comprehensive Package of Harm Reduction for PWID (continued)

Intervention	Comment/Recommendations
Antiretroviral therapy	• ART is effective in managing HIV infection in PWID. However, adherence may interfere with ART success. Intensive support is required including OST, enhanced counselling techniques and DOT. • Close monitoring of ART is necessary because of risk of drug-drug interactions, and renal and liver toxicity. • HIV-positive PWID should be offered comprehensive HIV care and treatment services including ART. When ART is provided with additional targeted support, PWID can achieve and maintain viral suppression similar to others' outcomes. • Oral PrEP (containing TDF) is recommended as an additional prevention choice for PWID at substantial risk of HIV infection as part of combination prevention and harm reduction approaches.
Community outreach	PWID face barriers to accessing formal facility-based health services due to stigma, discrimination and fear of victimization among other factors. Outreach either directly from the facility or through collaborations with community-based groups is an effective means of delivering harm-reduction interventions in addition to HIV prevention, care and treatment services. Peer-led, community based approaches are particularly useful in improving adherence and retention.

B. ART in HIV positive PWID

Table 12.2: Summary of ART recommendations for PWID

Care and Support	Recommendation/Additional Information
When to Start ART in HIV positive PWID	ART should be initiated in all individuals with HIV regardless of WHO clinical stage or CD4 cell count.
What to start with (first-line ART)	Irrespective of OST, PWID with HIV infection should be initiated on a first-line regimen of TDF + 3TC or FTC + ATV/r. Always consider the risk of transmitted drug resistance. For PWID with TB/HIV co-infection, replace rifampicin with rifabutin.
Second-line ART	TDF + 3TC + DRVr + RAL or DTG, discuss with an expert provider or a regional/national clinical support centre.
Treatment preparation and adherence counselling and support	Injection drug use is not a contra-indication to ART initiation. OST, though important in contributing to the success of ART in PWID, should not be a pre-requisite to initiation of ART. However, these patients require additional preparation and support to increase their chances of successful treatment including: • Harm reduction interventions • Thorough baseline assessment for important comorbid conditions like hepatitis, renal impairment, TB and depression or other psychiatric disorders. • Negotiation for, and access to (modified) directly observed therapy • Community outreach
Preventing and managing drug-drug interactions	• AZT, ABC, EFV and NVP should be avoided in patients on methadone maintenance therapy: - Methadone increases the levels of AZT by 41%, significantly increasing the risk of AZT bone marrow toxicity - ABC decrease methadone AUC by 22% while methadone decrease ABC by 34% • EFV and NVP decrease methadone levels by 57% and 46% respectively • There are no clinically relevant pharmacokinetic interactions between Atazanavir and methadone. - LPV/r reduces methadone AUC by 36% - DVR reduces methadone AUC by 40% - Ritonavir decrease methadone by 37% • Integrase inhibitors have no significant effects on methadone levels • Atazanavir/ritonavir substantially increases buprenorphine and plasma concentrations with possible cognitive effects • There are no reported adverse interactions of buprenorphine with NNRTI, NRTI and LPV/r including AZT • Rifampicin decreases the blood levels of methadone by 30 to 65%, resulting in opioid withdrawal symptoms. Though rifabutin also induces CYP 3A4, it however does not cause withdrawal symptoms. INH can be used safely with methadone or buprenorphine.
Monitoring	PWID on ART require more frequent monitoring and support to ensure adherence to treatment and harm reduction interventions, assess for and manage adverse drug reactions or drug-drug interactions.

13. Annexes

Annex 1: WHO Clinical Staging of HIV Infection in Infants and Children

Stage I • Asymptomatic • Persistent generalized lymphadenopathy (PGL) • Unexplained, asymptomatic hepatosplenomegaly	Stage II • Papular pruritic eruptions (PPE) • Seborrheic dermatitis • Fungal nail infections • Angular cheilitis • Linear gingival erythema • Extensive HPV or molluscum infection (>5% of body area/face) • Recurrent oral ulcerations (>2 episodes/ in 6 months) • Parotid enlargement • Herpes zoster (>1 episode/12 months) • Recurrent or chronic upper respiratory infection (URI): otitis media, otorrhoea, sinusitis (>2 episodes/6 months)
Stage III • Unexplained moderate malnutrition (-2SD or Z score) not responding to standard therapy • Unexplained persistent diarrhoea (>14 days) • Unexplained persistent fever (intermittent or constant, > 1 mo.) • Oral candidiasis (outside neonatal period) • Oral hairy Leucoplakia • Pulmonary tuberculosis • Severe recurrent presumed bacterial pneumonia (>2 episodes/12 months) • Acute necrotizing ulcerative gingivitis/ periodontitis • Lymphoid interstitial pneumonitis (LIP) • Unexplained anaemia (<8g/dL), neutropenia (<1000/mm3), or thrombocytopenia (<30,000/mm3) for >1 mo. • HIV-related cardiomyopathy • HIV-related nephropathy	Stage IV • Unexplained severe wasting or severe malnutrition (-3 SD or Z score) not responding to standard therapy • Pneumocystis pneumonia • Recurrent severe bacterial infections (>2 episodes/12 months, excluding pneumonia) • Chronic orolabial or cutaneous HSV (lasting > 1 mo) • Extra-pulmonary tuberculosis • Kaposi's sarcoma • Oesophageal candidiasis • CNS toxoplasmosis • Cryptococcal meningitis • Any disseminated endemic mycosis • Cryptosporidiosis or Isosporiasis (with diarrhoea > 1 month) • CMV infection of organ other than liver, spleen, lymph nodes (and onset age >1 month) • Disseminated mycobacterial disease other than tuberculosis • Candida of trachea, bronchi or lungs • Acquired recto-vesicular fistula • Cerebral or B-cell non-Hodgkin's lymphoma • Progressive multifocal leucoencephalopathy (PML) • HIV encephalopathy

NOTE: WHO Clinical Staging should be carried out only on children confirmed (by serology or DNA PCR) to be HIV infected

Annex 2: WHO Clinical Staging of HIV Infection in Adolescents and Adults

<table>
<tr>
<td>Stage 1
Asymptomatic
Persistent Generalized Lymphadenopathy (PGL)</td>
<td>Stage 2
Moderate unexplained weight loss (< 10% of presumed or measured body weight)
Minor mucocutaneous manifestations (seborrheic dermatitis, popular pruritic eruptions, fungal nail infections, recurrent oral ulcerations, angular cheilitis)
Herpes zoster
Recurrent upper respiratory tract infections (sinusitis, tonsillitis, bronchitis, otitis media, pharyngitis)</td>
</tr>
<tr>
<td>Stage 3
Unexplained severe weight loss (over 10% of presumed or measured body weight)
Unexplained chronic diarrhoea for longer than one month
Unexplained persistent fever (intermittent or constant for longer than one month)
Persistent oral candidiasis
Oral hairy leukoplakia
Pulmonary tuberculosis
Severe bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)
Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
Unexplained anaemia (below 8 g/dl), neutropenia (below 0.5 x 109/l) and/or chronic thrombocytopenia (below 50 x 109 /l)</td>
<td>Stage 4
Conditions where a presumptive diagnosis can be made using clinical signs or simple investigations:
HIV wasting syndrome
Pneumocystis jirovecipneumonia (PCP)
Recurrent severe bacterial pneumonia (≥ 2 episodes within 1 year)
Cryptococcal meningitis
Toxoplasmosis of the brain
Chronic orolabial, genital or ano-rectal herpes simplex infection for > 1 month
Kaposi's sarcoma (KS)
HIV encephalopathy
Extra pulmonary tuberculosis (EPTB)
Conditions where confirmatory diagnostic testing is necessary:
Cryptosporidiosis, with diarrhoea > 1 month
Isosporiasis
Cryptococcosis (extra pulmonary)
Disseminated non-tuberculous mycobacterial infection
Cytomegalovirus (CMV) retinitis or infection of the organs (other than liver, spleen, or lymph nodes)
Progressive multifocal leucoencephalopathy (PML)
Any disseminated mycosis (e.g. histoplasmosis, coccidiomycosis)
Candidiasis of the oesophagus or airways
Non-typhoid salmonella (NTS) septicaemia
Lymphoma cerebral or B cell Non-Hodgkin's Lymphoma
Invasive cervical cancer
Visceral leishmaniasis
Symptomatic HIV-associated nephropathy or HIV associated cardiomyopathy</td>
</tr>
</table>

Annex 3: Normal Developmental Milestones in Children[1]

Age	Milestones	Red Flags
3 months	• Turns head toward sound • Smiles • Raises head when on stomach • Brings hand to mouth • Watches faces intently • Recognises familiar people • Follows moving objects with eyes • Vocalizes	• Does not seem to respond to loud noises • Floppy or excessively stiff • Poor sucking or swallowing • No visual fixation or following • Asymmetry of tone or movement • Excessive head lag • Does not smile
6 months	• Sits unsupported or with minimal support • Babbles • Turns to caregiver's voice • Reaches for familiar persons • Reaches for objects • Shows likes and dislikes • Plays with feet when prone • Rolls over	• Floppiness or excessive stiffness • Failure to use both hands • No response to sound • Squinting or inability to move both eyes • Does not roll over
9 months	• Sits without support • Rolls over • Babbles and imitates sounds • Understands a few words, e.g. "bye-bye" or "no" • Able to drink from a cup and hold a bottle • Points at objects or people • Pulls to stand	• Floppiness or excessive stiffness • Unable to sit • No response to sound • Squinting or inability to move both eyes, follow object or face • Persistence of primitive reflexes
12 months	• May walk alone or "creep" • around furniture • Imitates actions • Looks for toys or objects that are out of sight • Responds to own name • Understands simple commands, e.g. "Close the door" • Feeds self, finger foods	• Unable to bear weight on legs • No single words • Does not point to objects • Does not use gestures, such as waving or shaking head • No response to sound • Unable to grasp objects
18 months	• Runs • Scribbles • Throws a ball • Climbs onto chair • Obvious hand preference • Can say 6-20 words • Spoon feeds • Imitates actions • Walks backward	• Failure to walk • Unable to understand simple • commands • Cannot say any words • Unable to grasp small objects
2 years	• Combines words • Asks for food, drink, and toilet • Handles spoon well; spoon feeds without mess • Pretend play • Looks at pictures	• Does not develop mature heel-toe walking pattern after • several months of walking, or walks only on toes • Does not use a 2-word sentence • Does not understand simple instruction • Poor coordination
3 years	• Climbs • Goes up and down stairs • Knows name and sex • Balances on one foot • Puts on a shirt • Speech is understandable	• Unstable walk • Few words, no sentences • No involvement in "pretend" play • No interest in other children
4 years	• Hops • Knows full name and age • Recognizes colours • Dresses and undresses • Make-believe play	• Speech difficult to understand because of poor articulation, omission, or substitutions of consonants • No interest in interactive games • No interest in other children • Does not use sentences

Regression of milestones between assessments should be considered a red flag

Adapted from Guidelines for Paediatric PITC for Zambia available at: http://cumc.columbia.edu/dept/icap/resources/peds/V6%20PITC%20Guidelines%20Appendices.pdf

Annex 4: Tanner Staging of Sexual Maturity in Adolescents

A. Tanner Staging - GIRLS

STAGE Approx. Age	GIRLS	
	Breast Development	Pubic Hair
1. 0-15 yrs	Pre-pubertal	Pre-pubertal
2. 8-15 yrs.	Breast bud stage with elevation of breast and papilla (thelarche); enlargement of areola	Sparse growth of long, slightly pigmented hair, straight or curled along labia
3. 10-15 yrs.	Further enlargement of breast and areola; no separation of their contour	Darker, coarser and more curled hair, spreading sparsely over junction of pubes
4. 10-17 yrs.	Areola and papilla form a secondary mound above level of breast	Hair adult in type, but covering smaller area than in adult; no spread to medial surface of thighs
5. 12.5 - 18 yrs	Mature stage: projection of papilla only, related to recession of areola	Adult in type and quantity, with horizontal (feminine) distribution

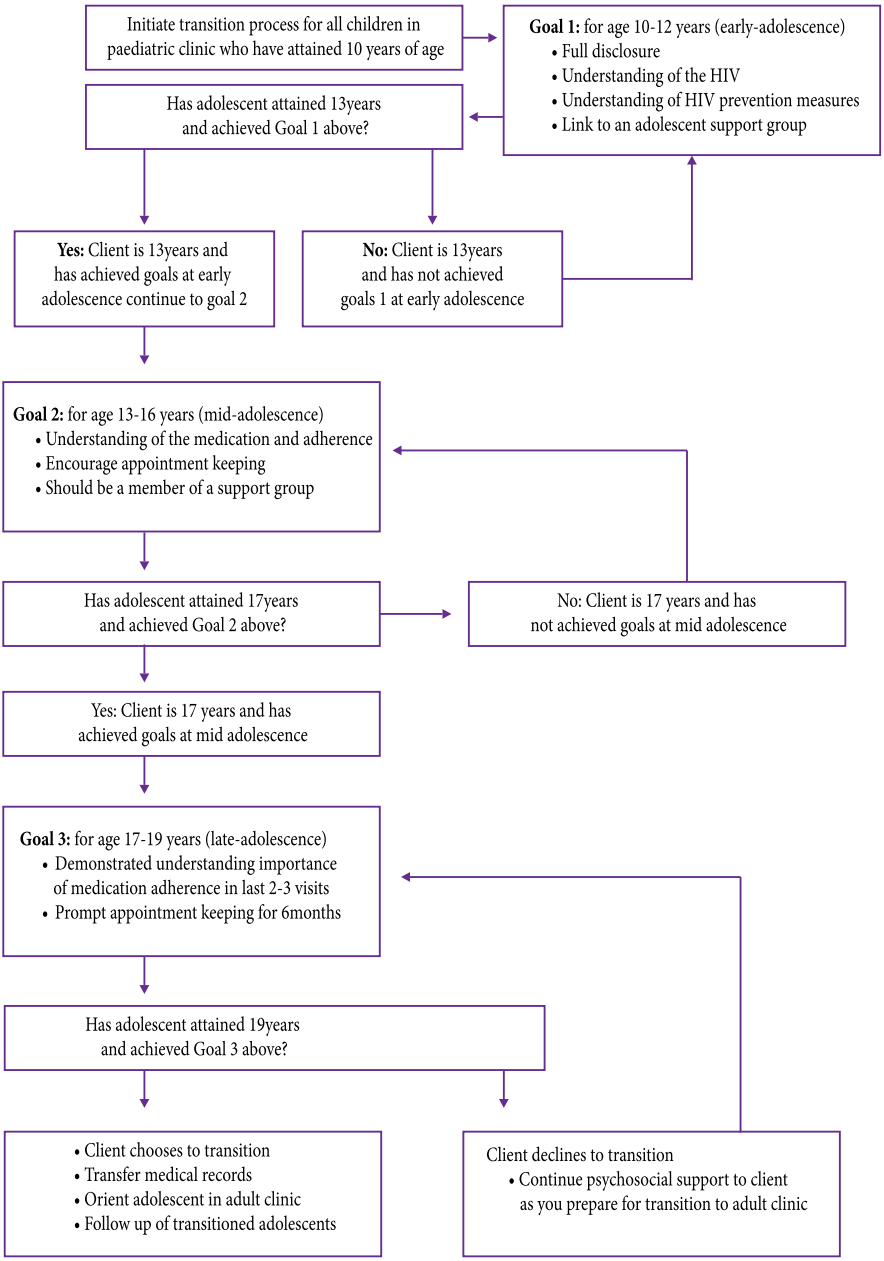
B. Tanner Staging - BOYS

STAGE Approx. Age	BOYS	
	External Genitalia	Pubic Hair
1. 0-15 yrs	Pre-pubertal	Pre-pubertal
2. 8-15 yrs.	Enlargement of scrotum and testes; scrotum skin darkens and changes in texture	Sparse growth of long, slightly pigmented hair, straight or curled at the base of the penis
3. 10-15 yrs.	Enlargement of penis (length at first); further growth of testes	Darker, coarser and more curled hair, spreading sparsely over junction of pubes
4. 10-17 yrs.	Increased size of penis with growth in breadth and development of glans; testes and scrotum larger, scrotum skin darker	Hair adult in type, but covering smaller area than in adult; no spread to medial surface of thighs
5. 12.5 - 18 yrs	Adult genitalia	Adult in type and quantity, with vertical (male) distribution

Annex 5: Age Appropriate Disclosure for Children and Adolescents

Age Characteristics	Stage of Disclosure	Provider Actions
0 - 4 years	No disclosure	At this stage no disclosure is done since the child is too young to understand about HIV
5 - 8 years	Partial disclosure	At this age the child can understand a lot. Define the virus as a germ and the CD4 as the soldier in the body that keep fighting and one has to take the drugs to strengthen the soldiers in the body.
9 to 12 years	Full disclosure	Full disclosure is important since • Most children at this stage are able to understand more about HIV and would have heard about HIV as part of formal education at school Follow the following stages in the disclosure process **Stage 1** Assessing the child social support system to ensure availability of sufficient support once disclosure is completed. **Stage 2** Assess the child's prior knowledge about HIV/AIDS including information given at school, any myths and misconceptions. Offer or reinforce accurate information **Stage 3** Use an imaginary exercise or story to assess child's reaction to disclosure of HIV status **Stage 4** Tell the child about their HIV status. Support parents to disclose to the child and clarify the mode of infection. Address immediate reaction and concerns a child might have
	Post-disclosure (1-2 weeks after full disclosure)	Find out from the parent/guardian if they have observed anything after disclosure, eg change in behavior. • Introduce the child to tell their story and emerge as a hero (a comic book may be a useful aid). • Link the child to a support group or with an older child who has been disclosed to. NB: Find out how the child is doing at every visit after full disclosure

Annex 6: Transition from Paediatric to Adolescent Services



Annex 7: Treatment of Cryptococcal Meningitis

Target population	Regimen	Induction (2 weeks)	Consolidation (8 weeks)	Maintenance	When to start ART
Adults	Preferred	Ampho B 0.7-1 mg/kg/day + Fluconazole 800 mg/day	Fluconazole 400-800 mg/ day	Fluconazole 200 mg/day till CD4 count > 200 cells/ ml for at least 6 consecutive months	Within 2 - 4 weeks
	Alternative	Fluconazole 1200 mg daily	Fluconazole 800 mg daily		Within 4 - 6 weeks
Children	Preferred	Ampho B 0-7-1 mg/kg/day + Fluconazole 12 mg/kg/day (up to max 800 mg/day)	Fluconazole 6-12 mg/kg/ day up to 400-800 mg/day	Fluconazole 6mg/kg/day up to 200 mg/day	Within 2-4 weeks
	Alternative	Fluconazole 12 mg/kg/day (up to max 1200 mg/day)	Fluconazole 12 mg/kg/day up to 800 mg/day	Fluconazole 6mg/kg/day up to 200 mg/day	

Managing and Monitoring for Amphotericin B Therapy

Adults

- Give 1 L of normal saline with 20 mmol of KCl over 2-4 hours before each controlled infusion of Ampo B given with 1 litre of 5% dextrose. Add 1-2 8 mEq KCl tablets orally twice daily. An additional one 8 mEq KCl tablets twice daily may be added in the second week. Include Mg supplementation at 250 mg tablets of Mg trisilicate twice daily.

Adolescents and Children

- Give 1 L of normal saline with 20 mmol of KCl over 2-4 hours before each controlled infusion of Ampo B. Darrows or Ringer's solutions can also be used.
- Avoid KCl replacement in patients with pre-existing renal impairment or hyperkalaemia

Managing hyperkalaemia and raised creatinine levels

- Obtain a routine baseline and twice weekly potassium creatinine.
  - If K < 3.3 mmol/L, administer KCL 40 mmol in normal saline or 1-2 tablets of KCl 8 hourly. Add magnesium. Monitor potassium daily
  - If creatinine level increases > 2 fold, omit dose of Ampho B, increase hydration to 1L 8 hourly. If there's improvement, re-start Ampho B at 0.7 mg/kg/day on alternate days. If no improvement, discontinue Ampho B, give fluconazole 1200 mg/day. Monitor creatinine daily.

Therapeutic lumbar punctures: For patients with raised intracranial pressure (opening pressure > 25 cmH2O, papilloedema) perform daily LP to remove 10 to 20 ml of CSF. If there is no improvement after 2 weeks, consult neurosurgery for possible placement of a CSF shunt.

Annex 8: HIV Education and Adherence Counselling Content Guide

HIV Education and Adherence Counselling
Note: for children/adolescents, the script below should be modified towards the caregiver

Section 1: Introductions, climate setting, and review of objectives for the session

- Ensure privacy and confidentiality
- Introductions of all participants
- Present the key message for each section using simple terms that the patient will understand, using analogies as appropriate
- Use IEC material when available
- Ask the patient if they have any questions at the end of each section, and then ask them to explain the main points back to you to confirm understanding
- If this is a follow-up session, review what they remember from previous sessions and adapt the session to address their needs

Section 2: HIV

- What is HIV
  - HIV stands for "Human Immunodeficiency Virus"
  - HIV is a virus that attacks the body's immune system. The immune system protects the body from infections
- How is HIV transmitted
  - Sexual contact
  - Needles
  - Exchange of blood and bodily fluids
  - Mother-to-child transmission
- Why should family members be tested for HIV
  - Sexual partners are at risk for already having HIV
  - All children born to HIV positive mothers are at risk for already having HIV
  - Encouraging partners/children to test for HIV now is the best way to identify HIV early, so they can also get into treatment
  - Starting treatment early will help them live long and productive lives
  - Whether they test positive or negative, they can be an important source of support for your own treatment

Section 3: Viral load

- What is viral load
  - Viral load is the amount of HIV in your body
  - When your viral load is high it means you have lots of HIV in your body; this causes damage to your body
  - Viral load is measured by a blood test
- How often is viral load measured
  - Viral load is measured after being on treatment for 6 months
  - After 6 months of treatment, we expect the amount of virus in your body to be very low; this means the virus is no longer damaging your body as long as you stay on treatment
  - Repeat viral load tests are done depending on how you are doing; if you are doing well on treatment then the viral load is measured after another 6 months, then every year
  - For children less than 5 years old, we also measure viral load at the start of treatment
- What do viral load measurements mean
  - After being on treatment for 6 or more months, your viral load should be less than 1,000
  - If your viral load is less than 1,000 it means your treatment is working well and you should continue taking it the same; the virus is not damaging your body any more
  - If your viral load is 1,000 or more it means your treatment is not working properly, usually because you have been missing some of your pills; the virus is damaging your body and you and the clinic team will need to work together to figure out how to fix the problem

Section 4: CD4 cells

- What are CD4 cells
  - CD4 cells are the immune cells that protect the body from infections
  - CD4 cells prevent infections and keeps the body healthy
  - CD4 cells are measured through a blood test, called CD4 count. For adults a normal CD4 count is above 500
- How are CD4 cells affected by HIV
  - HIV attacks and destroys CD4 cells
  - After years of constant attach from HIV, the CD4 count falls
- What happens when CD4 cells decrease
  - When the CD4 count falls too low (usually below 200), diseases called “opportunistic infections” are able to infect the body because the body cannot defend itself
  - Common opportunistic infections include: tuberculosis, pneumonia, skin problems, white spots in the mouth, and chronic diarrhoea
- How often is CD4 count measured
  - CD4 count is measured for all patients at the beginning of treatment, to see if you are likely to get any opportunistic infections
  - Once you start treatment for HIV we do not need to check CD4 count again, because you are not likely to get opportunistic infections, unless the treatment stops working

Section 5: Antiretroviral therapy (ART)

- What is ART
  - ART is a combination of 3 or more different medicines
  - ART fights HIV, lowering the amount of virus in the body
  - When the virus level is low then the CD4 count can increase
  - Increased CD4 count means the body is able to protect itself against opportunistic infections
- What are the benefits of ART
  - After a few weeks of taking ART you will begin to regain appetite and weight (if it has been affected)
  - Many people report an increase in their energy levels and general sense of well being
  - People can often return to work or school or care for their families
  - With ART, people with HIV can live a long and health life if they take it properly
- When is ART started
  - Everybody with HIV should start ART
  - Even if your CD4 count is high, the virus is doing damage inside of you and needs to be controlled
  - ART should be started as soon as you are ready, preferably within 2 weeks
  - The longer you wait to start ART, the more time the virus can damage your body, increasing your chances of getting sick or even dying
  - Sometimes ART is started a few weeks later if you have certain infections, or if you do not think you are ready to take them properly
- Does ART cure HIV
  - ART does not cure HIV
  - ART lowers the amount of virus in your body so your body can protect itself from infections
  - It does not remove the virus completely
- Can you still give HIV to others while taking ART
  - Transmission of HIV is very unlikely once your viral load is under control
  - However, you can still give HIV to other people, since the virus is not totally removed from the body
  - You should practice safer sex to reduce the chance of spreading HIV, including disclosure of HIV status to sexual partners and consistent and correct condom use
- How long is ART taken for
  - ART is a life-long treatment
  - Once you start ART, you need to take it every day for the rest of your life (either once a day, or twice a day, depending on which drugs you are on)
  - You must take the ART as prescribed and never miss a dose otherwise the treatment might fail the drugs stop working against the virus

Section 6: Treatment failure

- What happens if you stop taking ART
  - When you stop taking ART the virus begins to increase in your body very quickly
  - The virus goes back to the same high level it was at before you started ART
- What happens if you do not take ART regularly
  - The same thing happens: the virus begins to increase to high levels again
- What happens if the viral load increases
  - When the virus is allowed to increase again, it can change and get stronger, and becomes resistance to the ART
  - When the virus becomes resistant, the ART does not work against the virus anymore
  - Resistance happens by not taking the ART correctly and by starting and stopping the medications several times
  - When resistance occurs, this is called treatment failure
- What happens in treatment failure
  - In treatment failure, the ART no longer works because the virus has been resistant to it
  - If treatment fails, then it is necessary to use stronger, more expensive ART, but it still may not work as well
  - With the stronger ART you may need to take more pills every day, and you may have more side effects
  - If you become resistant to the new ART as well, then there may not be any drugs that can work for you, and the virus will increase quickly and your CD4 count will go way down
  - It is essential that you take your ART every day as prescribed so that you do not develop treatment failure, and can live a long and healthy life

Section 7: ART side effects

- What are the side-effects of ART
  - Sometime people can get side effects from taking ART
  - Side effects vary from person to person
  - Some people have none while other experience mild effects which are unpleasant but often manageable
  - Most side effects occur within the first few weeks of starting ART and then improve after a few weeks or months
  - Some common side effects include:
    - Headache
    - Loss of appetite
    - Skin rash
    - Fatigue
    - Nausea, vomiting, diarrhoea
    - Muscle pains
  - Usually side effect go away after some time
- What do you do if you notice any side effects
  - If you develop any side effects you should continue taking your ART as prescribed, without missing any doses, until you discuss with the clinician
  - If the side effects are mild then you can continue taking your ART without missing any doses, and then discuss the side effects with the clinician at your next appointment
  - If the side effects are bothering you too much then return to the clinic immediately, even if you do not have a scheduled appointment, to discuss what to do next; you can also call the clinic if you are not able to make it yourself immediately
  - Severe side effects include rash all over your body, or rash in your mouth or eyes, constant vomiting, inability to eat or retain food, or anything else that makes you think you should stop the ART
  - The clinician will help you manage the side effects, and occasionally the ART may need to be changed

Section 8: Adherence

- What is adherence
  - Following a care plan as agreed with the healthcare team
  - Attending clinic appointments as scheduled
  - Picking up medicines and taking them as prescribed
  - Getting lab tests according to the recommended schedule
  - Following nutritional recommendations
- How should ART be taken
  - You must take the correct dosage. If you take less than the dose prescribed the treatment will be effective and will result in resistance and treatment failure. Never share your ART with someone else
  - For children, the dosage keep changing as they grow
  - You must take ART the correct time of day
    - If your ART is supposed to be taken once per day, then pick a time when it will usually be convenient for you to remember, e.g. with dinner every day. If you are late taking your dose, you can still take it up to 12 hours later, and then continue with your regular schedule (e.g. if you take it at 7pm every evening but forget to take it one evening, you can still take it up to 7am the next morning, and then continue with your regular schedule at 7pm again. If you are more than 12 hours late you should skip the dose and just wait for your next one at 7pm)
    - If your ART is supposed to be taken twice per day, then you should set a convenient time to take your drugs approximately 12 hours apart (e.g. 8am and 8pm every day). It does not have to be exactly 12 hours apart if your schedule does not allow; the most important thing is to take them twice per day every day (e.g. you can take it at 6am and 8pm every day). If you are late taking your dose, you can still take it up to 6 hours later, and then continue with your regular schedule (e.g. if you take it at 8am and 8pm every day, but you forget to take your morning dose, you can still take it up to 2pm (6 hours later), then continue with your regular schedule at 8pm; if you are more than 6 hours later you should skip the dose and just wait for you next one at 8pm)
  - You must take ART according to dietary restrictions. Some ART should be taken with food, for some it does not matter, and a few require that you have an empty stomach. These dietary restrictions will be explained to you once your ART regimen is selected
  - It is essential to take ART as prescribed and not miss any doses
  - Some medications (prescription, non-prescription, and herbal) interact with ART and make them ineffective. Be sure to tell your clinician and pharmacist the names of all the medications (including traditional/herbal) that you are taking, and any time you are given new medications. Avoid use of alcohol
- What usually interferes with good adherence (can apply to the patient or to the caregiver)
  - Stigma: it is hard to take ART correctly if you need to hide it because you are worried about people finding out you have HIV
  - Disclosure: it is hard to take ART correctly if the people closest to you, particularly family members and close friends, do not know you have HIV
  - Change in routine: if your daily routine suddenly changes it may be difficult to remember to take your ART at the usual time
  - Travel: frequent travel, or unexpected travel (such as for a funeral) may interfere with taking ART, particularly if you do not have enough drugs with you for the entire trip
  - Alcohol and drug use: it is hard to remember to take ART when under the influence of alcohol or other drugs
  - Caregiver changes: every time a child has a new caregiver that person needs to learn about how and why ART is taken
  - Side effects: when people get side effects from ART they may not stop or reduce the amount of ART they are taking, hoping it will reduce the side effects
  - Pill burden/palatability: sometime the number of pills (or taste of syrups for children) makes it difficult to take ART correctly
  - Distance: choosing an HIV clinic that is far away from your home can make it difficult to come to appointments and pick drugs regularly
  - HIV knowledge: when people do not understand what HIV is, and why ART is important, they may not take their drugs properly. This also applies to children and adolescents, if they have not been told they have HIV and taught what it means
  - Mental health disorders: depression and other mental illnesses can make it difficult to take ART correctly
  - Religious beliefs: some people stop taking ART after faith-healing, although there has never been a case of someone being cured of HIV this way
- What might make it difficult for you individually to take your ART as prescribed
  - Ask the patient: Based on what you have learned so far, what challenges do you think you will have taking ART correctly, every day, for the rest of your life?
  - Discuss strategies to manage any expected barrier to adherence

- What can help you take ART as prescribed
  - Disclosure: It is easier to take your ART properly when the people close to you know your HIV status, so you do not have to try and hide your ART, or miss doses to avoid being seen. Family and friends can also provide additional support once they are aware you have HIV and understand more about it. We can help you disclose your HIV status to important family members or friends when you are ready
  - Treatment supporter: Having a "treatment buddy" can help you take your ART correctly; ask a friend, partner, or family member to remind you to take your ART. If possible, invite that person with you to some of your clinic appointments and counselling sessions so they can learn about ART, the importance of good adherence, side effects, etc
  - SMS reminder system (if SMS reminder system in place at the facility): Receiving a regular SMS, e.g. every week, can help you take your ART correctly. We enrol all our patients into this service for SMS reminders at our clinic, unless you do not want to receive them. The messages simply ask how you are doing, and do not mention HIV, ART, the clinic, or anything else that may reveal your HIV status to others
  - Support group: Joining a support group will help you learn from other people how they overcome challenges in living with HIV and taking ART correctly. Some support groups also have economic activities to help increase your income. We have support groups based at the health facility, and there are also support groups in the community
  - Other reminders:
    - Set a specific time of day to take your ART
    - Associate your ART with a specific event/s in your daily schedule (e.g. when you eat breakfast and dinner)
    - Set an alarm on your phone or watch
- What happens if you miss an appointment
  - The healthcare team will be concerned about you, and will try to contact you by phone
    - Confirm patient phone number and consent to call if misses an appointment or any urgent lab results
  - If we cannot contact you by phone we will try to call your treatment buddy
    - Confirm treatment buddy name and phone number, and consent to call if needed
  - If we cannot reach you or your treatment buddy, we may try and visit you at home
    - Confirm locator information and consent to perform home visits if needed
  - Once you are back in care, we will work with you to figure out what caused you to miss an appointment and how it can be prevented in the future
  - You will not be punished for missing an appointment

Section 9: Other medications

- What other medications will you take, in addition to ART
  - CPT: all PLHIV should take cotrimoxazole prophylactic therapy once per, in order to reduce the change of getting other infections such as pneumonia, malaria, and diarrhoea
  - IPT: all PLHIV should receive 6 months of isoniazid preventive therapy (unless they have active TB disease) in order to prevent development of TB
  - Other medications may be recommended for specific conditions

Section 10: Nutrition

- Why is nutrition important
  - When the viral load is high, your body uses a lot of energy trying to fight the virus
  - If your nutrition is poor you have more chance of getting other infections as well
  - You need to eat well so your body has everything it needs to fight HIV, and so you can feel good and look healthy
- What can you do to improve your nutrition
  - Eat a balanced diet
  - Try not to eat a lot of sugar, red meat, or fatty/fried foods
  - Try to eat plenty of whole grains, vegetables, fruit, beans, and fish
  - Drink plenty of clean safe water

Section 11: Follow-up

- How often will you need to come to clinic
  - Before starting ART: you should come to the clinic at least every week in order to get you prepared for ART so you can start as soon as possible
  - Soon after starting ART: after you start ART you should come to the clinic in 2 weeks in order to see if you have had any trouble taking your pills or have developed any side effects; then you can been seen after another two weeks for the same; then every month until your first viral load test
  - Once you have been on ART for a while: if your first viral load (after 6 months) is < 1,000 then you can be seen every 1-3 months. If your viral load is still < 1,000 after a year, then you may be able to go even longer between clinic appointments
  - Unscheduled visits: if you ever have any concerns, feel unwell, or need to speak with any of the clinic team then you can call or come to the clinic, even if you do not have an appointment scheduled for that day
- What will we be checking for during your clinic visits
  - At each visit you will be asked if you have had any illnesses since last visit, if you have had any trouble taking your ART, and if you are experiencing any side effects. You may need a physical exam or blood tests at some visits

Section 12: ART readiness assessment

- Are you ready to start ART today
  - Complete the ART Readiness Assessment (Table 5.3) for each patient to see if they should start ART today, and if not, to identify what issues need to be addressed before starting ART

Section 13: Management plan

- Which investigations will you have today
  - See table 3.2 and table 3.4 for recommended baseline and follow-up investigations respectively
- Which medications will you start today
  - May include: ART; CTX; IPT; other
- What else is required as you start or as you prepare to start ART
  - May include: assisted disclosure; support group referral; engagement of a treatment buddy; drug and alcohol counselling; depression management; referrals; other
  - For patients not starting ART today, management plan should include specific strategies to address any issues preventing/ delaying ART initiation
- When should you return to the clinic
  - Book appointment date for next visit, preferably with the same healthcare worker

Annex 9: Enhanced Adherence Counselling Content Guide

Enhanced Adherence Counselling for Patients with Suspected or Confirmed Treatment Failure
Note: for children/adolescents, the script below should be modified towards the caregiver

Session 1

Discuss Viral Load Results

- Assess patient's understanding of 'viral load', 'high viral load' and 'suppressed viral load'. Ask the patient to explain what each of these terms mean. Provide education if patient requires more explanation
- Provide VL result and explanation of result:

"You have a detectable viral load. This means your ART is not effective and HIV continues multiplying in your blood. If viral load is detectable, it is important to determine whether the treatment is failing due to drug resistance or poor adherence."

- How does the patient feel concerning the result?
- Explain the process of enhanced adherence:

"Patients with a high viral load come for at least 3 adherence counselling sessions to discuss what might cause a high viral and to look for solutions on how adherence can be improved. Another viral load test will be done after 3 months of good adherence to see if the ART can be continued or if we need to change treatment."

- Check whether the patient had previous problems with adherence and/or missed appointments.
- Ask:

"Why do you think your viral load is high?"

- Sometimes the patient already knows why his/her VL is detectable. Start by giving them a chance to provide their own explanation. Often they will admit that they are struggling with their adherence
- If they really don't know why their VL is high you can say:

"We notice that when people sometimes forget to take their ART everyday it gives the virus a chance to grow. Do you think that you sometimes forget your pills?"

Assess for Possible Barriers to Adherence

Cognitive Barriers (HIV and ART knowledge)

- Assess patient's knowledge about HIV and ART; correct any misconceptions

"What is HIV?"
"What is the immune system and CD4 cells?"
"What is ART and how does it work?"
"Why is it important to be adherent? And how?"
"Why do you have to come for follow-up appointments? What should you bring?"

Behavioural Barriers

- Review how the patient takes drugs

"Please explain how do you take your drugs, and at what time?"
"How does treatment fit in your daily routines?"

- Establish with the patient whether the time they are meant to take their medication is appropriate or whether the time is a problem. For example, if the patient has chosen 9 pm, but is already asleep in bed by 9 pm, then that is not a good dosing time. If the time is a problem then determine a new, more appropriate time with the patient based on their schedule
- Remind the patient/caregiver that a missed dose should be taken as soon as he/she remembers (up to 12 hours late if on a once-daily regimen, or up to 6 hours late if on a twice-daily regimen). The next dose should be taken at the usual time

"What reminder tools do you use? (e.g. mobile phone alarm)"
"What do you do in case of visits, and travel?"
- Travelling is always a risk for poor adherence or default to treatment. Encourage the patient to plan, to make sure they have enough medication on hand before and to remember to pack it
- Make sure that all relevant information is on the patient's appointment card and explain that if they are ever away from home and they are about to run out of medication that they must go to the closest ART clinic and show their appointment card

"What do you do in case of side effects?"
- Ask the patient if s/he has any side effects from the ARVs, and if they sometimes find it difficult to take ARV because of the side effects. Ask how s/he manages side effects and if it influences the way s/he takes the drugs.

"What are the most difficult situations for you to take drugs?"
- Check for alcohol or drug use. Ask the patient in a casual way (not in an accusing way) if they sometimes use substances; emphasize treatment planning in case they do

"Taking alcohol or drugs sometimes makes it difficult for us to remember to take treatment. If possible it is best to limit your use, but if you are planning to take any alcohol or drugs, it is important to plan ahead so that you don't forget to take your treatment"
"If you feel your alcohol or drug use is affecting your adherence, are you ready to be referred to some professionals that may help you to work on that problem?"

Emotional Barriers

- Review the patient's motivation:

"How do you feel about taking drugs every day?"
"What are your ambitions in life?"
- You can use motivation cards for this: Ask the patient to think of his or her own personal goals/dreams for the future. What are the 3 most important things they still want to achieve? Have them write them in their own words on a notecard. Encourage the patient to read the notecard every day, preferably right before they take their medication
- Mental health screening:

o Depression is an important reason of non-adherence. All patients with suspected or confirmed treatment failure should be screened for depression using the PHQ-9 tool (Table 4.14)
o The patient may be in any of the five stages of grief (because of their HIV diagnosis or for other reasons): denial and isolation; anger; bargaining; depression, or; acceptance. This needs to be assessed and addressed

Socio-economical Barriers

- Review the patient's disclosure of their HIV status

"Do you have any people in your life who you can talk to about your HIV status and ART?"
- Discuss how the patient can enlist the support of their family, friends, and/or co-workers in reminding them to take their medication if they have not already done so
- Support from a treatment buddy: if the patient came with treatment buddy, assess their input towards adherence. If patient did not come with treatment buddy, explain the role of a treatment buddy on treatment and encourage the patient to come with a person they trust next visit
- Support in family/community/support group: explore support systems, in addition to the treatment buddy, that the patient is currently using and options that the patient can start using. Discuss the advantages of joining a support group and any reasons the patient is hesitant to join
- Profession, income generating resources: review the patient's and family's sources of income and how well they cover their needs
- Specific barriers to come to health centre on regular basis: ask the patient if they have any challenges getting the clinic on a regular basis. Help the patient develop strategies to overcome those challenges
- Stigma and discrimination

"Are you ever worried about people finding out your HIV status accidentally?"
"Do you feel like people treat you differently when they know your HIV status?"
- Discuss if stigma is making it difficult for them to take their medications on time, or for them to attend clinic appointments
- Religious beliefs: find out if the patient has tried faith healing, or if they have ever stopped taking their medicine because of their religious beliefs

Referrals and Networking

- Review the patient's file to determine if they have been referred to other services. This includes referrals to social services, support groups, psychology services, nutrition services, medical clinics, substance abuse groups, etc
- Ask the patient if they attended the appointments, check in on their experience with the referral services and re-organize referrals as necessary
- Determine if the patient could benefit from a home visit

Develop Adherence Plan

- Go through each of the adherence challenges identified during the session and assist the patient to develop a plan that addresses each of the issues. It is important to let the patient come up with the solutions so that they own them
- Some examples of addressing adherence challenges:

o Behavioural barriers: using a reminder tool; using a pill box; redefining the medication schedule to fit with the patient's daily schedule; keeping an emergency dose of drugs when away from home

o Refer to clinician in case of side effects

o Socio-economical barriers: move on in disclosure process; identify a treatment buddy; join a support group; refer to CBO/NGO to learn about income generating activities

o Emotional barriers: emotional support or refer to clinician for mental health management

- Agree on a follow-up date for the next session

Session 2 (usually 2 weeks after Session 1, preferably with the same provider)

Review Adherence Plan

- Ask the patient if he/she thinks adherence has improved since the last visit. Enquire in a friendly way if any doses have been missed
- Review the patient's barriers to adherence documented during the first session and if strategies identified have been taken up. If not, discuss why not

Identify Any New Issues

- Discuss specific reasons why the patient may have missed their pills or a clinic appointment since the last counselling session, and determine if it is a new issue that wasn't addressed during the first session
- Discuss other issues have come up because of implementing the adherence plan (e.g. perhaps the disclosure process had unintended results)

Referrals and Networking

- Follow-up on any referrals made during the previous session
- Determine if the patient could benefit from a home visit

Develop Adherence Plan

- Go through each of the adherence challenges identified during the session and assist the patient to modify their original adherence plan to address each of the issues. It is important to let the patient come up with the solutions so that they own them
- Give another short motivational speech on how you believe in the patient! You know they can do this! Together you will make sure that they suppress their viral load!!
- Agree on a follow-up date for the next session

Session to Discuss Repeat Viral Load Results (after the repeat VL results are back, preferably with the same provider)

Discuss Viral Load Results

- If suppressed (VL < 1,000) CONGRATULATE the patient!!!

o Explain the way forward: will continue with same ART regimen and repeat the VL again in 6 months

- If not suppressed (VL ≥ 1,000)

o Explain the way forward: will probably need to switch to a new regimen ART after discussing as an MDT, and may need additional testing to see which regimen may work for the patient

o Summarize the case with the MDT; if the patient cannot switch to standard 2nd line ART, or is failing 2nd line ART, forward to the Regional or National HIV Clinical Technical Working Group for next steps

Annex 10A: Antiretroviral drug dosing for Children

Weight Range (kg)	Fixed dose combination									Weight Range (kg)
	Abacavir + Lamivudine	Zidovudine + Lamivudine	Zidovudine + Lamivudine	Efavirenz (EFV)	Nevirapine (NVP)	Nevirapine (NVP)	Lopinavir/ ritonavir (LPV/r)		Additional dosing for ritonavir for	
	TWICE Daily	TWICE Daily	TWICE Daily	OnceDaily	Once daily for first 2 wee then twice daily (use weig		TWICE Daily		TWICE Daily	
	60mg ABC + 30mg 3TC	60mg AZT +30mg 3TC tablets	60mg AZT + 30mg 3TC + 50mg NVP	200mg tablets	10 mg/ml suspension	200 mg tablets	80mg Lopinavir/ 20mg ritonavir per ml solution	200mg Lopinavir / 50mg ritonavir Tablets	Ritonavir liquid (80mg/ml as 90 ml bolttle)	
3 - 5.9	1 tab	1 tab	1 tab	_	5 ml	_	1ml	-	1 ml	3 - 5.9
6 - 9.9	1.5tab	1.5tab	1.5tab		8 ml	_	1.5 ml	-	1 ml	6 - 9.9
10 - 13.9	2 tab	2 tab	2 tab	1 tablet	10 ml	0.5 tab	2 ml	-	1.5 ml	10 - 13.9
14 - 19.9	2.5 tab	2.5 tab	2.5 tab	1.5 tablet	15ml	1 tab in am 0.5 tab in pm	2.5ml	1 tab twice daily	2 ml	14 - 19.9
20 - 24.9	3 tab	3 tab	3 tab	1.5 tablet	15ml	1 tab in am 0.5 tab in pm	3 ml	1 tab twice daily	2.5 ml	20 - 24.9
25 - 34.9	300+150 mg	300+150 mg	300/150/200 mg	2 tablets	_	1 tab	4 ml	2 tab in am 1 tab in pm	4 ml in am & 2 ml in pm	25 - 29.9

Use of Adult formulations in children

Tenofovir/Lamivudine and Tenofovir/Lamivudine/Efavirenz - can be used in children older than 10 years and above 35 kgs. Reference should be made to the national guidelines for dosing.

Notes
Paediatric fixed dose combinations (FDCs) are available as ABC/3TC, AZT/3TC and AZT/3TC/NVP. All children requiring ART should be put on appropriate FDCs based on their weight.

ABC/3TC tablets - can be chewed or crushed or dispersed in 5 - 15 ml of water or onto a small amount of food and immediately ingested. Children above 25 kg should receive adult dose of ABC 300 mg + 3TC 150 mg twice daily.

AZT/3TC and AZT/3TC/NVP can be dispersed in 5 - 15 ml of water.
For an adolescent on ABC-based regimen, consider transitioning to TDF/3TC/EFV if the weight remains consistently > 35 kg (at least 2 readings one month apart). Available TDF/3TC and TDF/3TC/EFV FDCs can be used in children older than 10 years and above 35 kg in weight.

Single formulations
These formulations should only be used where available paediatric or adult FDCs cannot be used.
Abacavir (ABC) – tablets may be swallowed whole or crushed.
Lamivudine (3TC) – tablets may be swallowed whole or crushed
Efavirenz 200 mg – tablet is double scored and may be divided into four or two equal parts. Tablet may be crushed and dispersed in water (5-15 ml) or onto a small amount of food and ingested immediately.
Lopinavir/ritonavir – dose is calculated based on Lopinavir component. Oral solution should be taken with food. Oral solution must be refrigerated until dispensed. After removing from refrigeration the oral solution is stable for 60 days (2 months) at room temperature (up to 25° C). Where temperatures are expected to exceed 25°C, the feasibility of dispensing smaller amounts and giving more frequent refills should be considered (for instance, no more than monthly supplies dispensed at one time). The amount of solution has been rounded up to nearest ½ ml for easier measurement as per the manufacturer's recommendation.
Ritonavir liquid - Children with TB/HIV co-infection who are on LPV/r based ART will need additional dosing with ritonavir to make LPV: RTV as 1:1 and given as indicated. The dosing is rounded off to nearest ml for ease of administration of RTV.

Annex 10B: Dosing of boosted Atazanavir in Children

Strength of capsule	3-5.9kg	6-9.9kg	10-13.9kg	14-19.9kg	20-24.9kg	25-34.9 kg
ATV 100mg	-	-	1	2	2	2 or 3
RTV 100mg tab	-	-	1	1	1	1

Annex 10C: Dosing of Atazanavir (powder 50 mg/sachet) in Children

ATV Powder 50mg/packet		RTV oral liquid 80mg/ml
10 to <15 kg	ATV 200mg (4 packets)	80mg (1ml)
15 to <25 kg	ATV 250mg (5 packets)	80mg (1ml)
≥ 25kg	Powder not recommended	

Annex 11: Drug-drug interactions: overlapping drug toxicity

Bone marrow suppression	Peripheral neuropathy	Pancreatitis	Nephrotoxicity	Hepatotoxicity	Rash	Diarrhoea	Ocular effects
Amphotericin B Cotrimoxazole Dapsone Flucytosine Ganciclovir Hydroxyurea Interferon- Primaquine Pyrimethamine Zidovudine	Didanosine Isoniazid Vincristine	Didanosine Lamivudine (esp in children) Stavudine Cotrimoxazole Ritonavir Pentamidine	Acyclovir Adefovir high dose Aminoglycosides Amphotericin B Cidofovir Foscarnet Pentamidine Tenofovir	Abacavir Atazanavir Atovaquone Cotrimoxazole Dapsone Efavirenz Nevirapine Sulfadiazine Voriconazole	Abacavir Atazanavir Atovaquone Cotrimoxazole Dapsone Efavirenz Nevirapine Sulfadiazine Voriconazole	Atovaquone Clindamycin LPV/r Ritonavir	Cidofovir Ethambutol Linezolid Rifabutin Voriconazole

Annex 12 A: Use of Nucleoside & Nucleotide Reverse Transcriptase Inhibitors in Adults

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
Zidovudine (AZT or ZDV) Available in 300mg tablets and as FDC with 3TC and 3TC/NVP	300mg/ dose BD	Take without regard to meals	Bone marrow suppression), including anaemia; granulocytopenia; headache; gastrointestinal intolerance; myopathy; myositis; liver toxicity; discoloured nails; lactic acidosis and severe hepatomegaly with steatosis (fatal cases have been reported).	Monitor for anaemia in the first 3 months of treatment
Lamivudine (3TC) Available in 150mg tablet and as FDC with AZT and AZT/NVP , D4T and D4T/NVP and with TDF and TDF/EFV	150mg/ dose BD	Take without regard to meals.	Headache; fatigue; nausea; diarrhoea; skin rash; pancreatitis; peripheral neuropathy; hepatotoxicity/ hepatitis; lactic acidosis and severe hepatomegaly with steatosis (rare fatal cases have been reported).	A well-tolerated drug. Adjust dose in renal impairment. Also active against hepatitis B. Ideally, patients should be screened for hepatitis B virus (HBV) before starting therapy; exacerbation of hepatitis B has been reported in patients on discontinuation of 3TC.
Abacavir (ABC) Available in 300mg tablets and in combination with 3TC and DTG	300mg/ dose BD	Take without regard to meals. Alcohol increases ABC levels by 41%	Hypersensitivity reaction (potentially fatal) whose symptoms include fever, fatigue, malaise, nausea, vomiting, diarrhoea and abdominal pain or respiratory symptoms such as shortness of breath, lymphadenopathy, ulceration of mucous membranes and skin rash. Patients suspected of having hypersensitivity reaction should have ABC stopped and never be restarted. Pancreatitis; lactic acidosis with hepatic steatosis is rare.	Educate patient on hypersensitivity reaction. Once hypersensitivity has occurred, the patient should never be re-challenged with ABC. Avoid alcohol while on ABC.

Emtricitabine (FTC) Available in 200mg capsules and as FDC with TDF and TDF/EFV	200mg/ dose OD	No food restrictions	Well tolerated. Lactic acidosis and severe hepatomegaly with steatosis (fatal cases have been reported); headache; diarrhoea; nausea; rash; skin discoloration.	Effective against hepatitis B. Ideally, patients should be screened for chronic hepatitis B virus (HBV) before starting therapy; exacerbation of Hepatitis B has been reported in patients on discontinuation of FTC. Decrease dosage in patients with renal impairment Monitor renal function if combined with TDF. When used in combination with TDF, should not be given to patients with a creatinine clearance of <30ml/min. Should not be used with or after failure of 3TC
Tenofovir disoproxil fumarate (TDF) Available in 300mg tablets and as FDC with 3TC and 3TC/ EFV	300mg/ dose OD	No food restrictions	Lactic acidosis and severe hepatomegaly with steatosis (fatal cases have been reported with nucleoside analogues); renal toxicity; Pancreatitis	Should not be used with ddI. Should never be used in triple nucleoside combinations with 3TC+ddI/ABC. Renal function should be monitored while on TDF. Ideally, patients should be screened for chronic hepatitis B virus (HBV) before starting therapy; Exacerbation of hepatitis B has been reported in patients on discontinuation of TDF. When used in combination with 3TC, should not be given to patients with a creatinine clearance of <30ml/min. When used with ATV levels of ATV reduced significantly therefore combine with RTV
Tenofovir alafenamide (TAF) Available as a co-formulation of FTC or elvitegravir + cobicistat + FTC + TAF OR rilpivirine + FTC + TAF	As TAF 25 mg + FTC 200 mg OD	No food restrictions	Well tolerated. GIT upsets, raised serum creatinine, proteinuria and renal toxicity (but to a lesser degree than TDF).	RTV and cobicistat increase TAF levels. DRV decreases TAF levels. Boosted PI increase TAF levels but the PI levels are not affected. Avoid co-administration with rifabutin, rifampicin and phenytoin.

Annex 12 B: Non-Nucleoside Reverse Transcriptase Inhibitors for Adults

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
Nevirapine (NVP) Available in 200mg tablets and as FDC with AZT/3TC and D4T/3TC	200mg/ dose OD for first 2 weeks then 200mg/ dose BD	Take without regard to meals.	Skin rash (may be severe, requiring hospitalization, and life-threatening, including Stevens-Johnson syndrome, toxic epidermal necrolysis); hepatitis; fever, nausea, headache.	Use with caution in women with baseline CD4>250 or in men with baseline CD4>400. Liver function tests in the first 3 months of treatment. Should not be used with Rifampicin in TB patients. Avoid NVP in patients requiring prolonged treatment with Fluconazole because of increased NVP levels with possibility of increased toxicity. Use alternative antifungal drugs for treatment of oral candidiasis in patients on NVP
Efavirenz (EFV) Available in 200mg & 600mg tablets and as FDC with TDF/3TC	600mg OD Best taken at bedtime	Can be given with food, but avoid high fat meals which increase absorption. Preferably taken on an empty stomach.	CNS symptoms (somnolence, insomnia, abnormal dreams, confusion, hallucination, amnesia, etc. Avoid in patients with history of psychiatric disease); Skin rash; avoid use in during the first trimester	Can be used with rifampicin in TB patients
Etravirine Available in tablets of 200 mg	200 mg BD	To be taken with food	Severe but rare: SJS and erythema multiforme Common & minor: Rash, nausea, vomiting, diarrhoea, abdominal pain, hepatotoxicity, dyslipidaemia and CNS disturbances (less than EFV)	Avoid concurrent use with rifampicin, and boosted tipranavir.

Annex 12 C: Use of Protease Inhibitors in Adults

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
Lopinavir/ritonavir (LPV/r, Kaletra) Available as 200mg + 50mg RTV	[LPV 400 mg + RTV 100 mg] 2 tablets BD	Take with food. Moderate fat increases bioavailability.	GI intolerance; nausea; vomiting; diarrhoea	Tablets should be swallowed whole
Atazanavir (ATV) Available in 100mg, 150mg, 200 mg capsules Available as FDC with RTV	400mg OD ATV 300mg / RTV 100mg OD	Take 2 hours before or 1 hour after antacids and buffered medications such as buffered ddI (reduced ATV concentrations if administered together) Take with food.	Jaundice; headache; fever; depression; nausea; diarrhoea and vomiting; paraesthesia; spontaneous bleeding episodes in haemophiliacs.	Indirect hyperbilirubinaemia. When used with TDF should always be given with RTV. Experienced patients should also be given ATV/RTV.
Ritonavir (RTV) Available as 100mg capsules Capsules should be refrigerated until dispensed; stable at room (up to 25°C) for 30 days	Recommends for use as a booster of other PIs	Administration with food increases absorption and helps reduce gastrointestinal side effects.	Exacerbation of liver disease; fat redistribution and lipid abnormalities; diarrhoea; abdominal discomfort; headache; nausea; paraesthesia; skin rash; spontaneous bleeding episodes in haemophiliacs.	Potent CYP450 inhibitor, thus its use as a booster of other PIs
Darunavir (DRV)	DRV 600 mg/ RTV 100 mg BID OR DRV 800 mg/ RTV 100 mg OD (only if PI naïve)	Take with a meal to limit ADR	GIT upsets, rash, dyslipidaemia, hepatitis. Caution in patients with sulphur allergy.	Metabolized by CYP3A and is an inhibitor of CYP3A. Contains sulphur moiety. Monitor liver functions especially in patients at risk or with pre-existing liver disease. May cause hormonal contraceptive failure.

Annex 12 D: Integrase Strand Transfer Inhibitors - INSTIs

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
Dolutegravir (DTG) Available FDCs as ABC 600 mg + 3TC 300 mg + DTG 50 mg	50 mg once daily If co-administering with EFV, carbamazepine, and rifampicin, use DTG 50 mg BD	No food restrictions	Rare - Hypersensitivity; Hepatotoxicity especially in those with HBV and HCV infection. Fatigue	Interacts with carbamazepine, phenobarbital and phenytoin, use alternative anticonvulsants. Administer at least 2 hours before or after taking supplements or antacids containing Mg, Al, Fe, Ca and Zn.
Raltegravir (RAL)	ADULT and CHILD over 16 years, 400 mg BD	Can be taken with or without food	Nausea, vomiting, diarrhoea, flatulence, constipation Severe skin (SJS and TEN) and hypersensitivity reactions have been reported	Mainly for salvage treatment Contraindicated in breast-feeding mothers Safety in paediatric patients has not been established

Annex 13 A: Drug-drug interactions - NNRTIs

Drugs Affected	Nevirapine (NVP)	Efavirenz (EFV)
ANTIFUNGALS		
Ketoconazole	Levels: ketoconazole ↓ 63% NVP ↑ 15 – 30% Dose: Not recommended	No data
Voriconazole	Metabolism of Voriconazole may be induced by NVP. Voriconazole may inhibit NNRTI metabolism. Frequently monitor for NNRTI toxicity and antifungal outcome.	Levels: EFV ↑ 44% Voriconazole ↓ 77% This combination is not recommended.
Fluconazole	NVP Levels: Cmax, AUC, and Cmin ↑100% Fluconazole Levels: No change Risk of hepatotoxicity may increase with this combination. If concomitant use is necessary, recommend monitoring NVP toxicity.	No clinically significant changes in EFV or Fluconazole concentrations.
ANTI-MYCOBACTERIALS		
Rifampicin	Levels: NVP ↓ 20%-58%. Virologic consequences are uncertain; the potential for additive hepatotoxicity exists. Use of this combination is not recommended; however, if used, co administration should be done with careful monitoring.	Levels: EFV ↓ 25%. Dose: Consider ↑ EFV to 800 mg QD.
Clarithromycin	Levels: NVP ↑ 26%. Clarithromycin ↓ 30%. Monitor for efficacy or use alternative agent.	Levels: Clarithromycin ↓ 39%. Monitor for efficacy or use alternative agent.
ORAL CONTRACEPTIVES		

	Levels: ethinyl estradiol ↓ approx 20%. Use alternative or additional methods.	Levels: Ethinyl estradiol ↑ 37%. No data on other components. Use alternative or additional methods.
LIPID-LOWERING AGENTS		
Simvastatin Lovastatin	No data	Levels: Simvastatin AUC ↓ by 58%; EFV unchanged Dose: Adjust simvastatin dose according to lipid responses, not to exceed the maximum recommended dose
Atorvastatin	No data	Levels: Atorvastatin AUC ↓ 43%; EFV unchanged. Dose: Adjust atorvastatin dose according to lipid responses, not to exceed the maximum recommended dose.
Pravastatin	No data	No data

Nevirapine (NVP)		Efavirenz (EFV)
ANTICONVULSANTS		
Carbamazepine Phenobarbital Phenytoin	Unknown Use with caution. Monitor anticonvulsant levels.	Use with caution. Monitor anticonvulsant levels.
METHADONE	Levels: NVP unchanged. Methadone ↓ significantly. Opiate withdrawal common when this combination is used. Increased methadone dose often necessary. Titrate methadone dose to effect.	Levels: Methadone ↓ 60%. Opiate withdrawal common, increase methadone dose often necessary. Titrate methadone dose to effect.
MISCELLANEOUS	No data	Monitor warfarin when used concomitantly.

Annex 13 B: Drug-drug interactions - PIs

Drugs Affected	Atazanavir Ritonavir (RTV)	Ritonavir (RTV)	Darunavir	Lopinavir (LPV)
ANTIFUNGALS				
Itraconazole	Limited data, minimal effect	No data, but potential for bi-directional inhibition between Itraconazole and RTV, monitor for toxicities. Dose: dose adjustment for patients receiving >400 mg Itraconazole may be needed, or consider monitoring Itraconazole level.	↑ Levels of azoles and DRV	Levels: itraconazole ↑ when administered with LPV/r. Dose: itraconazole – consider not to exceed 200 mg/day or monitor level and toxicity
Ketoconazole	Limited data, minimal effect	Levels: Ketoconazole ↑ 3X. Dose: Use with caution; do not exceed 200 mg ketoconazole daily.	↑ levels of azoles and DRV	Levels: LPV AUC ↓ 13% Azole ↑ 3-fold. Dose: Use with caution; do not exceed 200 mg ketoconazole daily.
ANTI-MYCOBACTERIALS				
Rifampicin	Atazanavir AUC: decreased 72%; Cmax: decreased 53%; Cmin: decreased 98%	Levels: RTV ↓ 35%. Dose: No change. Increased liver toxicity possible. Co-administration may lead to loss of virologic response is RTV sole PI. Alternate anti-mycobacterial agents, such as rifabutin, should be considered.	↓ levels of DRV	Levels: LPV AUC ↓ 75%. Should not be co administered as a safe and effective dose of LPV/r that can be given with rifampicin has not been established.[Σ]
Clarithromycin	larithromycin AUC: increased 94%;	Levels; Clarithromycin ↑ 77%. Dose: Adjust clarithromycin dose for moderate and severe renal impairment.	↑ levels of clarithromycin by 59%	Levels: ↑ Clarithromycin AUC 77%. Dose: Adjust clarithromycin dose for moderate and severe renal impairment.

ORAL CONTRACEPTIVES				
	Ethinyl estradiol AUC: ↓	Levels: Ethinyl estradiol ↓ 40%. Use alternative or additional method.	Ethinyl estradiol AUC: ↓ 44%	Levels: Ethinyl estradiol ↓ 42% Use alternative or additional method.
LIPID-LOWERING AGENTS				
Simvastatin Lovastatin	Avoid co-administration	Levels: potential for large increase in statin levels. Avoid concomitant use.	Avoid	Levels: Potential for large increase in statin levels. Avoid concomitant use.
Atorvastatin	Minimal interaction	Levels: 450% ↑ when administered with SQV/RTV combination. Use lowest possible starting dose of atorvastatin with careful monitoring.	↑ AUC four-fold	Atorvastatin AUC ↑ 5.88-fold. Use lowest possible starting dose of atorvastatin with careful monitoring.
Pravastatin	Minimal interaction	Levels: 50% ↓ when administered with SQV/RTV combination. Dose: Pravastatin dosage adjustment based on lipid response.	↑ AUC 81%	Pravastatin AUC ↑ 33%; no dosage adjustment necessary.
ANTICONVULSANTS				
Carbamazepine Phenobarbital Phenytoin	Reduce ATV levels	Carbamazepine; ↑ serum levels when co-administered with RTV. Use with caution. Monitor anticonvulsant levels.	Avoid	Many possible interactions: Carbamazepine: ↑ levels when co-administered with RTV. Use with caution. Monitor anticonvulsant levels. Phenytoin: levels of LPV, RTV, and ↓ levels of Phenytoin when administered together. Avoid concomitant use or monitor LPV level.

METHADONE	No interaction with upboosted ATV. Increased metabolism of methadone with boosted ATV	Methadone ↓ 37%. Monitor and titrate dose if needed. May require ↑ methadone dose.	↓ levels of methadone by 16%	Methadone AUC ↑ 53%. Opiate withdrawal may occur. Monitor and titrate dose if needed. May require ↑ methadone dose.
ERECTILE DYSFUNCTION AGENTS				
Sildenafil	Use reduced dose of sildenafil	Sildenafil AUC ↑ 11 fold. Use cautiously. Start with reduced dose of 25 mg every 48 hours and monitor for adverse effects		Sildenafil AUC ↑ 11-fold in combination with RTV. Do not exceed 25 mg every 48 hours.
MISCELLANEOUS	Decreased GI absorption of atazanavir due to reduced acidity	Theophylline ↓ 47%, monitor theophylline levels. RTV 100 mg bid significantly increase systemic exposure of inhaled (oral or nasal fluticasone, may predispose patients to systemic corticosteroid effects. Co-administration not recommended unless benefit of fluticasone outweighs the risk.	↓ warfarin levels	

Annex 14: Community ART distribution assessment form

Health Facility Assessment to Provide Community ART Distribution		
Facility name:	**MFL code:**	**Date of assessment:**

Instructions for completion:

- Tick the square most applicable to your institution
- Total the scores in the place provided at the bottom
- Use the interpretation key below to interpret the scores

Health system domains for community ART distribution	Yes = 2	Partial = 1	No = 0
Leadership: Has the facility identified a focal person to oversee stable model of differentiated care and community ART distribution?			
Finance: Does the facility have resources to distribute ART to PLHIV in the community for at least six months?			
Human resources for Health: Has the facility identified health care providers for distributing ART (Peer educators, Lay counselors and / or Community Health Volunteers)?			
If 'Yes' how many have been identified?			
How many of them have been trained on the community ART distribution standard operating procedures?			
Service delivery: Viral load uptake >90%			
Has the facility established differentiated model of care for stable PLHIV?			
Does the facility have an active psychosocial support program for PLHIV?			
Has the facility identified community locations for community ART groups?			
Commodity management: Does the facility have at least three months of ART and one month buffer stock available on site?			
Has the facility identified a focal person to pre-pack ART for community distribution?			
Does the facility have adequate supplies / materials to pre-pack ART?			
Health information systems: Does the facility have an established system to monitor patient outcomes specifically retention, lost to follow-up, mortalities and viral load suppression?			
Is the facility able to establish recording and reporting systems for community ART?			
Total Score (Maximum expected score = 28)			

Assessors recommendations:

Final assessment outcome:

Facility can initiate community ART distribution ☐

Facility to implement assessors recommendations and be re-assessed thereafter ☐

Names of assessors: Signature of assessors:	Name of health facility manager: Signature of health facility manager:

Annex 15: List of Reviewers and Participating Institutions

A. Evidence reviewers

The following team contributed to review of specific evidence including implementation experiences locally:

Birth testing of infants & early infant diagnosis: Laura Oyiengo (NASCOP), Irene Inwani (KNH), Dalton Wamalwa (UON), Joe Mbuthia (KPA/Getrudes), Teresa Alwar (UNICEF), Bhavna Chohan (KEMRI)

HIV Testing Services Operational considerations: Lillian Otiso (LVCT Health), Sheikh Mohamed (NASCOP), Michael Kiragu (LVCT Health)

Package of Care; Cotrimoxazole use: Franchesca Odhiambo (UMB)

Non-communicable diseases & HIV: Loice Achieng (UON)

ARV use (when and what to start, adherence support): Brian Chirombo (WHO), Irene Mukui (NASCOP), Shobha Vakil (NASCOP/HRH CBP), Angela McLigeyo (CHS), Caroline Middlecote (CHAI), Justus Oganda (CHAI), Davis Karambi (CHAI)

ARV use in PWID: Franchesca Odhiambo (UMB)

Viral load Monitoring for ART: Sylvia Ojoo (UMB)

Use of DR testing in patient management: Michael Chung (UW), Lisa Frenkel (UW), Horacio Duarte (UW), Dalton Wamalwa (UON), Bhavna Chohan (Kemri)

Operational guidelines for test & Treat (Differentiated Care): Sylvester Kimaiyo (Ampath Plus) , Suzanne Goodrich (Ampath Plus), Patrick Oyaro (RCTP-FACES), James Ayieko (KEMRI) Lisa Abuogi (University of Colorado), Elvin Geng (UCSF), Jill Haggey (UCSF) Rena Patel (UW) Edwin Mulwa (KEMRI) Jayne Lewis-Kulzer (UCSF) Craig Cohen (UCSF) Jeremy Penner (UCSF) Xuan Li (UCSF) Zachary Kwena (KEMRI) Julie Kadima (KEMRI) Hilary Wolf (Georgetown University) , Brian Chirombo (WHO)

Implications of longer dispensing periods on supply chain: Susan Njogo) NASCOP), Cecilia Muiva (MSH –HSCM), Joseph Mukoko (MSH –HSCM)

Pre-exposure prophylaxis: Nelly Mugo (Kemri), Prince Bahati (IAVI), Michael Kiragu (LVCT Health)

B. Guideline review workshop participants;

The following participated in the workshop that following evidence reviews made the final recommendations for the guidelines

AMPATH Plus: Sylvester Kimayo, Dennis Osiemo, Moses Mogesi; **Aphia Plus Imarisha:** Leonora Okubasu; **Aphia Plus Rift/FHI 360**: Everline Ashiono; **Aphia Plus Western Kenya:** Eric Mbati, Francis Onyango, **Bungoma County Referral Hospital:** Felicitas Makokha; **CDC-Kenya:** Abraham Katana, Hellen Mutai, Lennah Nyabiage, Herman Weyenga, Dunstan Achwoka, Immaculate Mutisya, Kenneth Masamaro, Evelyne Ngugi, Agnes Langat, Jonathan Mwangi, Marie Downer, Patricia Oluoch, Odylia Muhenje; **CHAI:** Philip Muchiri, Davis Karambi, Kennedy Mureithi; CHS: Fridah Njogu-Ndongwe, Angela Mcligeyo; **EGPAF:** Lucy Matu; **FACES:** Patrick Oyaro, Jeremy Penner; **IAVI:** Prince Bahati; **ICAP:** Maureen Syowai; **Intrahealth International:** Irene Chami; **Kabarak University**: Wesly Bor; **KEMRI:** Bhavna Chohan, Nelly Mugo; **KEMRI-SEARCH:** James Ayieko; **KESWA**: Carolyne Njoroge; **KNH:** Irene Inwani, John Kinuthia, Margaret Makanyengo; **KPA**: Joe Mbuthia, Doris Kinuthia; **LVCT** Health: Lilian Otiso, Michael Kiragu; **M2M:** Milker Simba; **Maseno University**: John Kaguthi; **MOH-NCD unit**: Martin Mwangi; **MSF-France**: Alexandra Vandenbulche; **MSH**: Ndinda Kusu; **NACC:** Celestine Mugambi; **NASCOP:** Martin Sirengo, Irene Mukui, Maureen Kimani, Joyce Wamicwe Caroline Olwande, Rose Wafula, Jacob Odhiambo, Laura Oyiengo, Sheikh Mohamed, Muthoni Karanja, Barbara Mambo, Linda

Misiko, Susan Njogo, Evans Imbuki, Helgar Musyoki, Mohamud Mohamed, Pauline Mwololo, Ruth Musyoki, Japheth Gituku, Lucy Kinyua Maureen Inimah, Winnie Owiti, Dorothy Mwagae, Edward Omondi, Precious Otieno, Susan Nzula Mutua; **NASCOP/HRH-CBP:** Shobha Vakil, Eunice Mutemi; **NEPHAK:** Nelson Otuoma; **NHRL:** Nancy Bowen; **NLTD-P:** Christine Wambugu; **PHDA:** Naomy Siele, Kimani Mbugua; **Siaya County Referral Hospital:** James Wagude; **University of Maryland, Baltimore:** Sylvia Ojoo, Emily Koech, Francesca Odhiambo, Leonora Okubasu ; **UNICEF:** Teresa Alwar; **University of Washington:** Michael Chung; **University of Nairobi:** Ruth Nduati, Elizabeth Obimbo, Dalton Wamalwa, Jared Mecha, Onesmus Gachuno, Loice Achieng, Judy Kamau ; **USAID:** James Batuka, Maurice Maina, Isabella Yonga, Salome Okutoyi, Stanley Bii; **USAID/HP Plus:** Daniel Mwai; **World Health Organization - Kenya:** Brian Chirombo; **WRP/ DOD:** Isaac TsiKhutsu

C. External reviewers

Ampath plus: Winston Nyandiko **CDC Atlanta:** Laura Broyles; **CDC-Kenya:** Lucy Nganga ; **Clinton Health Access Initiative:** Anna Osborne, Stephanie Denamps, Carolina Kwok, Regina Osih Paolo Maggiore, Nandita Sugandhi; **EGPAF Kenya:** Anne Mwangi, Joram Sunguti ; **ICAP:** Stephen Arpadi, Ruby Fayorsey, Eduarda Gusmao, Veronique Bortolotti, Mercy Karanja; **Kenyatta National Hospital:** David Bukusi ; **LVCT Health:** Linah Digolo ; **Migori County Referral Hospital:** Grace Nalwa ; **UCSF:** Elvin Geng ; **UNAIDS:** Henry Tabifor; **UNICEF:** Anurita Bains, Laurie Gulaid, Jacqueline Dache, Eric MaqC Gitau, Ulrike Gilbert ; **Univerity of Colorado:** Lisa Abuogi ;**University of Maryland:** Douglas Watson; **University of Nairobi:** Marybeth Maritim, Elizabeth Kubo ; **University of Washington**: Ann Melvin, Brian Wood, Jared Baeten, Aliza Monroe, Ruanne Barnabas ,Ann Collier, Susan Graham; **World Health Organization - AFRO:** Frank Lule, Fabian Ndenzako ; **World Health Organization - Geneva:** Satvinder Singh, Martina Penazzato, Rachel Baggaley, Silvia Bertagnolio, Nathan Ford, Cheryl Johnson

Service provider and County reviews

Feedback on the guidelines was provided from County Health Management Teams from 47 counties and health care providers from selected facilities in Siaya County, Kenyatta National Hospital, Kirinyaga County, Kiambu County and facilities supported through Ampath Plus

D. Participating Organizations and Agencies

AmpathPlus	Academic Model Providing Access to Healthcare
APHIA	AIDS, Population and Health Integrated Assistance Program
CDC	Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CHS	Centre for Health Solutions - Kenya
EGPAF	Elizabeth Glasier Pediatric AIDS Foundation
FACES	Family AIDS Care and Education Services
IAVI	International AIDS Vaccine Initiative
ICAP	ICAP at Columbia University's Mailman School of Public Health
KEMRI	Kenya Medical Research Institute
KESWA	Kenya Sew Workers Alliance
KNH	Kenyatta National Hospital
KPA	Kenya Paediatric Association
M2M	Mothers 2 mothers program
MOH-NCD	Ministry of Health-Non-communicable diseases unit
MSF	Medicines San - Frontiers
MSH	Management Sciences for Health
NACC	National AIDS Control Council
NASCOP	National AIDS & STI Control Program
NEPHAK	National Empowerment Network of People living with HIV/AIDS in Kenya
NHRL	National HIV Reference Laboratory
NLTD-P	National Tuberculosis, Leprosy & Lung Diseases -Program
PHDA	Partners for Health and Development in Africa
UCSF	University of California San Francisco
UNICEF	United Nations Children's Emergency Fund
UMB	University of Maryland Baltimore
UON	University of Nairobi
UW	University of Washington
USAID	United States Agency for International Development
USAID/HP plus	United States Agency for International Development - Health Policy Plus
WHO	World Health Organization
WRP/DOD	Walter Reed Project-Department of Defense

Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya

2016 Edition

National AIDS and STI Control Program (NASCOP)
P. O. Box 19361 - 00202, Nairobi, Kenya
Tel: +254 020 263 0867
Email: info@nascop.or.ke
Website: www.nascop.or.ke