Kenya HIV Prevention and Treatment Guidelines, 2022

2022 Edition

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Kenya HIV Prevention and Treatment Guidelines, 2022 edition contain relevant information required by healthcare 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) at 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:

Ministry of Health, National AIDS & STI Control Program. Kenya HIV Prevention and Treatment Guidelines, 2022 Edition. Nairobi, Kenya: NASCOP, Aug 2022. Print.

Design and Layout: Collins Etemesi - NASCOP
ISBN: 13-978-9966-038-31-9

Foreword

Kenya is committed to achieving the UNAIDS 95–95–95 testing and treatment targets among people living with HIV within all sub-populations and age groups.

The 2022 edition of the 'Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya' is an update of the comprehensive HIV prevention, Care and treatment guidelines released in 2018. These guidelines are aligned with the Ministry of Health's mission of providing the highest standard of health for all Kenyans and one of the Government of Kenya's Big Four Agenda on Universal Health Coverage.

The theme of the 2022 guidelines is refocusing efforts in the management of Advanced HIV Disease to reduce HIV/AIDS related morbidity and mortality. While Kenya has made tremendous progress in HIV Prevention, Care and Treatment through introduction of better medicines, diagnostics and patient centered approaches in service delivery, Advanced HIV Disease continues to be a challenge. These guidelines intend to widen access to key diagnostics and medicines to manage the most common causes of illness and death. Further, emphasis on integrated delivery of patient-centered HIV, TB, NCDs, mental health and sexual and reproductive health services has been included.

These guidelines provide key recommendations on HIV testing services and linkage to prevention and treatment; initial evaluation and follow up of PLHIV; standard package of care for PLHIV; adherence preparation monitoring and support; antiretroviral therapy in infants, children, adolescents and adults; prevention of mother to child transmission of HIV, Syphilis and Viral Hepatitis; TB/HIV coinfection; Hepatitis B & C/HIV co-infection; use of ARVs for post and pre-exposure prophylaxis for HIV uninfected populations; and HIV services for people who inject drugs.

The guidelines are an important tool meant to be used by service providers at all levels of the health sector in Kenya. They 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 of ending AIDS by 2030 as a key national health strategic objective.

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Acknowledgements

The 2022 Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya has been a long-awaited document as the revision was greatly affected by the COVID-19 pandemic. The document has been updated through the collaborative effort of multiple stakeholders, both individuals and institutions, that contributed to the extensive consultations led by NASCOP HIV Care and Treatment Program.

With much appreciation, I acknowledge all the institutions, both local and international, government ministries and departments whose staff spent long hours, both virtually and in person, in the review, writing and finalization of this document.

I take this opportunity to appreciate the efforts of the Ministry of Health officers at NASCOP and other institutions who coordinated and provided leadership during the review process. Compliments to the guidelines review secretariat and the special task force who worked tirelessly to ensure that the team produced a great quality document. Particular appreciation to the NASCOP team and numerous TA's who were instrumental in compiling the evidence review and developing the guidelines. Special thanks to the consultants; Jeremy Penner, Irene Mukui, and Herb Harwell for their dedication to this process.

Financial support for the review process, printing and launch of this document was provided by the Global Fund, UNITAID through CHAI, the US government through the Centers for Disease Control and Prevention and ICAP at Columbia University through the USAID-funded RISE-Kenya Project, WHO and UNICEF - Kenya.

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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
ALP	Alkaline Phosphatase
AHI	Acute Hiv Infection
ANC	Antenatal Care
A&E	Accident And Emergency
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
CrCl	Creatinine Clearance

Other Acronyms and Abbreviations	
HTS	HIV Testing Services
ICF	Intensified Case Finding
IEC	Information, Education and Communication
INH	Isoniazid
INSTI	Integrase Strand Transfer Inhibitor
IPD	In-Patient Department
IPT	Isoniazid Preventive Therapy
IPV	Intimate Partner Violence
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
L&D	Labor And Delivery
LIVES	Listen, Inquiry, Validate, Enhance Safety and Support
LLV	Low Level Viremia
LRF	Laboratory Requisition Form
LP	Lumbar Puncture
MAC	Mycobacterium Avium Complex
MAT	Medically Assisted Therapy
MCH	Maternal Child Health
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
NACS	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
NSP	Needle and Syringe Programmes
NRTI	Nucleotide Reverse Transcriptase Inhibitor
OD	Once Daily

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
DICEs	Drop-In-Centres
DMS	Director of Medical Services
DNA	Deoxyribonucleic acid
DOT	Directly observed therapy
DS	Double strength
DRT	Drug Resistance Testing
ED - PrEP	Event Driven PrEP
EDTA	Ethylenediaminetetraacetic acid
ECP	Emergency contraceptive pill
EID	Early Infant Diagnosis
eMTCT	Elimination of Mother to Child Transmission
EPTB	Extra-pulmonary Tuberculosis
FDA	Food and Drug Administration
FBC	Full Blood Count
FBS	Fasting Blood Sugar
FDC	Fixed Dose Combination
FLP	Fasting Lipid Profile
FP	Family Planning
FTC	Emtriciatabine
GIT	Gastro-intestinal tract
GOK	Government of Kenya
GBV	Gender-Based Violence
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
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
PrEP	Pre-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
PLLV	Persistent Low-level Viremia
PML	Progressive Multifocal Leukoencephalopathy
PMTCT	Prevention of mother-to-child transmission
PPE	Papular Pruritic Eruptions
PrEP	Pre-exposure Prophylaxis
PTB	Pulmonary Tuberculosis
PWID	People Who Inject Drugs
NHCSC	National HIV Clinical Support Centre
RAST	Rapid Assessment Tool
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
TB LAM	Tuberculosis Lipoarabinomannan
TDF	Tenofovir
TT	Tetanus Toxoid
TWG	Technical Working Group
ULN	Upper Limit of Normal
UTI	Urinary Tract Infection
VIA	Visual Inspection with Acetic Acid
VILI	Visual Inspection with Lugol's Iodine
VL	Viral Load
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

1. Summary of Key Recommendations

1.1 HIV Testing Services (HTS) and Linkage to Treatment and Prevention

- HIV testing should be voluntary and conducted ethically in an environment where Consent, Confidentiality, Counselling, Correct results, Connection (linkage) and Creating an enabling environment can be assured
- To optimize access to testing services, HIV testing can be conducted in 2 different settings:
    - Facility-based
    - Community-based
- Targeted HIV testing is recommended which involves index client listing of contacts, HIV self-testing and use of HTS screening tool to identify people at risk of HIV infection as eligible for testing
- Serial testing, using approved rapid HIV antibody testing kits, is used to diagnose HIV infection in children older than 18 months, adolescents, and adults. An HIV-positive diagnosis will be made using three consecutive reactive assays

1.2 Initial Evaluation and Follow-up for PLHIV

- Initial clinical evaluation of PLHIV entails CD4 monitoring, which is recommended for:
    - Baseline investigation for all PLHIV
    - Any patient with suspected treatment failure
    - Any patient returning to care after interrupting treatment for >3 months
    - Any patient on fluconazole maintenance therapy or on dapsone as prophylaxis, to determine when prophylaxis can be discontinued
- Advanced HIV Disease is defined as:
    - Adults, adolescents, and children five years and older as having a CD4 cell count of less than 200 cells/mm^3 or
    - WHO clinical stage 3 or 4 disease
    - All children younger than five years
- All PLHIV presenting with Advanced HIV Disease (AHD) should be offered a package of care that includes timely initiation of ART, screening, diagnosis, prophylaxis, and management of opportunistic infections.
- Frequency of routine VL monitoring:
    - For PCR positive HEIs: at baseline (at the time of ART initiation)
    - Age 0-24 years old: 3 months after ART initiation, and then every 6 months
    - Age ≥ 25 years old: 3 months after ART initiation, then at month 12, and then annually

- Pregnant or breastfeeding: at confirmation of pregnancy (if already on ART) or 3 months after ART initiation (if ART initiated during pregnancy/breastfeeding), and then every 6 months until complete cessation of breastfeeding
- Before any drug substitution (if no VL result available from the prior 6 months)
- Three months after any regimen modification (including single-drug substitution)

- PLHIV should receive differentiated care based on initial evaluation (advanced vs. well) and follow up (established vs not established on ART)

1.3 Standard Package of Care for PLHIV

Consists of 8 components:

1. Antiretroviral Therapy

- All PLHIV are eligible 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 (except for patients with cryptococcal meningitis or TB meningitis)

2. Positive Health, Dignity, and Prevention, GBV/IPV & HIV Education and Counselling

- All patients should be counselled and supported for disclosure of HIV status; partner/ family testing and engagement; condom use; family planning; sexually transmitted infections screening; treatment adherence; and pre-exposure prophylaxis for HIV-negative sexual partners
- All females aged 15-49 years and emancipated minors accessing HIV care services should be screened for Intimate Partner Violence (IPV) as part of the standard package of care
- All PLHIV should be provided with HIV education and counselling

3. Screening for and Prevention of Specific Opportunistic Infections

Cotrimoxazole Preventive Therapy (CPT) is no longer recommended as life-long prophylaxis, and is only recommended in the following sub populations, unless they have an allergy to sulfur drugs or develop toxicity from CPT

- All HIV Exposed Infants
- HIV infected children < 15 years of age
- All PLHIV ≥ 15 years of age:
  - Living in malaria-endemic zones *(Refer to the National Guidelines for the Diagnosis, Treatment and Prevention of Malaria in Kenya for the current Kenya Malaria endemicity map)*
  - Presenting with WHO stage 3 or 4 event, or meeting the AHD criteria
  - Suspected treatment failure
- All Pregnant and Breast-feeding women

- 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/mm^3 (or CD4% ≤ 25% for children ≤ 5 years old), and should be discontinued once a patient achieves viral suppression and a sustained CD4 count of > 200 cell/mm^3 (or > 25% for children ≤ 5 years old) for at least 6 months
- All PLHIV should be screened for TB at every visit using the Intensified Case Finding (ICF) tool and assessed for TB Preventive Therapy (TPT) if screened negative for TB
- All adolescent and adult PLHIV with a baseline CD4 count of ≤ 200 cells/mm^3 should be screened for cryptococcal infection using the serum CrAg test

4. Reproductive Health Services

- All PLHIV should be screened for STI at every clinic visit
- Pregnancy status should be determined for all women of reproductive age at every visit and their contraception need determined and met
- All HIV positive women between the ages of 18 - 65 years should be screened for cervical cancer (HPV testing conducted every 2 years or Annually if using VIA-VILI)

5. Screening for and Management of Non-Communicable Diseases

- All PLHIV should be screened for hypertension, diabetes mellitus, dyslipidaemia, and renal disease annually.
- Routine screening should be provided for early detection of cervical cancer, breast cancer, bowel cancer, and prostate cancer

6. Mental Health Screening and Management

- All PLHIV should receive basic screening for depression and anxiety before initiating ART, and annually thereafter, and whenever there is a clinical suspicion
- All PLHIV should be provided for and linked with support structures to maintain general well-being addressing issues that could affect their mental health
- All adults and adolescents should be screened for alcohol and drug use before initiating ART and regularly during follow-up
- All caregivers should also receive baseline and follow-up screening for depression and alcohol/drug use

7. Nutrition Services

- All PLHIV should receive nutritional assessment, counselling, and support tailored to the individual needs of the patients
- All infants irrespective of HIV status should be exclusively breastfed for the first 6 months of life, with timely introduction of appropriate complementary foods after 6 months, and continued breastfeeding up to 24 months or beyond

8. Prevention of Other Infections

- PLHIV (including children) should receive vaccinations as recommended by the National Vaccines and Immunization Program
- All PLHIV should receive vaccination for COVID-19 following national guidelines for age and dosing

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
- All patients with durable viral suppression (2 consecutive viral load results with <50 copies) should be offered messaging on Undetectable=Untransmittable (U=U).
- 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 3 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 (which should be done urgently using a case-management approach)

1.5 Antiretroviral Therapy for 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 (Viral Load <50 copies/LDL)
- All individuals with confirmed HIV infection are eligible for ART, irrespective of CD4 count/%, 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 start ART
- ART should be started in all patients as soon as possible, even on the same day as confirming their HIV diagnosis (and preferably within 2 weeks)
- **Preferred first-line ART for infants, children, adolescents and adults**
    - Birth to 4 weeks: AZT + 3TC + NVP
    - > 4 weeks to < 15 years old
        - < 30 kg: ABC + 3TC + DTG
        - ≥ 30 kg: TDF + 3TC + DTG
    - ≥ 15 years old: TDF + 3TC + DTG
- Children and adolescents who are virally suppressed but are NOT on the preferred first-line ART regimen should be assessed for transition and transitioned to the preferred regimen
- Treatment failure is suspected when a patient has a VL ≥ 1000 copies/ml after at least 3 months of using ART. Treatment failure is only confirmed when VL is ≥ 1,000 copies/ml after assessing for and addressing poor adherence or other reasons for high VL, and then repeating VL after at least 3 months of excellent adherence to allow for viral re-suppression

- Persistent low-level viremia (pLLV) is defined as having VL 200 - 999 copies/ml on two or more consecutive measures. These patients are at increased risk of progression to treatment failure, development of ARV resistance and death and therefore require a similar case management approach as patients with an initial VL ≥ 1,000 copies/ml
- All PLHIV with a detectable VL ≥ 200 copies/ml (unsuppressed): assess for and address potential reasons for viremia, including intensifying adherence support, and repeat the VL **after 3 months of excellent adherence**
    - If the repeat VL is < 200 copies/ml (suppressed) then continue routine monitoring
    - If the repeat VL is ≥ 1,000 copies/ml (suspected treatment failure), prepare for change to an effective regimen (Figure 5.2 and Table 6.10)
    - If the repeat VL is 200 - 999 copies/ml (low level viremia), reassess adherence and other causes of viremia and repeat VL after another 3 months of excellent adherence

1.6 Prevention of Mother to Child Transmission of HIV/Syphilis/HBV

- Prevention of mother-to-child transmission (PMTCT) of HIV, Syphilis and Hepatitis B (triple elimination) should be offered as part of a comprehensive package of fully integrated, routine antenatal care interventions
- All pregnant women, unless known positive, should be counseled and tested for HIV, Syphilis (using the HIV-Syphilis dual test) and HBV during their first ANC visit, and if negative a repeat HIV-Syphilis dual test should be performed in the 3rd trimester.
- **Lifelong ART should be initiated in all pregnant and breastfeeding women living with HIV, regardless of gestational age, WHO clinical stage or CD4 count**
- ART should be started as soon as possible, ideally on the same day HIV diagnosis is made, with ongoing enhanced adherence support
- The preferred first line ART regimen for pregnant and breastfeeding women is TDF + 3TC + DTG
- For pregnant and breastfeeding women newly initiated on ART, obtain VL 3 months after initiation, and then every 6 months until complete cessation of breastfeeding
- For HIV positive women already on ART at the time of confirming pregnancy or breastfeeding, obtain a VL irrespective of when prior VL was done, and then every 6 months until complete cessation of breastfeeding
- For pregnant or breastfeeding women with a VL ≥ 200 copies/ml (unsuppressed): assess for and address potential reasons for viremia, including intensifying adherence support, and repeat the VL **after 3 months of excellent adherence**
    - If the repeat VL is < 200 copies/ml (suppressed) then continue routine monitoring
    - If the repeat VL is ≥ 1,000 copies/ml (treatment failure), prepare for change to an effective regimen
    - If the repeat VL is 200 - 999 copies/ml (low level viremia), reassess adherence and other causes of viremia and consult the Regional or National TWG

- All HIV exposed infants (HEI) should be tested with DNA PCR within 6 weeks of age or first contact thereafter; if negative then another DNA PCR at 6 months, and if negative then repeat DNA PCR at 12 months.
- All HEI should receive infant ARV prophylaxis consisting of 6 weeks of AZT + NVP and thereafter NVP should be continued until 6 weeks after complete cessation of breastfeeding
- All infants irrespective of HIV status should be exclusively breastfed for the first 6 months of life, with timely introduction of appropriate complementary foods after 6 months, and continued breastfeeding up to 24 months or beyond

1.7 TB/HIV Co-infection Prevention and Management

- All healthcare settings should implement TB infection control recommendations to reduce the risk of transmission of TB among patients, visitors and staff
- Symptom-based TB screening using the ICF tool MUST be performed for all PLHIV at every clinic visit
  - Patients who screen negative should be assessed for and provided with TB preventive therapy (TPT)
  - Patients who screen positive (presumptive TB) must complete definitive diagnostic pathways
- **The GeneXpert Ultra MTB/Rif test is the preferred test for diagnosis of TB and rifampicin resistance in all presumptive TB cases**
- TB-LAM can be used as an adjunct rapid point-of-care diagnostic test for PLHIV: with advanced HIV disease (WHO stage 3 or 4 or CD4 count ≤ 200 cells/mm^3 (or CD4% ≤ 25% for children ≤ 5 years)) with presumptive TB, or; any danger signs of severe illness, or; currently admitted to hospital
- Patients diagnosed with TB/HIV co-infection should start anti-TB treatment immediately and initiate ART as soon as anti-TB medications are tolerated, preferably within 2 weeks (unless they have TB meningitis, in which case ART should be deferred for 4 to 8 weeks)
- Patients with TB/HIV co-infection who are already on ART should start anti-TB treatment immediately and continue ART, making any required adjustments to the ART regimen based on known drug-drug interactions and monitoring toxicity
- 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 adolescents and adults should be screened for HBV infection, using serum HBsAg, as part of initial evaluation; children who did not complete routine childhood immunizations should also be screened for HBV and vaccinated if negative.
- PLHIV without evidence of hepatitis B infection (HBsAg negative) should be vaccinated against hepatitis B
- The recommended first-line ART for adults with HIV/HBV co-infection is TDF+ 3TC + DTG
- HCV serology should be offered to individuals at risk of HCV infection
- Direct acting antiviral therapies (DAAs) for treatment of HCV have 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
    - <15 years old
        - < 30 kg: ABC + 3TC + DTG
        - ≥ 30 kg: TDF + 3TC + DTG
    - ≥ 15 years old
        - TDF + 3TC + DTG

1.10 Pre-Exposure Prophylaxis (PrEP)

- PrEP should be offered to HIV negative individuals at substantial ongoing risk of HIV infection (including the seronegative partner in a discordant relationship)
- PrEP works if taken as prescribed. However, it does not prevent other STIs or unintended pregnancies, therefore, additional protection should be offered.
- PrEP should only be offered to clients ≥15 years of age who are sexually active after eligibility assessment using the following parameters:
    - Laboratory: HIV negative
    - Medical (for oral PrEP): no contraindication to TDF; no severe renal diseases; weight ≥ 30 kg
    - Client readiness: client must be willing to take PrEP as prescribed, and adhere to associated follow up and HIV testing (at enrollment, at month 1 and thereafter every 3 months)
- The recommended ARV regimen for Oral PrEP is TDF/FTC (alternative TDF/3TC), available in two dosing strategies:
    - Daily oral PrEP: TDF (300 mg) + FTC (200 mg) once daily
    - Event-driven PrEP: Event driven PrEP is where oral PrEP is used in men having sex with men when an isolated sexual act is anticipated. The dose is two pills of TDF/FTC taken between 2 and 24 hours (preferably closer to 24h) before the anticipated sexual act; then, a third pill taken 24 hours after the first two pills; and then a fourth pill taken 24 hours after the third pill ("2+1+1").

1.11 People Who Inject Drugs (PWID) and HIV

- PWID should be offered regular HIV testing and counselling and be linked to comprehensive HIV treatment and prevention services including harm reduction counselling and support
- The recommended first-line ART for adult PWID is TDF + 3TC + DTG
- PWID should be offered screening, diagnosis, treatment and prevention of STIs as part of comprehensive HIV prevention and care
- 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 HCV serology) at first contact
- All PWID should be linked to Needle and Syringe Programs (NSP) to access sterile injecting equipment
- All PWID should be linked to Medically Assisted Therapy (MAT)

2. HIV Testing Services and Linkage to Treatment and Prevention

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

HIV testing should be voluntary and conducted ethically in an environment where the six Cs principles of Consent, Confidentiality, Counselling, Correct results, Connection (linkage) to care and other appropriate post-test services and creating an enabling environment are adhered to.

Targeted HIV testing is the major strategic shift, involving index client listing of contacts, HIV self-testing and use of HIV screening tools to identify people at risk of HIV infection as eligible for testing, except in the case of PMTCT and key populations.

2.1 Settings for HIV Testing

In Kenya, HTS is delivered in two broad settings: facility-based and community-based settings

2.1.1 Facility-based testing

- The HTS screening tool should be used to facilitate prioritization of testing for persons at risk of HIV infection; those diagnosed with sexually transmitted infections, with multiple sexual partners, key populations, and those with possible or known HIV exposures, such as sexual or needle sharing partner of a person living with HIV or of a person of unknown HIV status
- Providers should undertake a thorough risk assessment using the validated NASCOP screening tools (Annex 17) to identify clients at risk and those eligible for a HIV test.
- HTS should be offered only to clients who consent
- Clients who are not eligible for testing should receive HIV prevention messages and be offered services as appropriate
- Clients who test HIV positive should be linked to care while those who test negative should be linked to HIV prevention services
- Patients starting HIV care should receive disclosure counselling and support, and be offered family, sexual and needle-sharing partner testing

As much as possible, HIV testing services should be integrated into care pathways at all service delivery points including adult and pediatric inpatient units, outpatient units, maternal and child health clinics, SRH/family planning clinics, TB clinics, specialty clinics, gender-based violence (GBV) care units and service delivery points for key and priority populations.

2.1.2 Community–based testing

Targeted community based HTS offers additional opportunities to identify and link people to HIV treatment and prevention. This setting is especially important for testing children and partners of index clients through index testing, as well as outreach to key and priority populations, orphans, and vulnerable children (OVCs), adolescents, youth and targeted testing in workplaces.

2.2 HTS strategies

The major HTS strategies to identify people living with HIV but unaware of their status are:

2.2.1 HIV Self-Testing (HIVST)

- HIVST allows individuals to collect their own specimen, perform the test, and interpret the results on their own, conducted either within a health facility, at home or in any other convenient place.

HIVST can be conducted with or without direct assistance by a trained person.

- HIVST is a screening test and is not sufficient to make an HIV-positive diagnosis. A reactive (positive) self-test result should therefore be confirmed using the validated national testing algorithm by an HTS-trained service provider.
- HIVST should be performed using MoH approved HIV rapid diagnostic test kits that are either blood-based or oral fluid based.
- HIVST may have the greatest benefit in reaching specific populations such as partners of newly diagnosed PLHIV; partners of pregnant women attending antenatal care (ANC); contacts of patients treated for STIs; hard-to-reach populations such as men, adolescents, and young people, as well as key populations, such as MSM and sex workers.

HIVST is a screening test and does not provide a diagnosis. All reactive (positive) self-test results must be confirmed in a health facility according to nationally set standards

2.2.2 Index Testing referred to as partner testing/partner notification services, is an approach whereby the exposed contacts (i.e., sexual partners, biological children and anyone with whom a needle was shared) of an HIV-positive person (i.e., index client), are elicited and offered HIV testing services

2.2.3 Voluntary Counselling and Testing (VCT): This involves provision of targeted HIV testing to clients who willingly present to HTS facilities for testing for diverse reasons, including self-assessed risk.

2.2.4 Social Network Strategy (SNS)- this involves offering to index clients self-guided options to informally extend links to HIV testing and other services to a **broader set of social-, sexual-, and injecting-network members** who have an elevated risk of HIV infection. The index client for SNS can either be PLHIV or HIV negative persons with increased risk for HIV infection.

Providing targeted HTS for different populations and in different settings increases opportunities for access to knowledge of HIV status and to a range of HIV treatment and prevention services. Table 2.1 summarizes key recommendations for HTS for different sub-populations.

Table 2.1: HTS Recommendations for Different Populations and Settings

Population	Recommendation
Birth testing of infants born to known HIV-positive mothers (Figure 2.2)	• Birth testing (HIV testing of infants at birth or at first contact within 2 weeks after birth) can be conducted where feasible and in settings where return of results is feasible within 24 hours and ART can be initiated immediately*). Infants tested at birth must be tested at the 6 weeks immunization visit regardless of the results of the initial test at birth. • 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 new sample for confirmatory HIV DNA PCR and baseline viral load taken at the time of ART initiation **(ART initiation is based on the initial HIV DNA PCR result)**
Infants and children aged less than 18 months (Figure 2.1)	• 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 at the 6-week immunization visit or first contact. If the mother declines to be tested or is not available for testing, then conduct a rapid HIV antibody test for the child to determine exposure (if antibody test is positive this confirms HIV exposure) • When HIV exposure is confirmed, ARV prophylaxis should be started immediately. • All HEIs should have DNA PCR testing at the 6-week immunization visit or first contact thereafter. • 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 new sample for confirmatory HIV DNA PCR and baseline viral load taken at the time of ART initiation **(ART initiation is based on the initial HIV DNA PCR result)** • All HEI with initial HIV negative results should continue infant ARV prophylaxis and be followed as HEIs, including additional PCR testing at 6 months and 12 months, and antibody testing at 18 months and every 6 months during breastfeeding, and at 6 weeks after complete cessation of breastfeeding
Children older than 18 months till age 9 years (Figure 2.3)	• Conduct HIV testing and counselling for all children of adults living with HIV as soon as possible after confirming the HIV positive status of the adult. Within health facilities, testing should be conducted at in-patient wards, nutrition clinics, and all high HIV burden settings.
Adolescents and young people (10 - 24 years) (Figure 2.3)	• Targeted HIV testing services should be offered to adolescents and young people who are screened and found eligible for HIV test. HIV prevention services should be offered to clients who test negative while those who test positive should be linked to HIV care. • Adolescents aged above 10 years, should be tested with the written consent of a parent or guardian, and are also required to give assent. • Adolescents who are emancipated minors irrespective of age, can give their own consent. • All adolescents should be counselled on 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, HIV testing and counselling should be offered to their partners and children where appropriate. • All uncircumcised adolescent males who test HIV negative should be counselled about the prevention benefits of VMMC and linked to VMMC services if they agree

Table 2.1 Cont.

Pregnant and breastfeeding women	• During the first ANC visit, HIV testing of pregnant women should be done using a dual test for HIV and syphilis, unless the woman is known to be living with HIV. • Women who test negative for both HIV and Syphilis should be offered a repeat HIV-Syphilis dual test in the third trimester. • Prevention services should be offered to all pregnant and breastfeeding women who test HIV negative. They should be screened for eligibility and willingness for PrEP. • At labor and delivery, HIV testing should be done for all women with unknown HIV status and those who previously tested negative (even if tested negative in the third trimester). • All breastfeeding mothers (unless known HIV positive) should be counselled and tested at the 6-week infant immunization visit. The HIV test (if negative) should be repeated every 6 months until complete cessation of breastfeeding. • For mothers considered to be at high risk of HIV infection, retesting postnatally should be done every 3 months; these include mothers categorized as key population; in a HIV discordant relationship, or having ongoing sexual or injecting behavior that places her at risk, including new or multiple sexual partners. • Mothers should be counselled on 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 referral and linkage for prevention, care, and support services. • All HIV positive pregnant and breastfeeding women enrolled into care should receive counselling and support (assisted disclosure), case management and follow-up. It should also include linkage to general care for ANC, delivery and post-natal care • All spouses/partners as well as children of pregnant and breastfeeding women testing HIV positive should be offered HIV testing and counselling.
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 (facility-based or community-based) should be encouraged for all partners including sexual partners, needle sharing partners, and children of index clients, with appropriate linkage to treatment and prevention services.

Table 2.1 Cont.

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, or through targeted outreach and testing at key and vulnerable population service delivery points (e.g., drop-in centers). • Key populations that test negative should be retested quarterly. • Link all who test HIV positive to treatment and prevention services. • Prevention services should be recommended, including consistent and correct use of condoms and use of sterile needles and syringes. They should be screened for eligibility and willingness for PrEP. • All uncircumcised males who test HIV negative should be counselled on the prevention benefits of VMMC and linked to VMMC services if they consent
Targeted HIV testing and counselling of adults	• All adults eligible for testing should be offered HTS and encouraged to know their HIV status and the status of their partners. • For those that test negative, re-testing is recommended if there is a new risk exposure. • HIV positive adults should be counseled for immediate ART initiation. • Link all adults identified as HIV positive to treatment and prevention services. • Clients who are not eligible for testing should receive HIV prevention messages and be offered services, as appropriate. • All males who test HIV negative should be counselled on the prevention benefits of VMMC and linked to VMMC services if they consent

2.3 Package of HIV Testing Services

An HIV testing and counselling session consists of:

- A pre-test session
- HIV testing
- Assessment for other health-related conditions or needs (while HIV tests are running)
- A post-test session (including index testing)
- Referral and linkage to other appropriate health services (as part of the post-test session)

The HIV testing service package is summarized in Table 2.2.

Table 2.2: Summary of HIV Testing Services Package

Pre- Test Counselling

Pre-test counselling may be provided to an individual or a couple presenting for HTS. Group information can also be offered during pre-test.

The objectives of the pre-test counselling session are to:

- Provide information on the benefits of knowing one's HIV status, including outcomes for people on ART and undetectable = Untransmittable (U=U).
- Provide an explanation for the HIV testing process including time the session will take, confidentiality, and interpretation of test results
- Obtain informed consent for HIV testing.
- Explore the client's risk of HIV infection.
- Discuss the importance of disclosure to partners and other family members.
- Explain the benefits of couple testing and partner services/index testing.

Provide information on available post-test services, including referrals for prevention or HIV care services

Perform test.

The goal of HIV testing is to:

- Provide accurate HIV diagnosis as per the nationally approved testing algorithm
- Provide same day HIV test results

During the 15 minutes as you wait for the test results:

- Discuss Combination Prevention e.g., PrEP, PEP, Risk Reduction, STI treatment, condom information and demonstration, VMMC, Elimination of Mother to Child Transmission of HIV (eMTCT)
- Screen, provide information and referrals for; Intimate Partner Violence (IPV), STI and cancer screening, Tuberculosis (TB), Family planning/contraceptive needs, etc.
- Establishing number of sexual contacts and biological children for the purpose of index testing.
- Document in the HTS, Lab, referral and linkage register (MOH 362).

Discuss further on index testing and HIVST as you perform the second and the third test, as per the national algorithm, for the clients who test positive with the screening test

Post-test counselling

- Check if the client is ready for results and help them to interpret.
- Check what the client understands by the results.
- Allow the client to share his/her initial reactions and verbalize their initial feelings.
- Explore and acknowledge client's immediate feelings and concerns.

Offer necessary support

Table 2.2 Cont.

<table>
<tr>
<td>NEGATIVE RESULT
– Explain test results.
– Review implications of being HIV negative.
– Support clients to develop a risk reduction plan (see HTS operational manual)
– Provide information on methods to prevent HIV acquisition.
– Provide male and/or female condoms, lubricant, and guidance on their use.
– Emphasize on importance of knowing the status of sexual partners and information about the availability of partner and couples testing services.
– Referral and linkage to relevant HIV prevention services
Explain the need for repeat testing for people who test negative but report risky behavior within the prior 4 weeks (i.e., unprotected sex with a partner of unknown status or Known HIV positive status); if they test HIV negative again after 4 weeks and are at ongoing risk of HIV acquisition, they should be advised to return for testing every 3 months</td>
<td>POSITIVE RESULT
– Review implications of being HIV positive.
– Help the index client to cope with emotions arising from the diagnosis.
– Discuss immediate concerns and help for the client to decide who in his or her social network may be available to provide immediate support.
– Discuss positive living.
– Provide clear information on ART and its benefits for maintaining health and reducing the risk of HIV transmission, as well as where and how to access ART
– Refer clients who turn HIV positive to CCC for linkage to treatment.
– Revisit index testing and HIVST to determine partner notification plan/approach (refer to HTS operational manual and APNS operational Manual).
– Discussion of the risks and benefits of disclosure to partners; couples counselling should be offered to support mutual disclosure.
Encourage and offer HIV testing for sexual partners, injecting partners, biological children, and other family members, which can be done through couples testing, family testing and/or assisted partner notification service.</td>
</tr>
<tr>
<td colspan="2">Assessment of other health related conditions
Assess risk for sexually transmitted infections (STIs) and opportunistic infections that would also require management</td>
</tr>
<tr>
<td colspan="2">Referral and linkage to care
Obtain accurate locator information from the index client (physical location, phone number)
Physically escort the client for re-testing and linkage to ART
Document the outcomes of partner follow up(s)</td>
</tr>
<tr>
<td colspan="2">Post-Test Counseling in the Era of Test-and-Treat
Post-test counselling should, at a minimum, include three key messages that being 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 from 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</td>
</tr>
</table>

2.4 Age-Specific HIV Testing Algorithms

2.4.1 Early Infant Diagnosis

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

HIV exposure of an infant or child can occur in utero, at labour and delivery and through breast milk. Confirmation of HIV infection should immediately follow.

All HIV exposed infants (HEI) should be tested with DNA PCR within 6 weeks of age or first contact thereafter; if negative then another DNA PCR at 6 months, and if negative then repeat DNA PCR at 12 months.

If the HEI develops symptoms suggestive of HIV as per WHO staging criteria, an additional DNA PCR test should be conducted immediately.

An antibody test should be performed for all HEI at 18 months of age and every 6 months thereafter during breastfeeding, and at 6 weeks after complete cessation of breastfeeding (Figure 2.1).

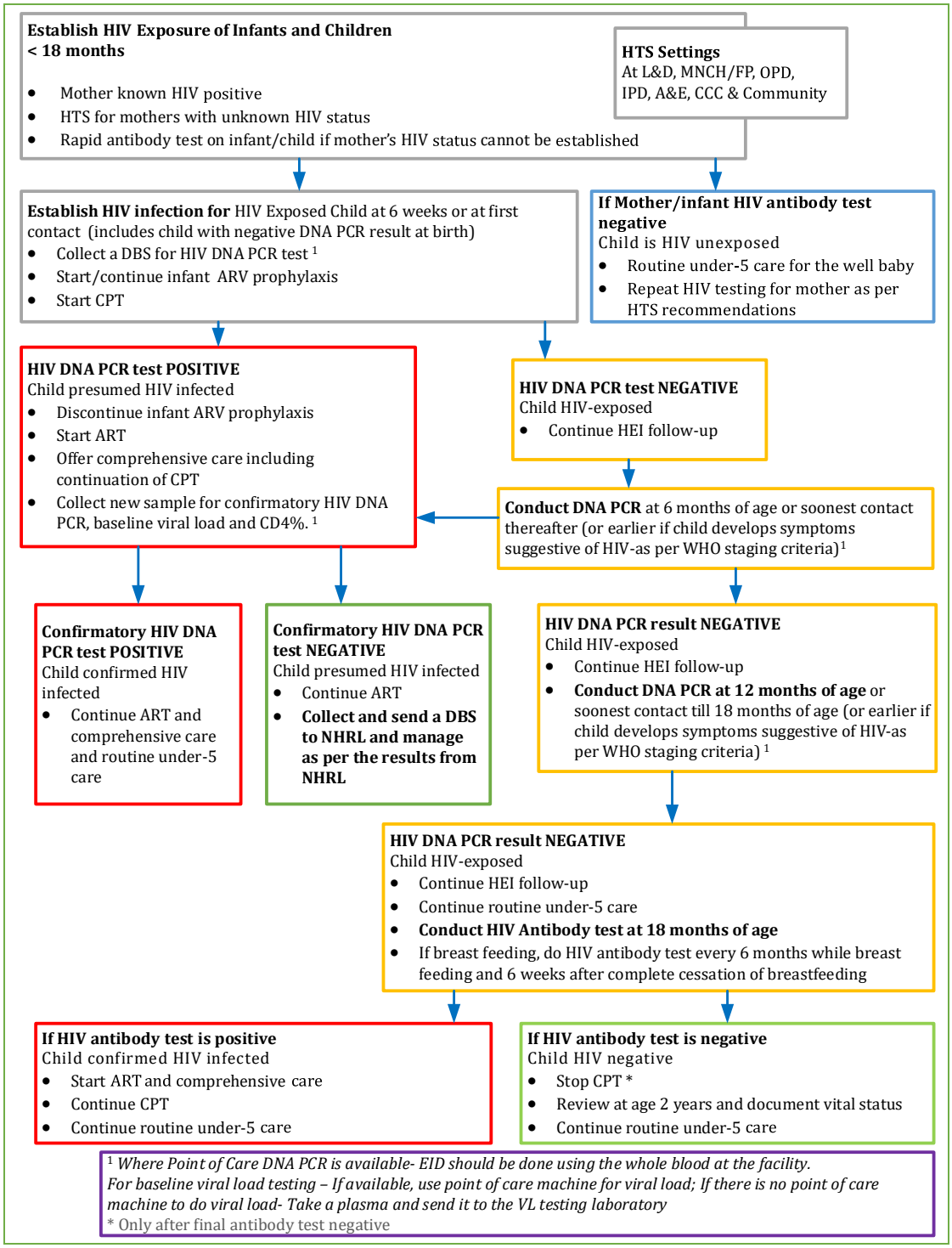


Figure 2.1 Algorithm for Early Infant Diagnosis in Infants and Children < 18 months of age

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 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 2.3. ART can be initiated while awaiting HIV DNA PCR results to confirm HIV infection.

Table 2.3: Presumptive Diagnosis of HIV in children <18 months while awaiting DNA PCR Results

HIV antibody test positive AND symptomatic with;

2 or more of the following:

- Oral candidiasis/thrush
- Severe pneumonia
- Severe sepsis

OR any of the of following:

- Any WHO Clinical Stage 4 condition
- Recent maternal death (if likely to have been HIV-related) or advanced HIV disease in mother
- Child's CD4% < 25%

2.4.1.2 Birth Testing

Birth testing is defined as HIV testing (with DNA PCR) at birth or around birth for infants born to HIV-positive mothers. Birth testing has the potential to improve survival for infants who are infected during pregnancy, around labour and delivery by identifying them early for rapid ART initiation. Do not use cord blood for birth testing as this could result in false positive results.

A DNA PCR test can be offered at birth or around birth where feasible.

ALL children initially tested at birth should be retested at 6 weeks of age and the EID algorithm followed (Figure 2.2.)

Considerations for providing birth testing:

Birth testing may be prioritized for newborns who are at high risk of HIV acquisition including those born to:

- Mothers who seroconvert during pregnancy.
- Mothers who have unsuppressed or unknown viral loads during delivery.
- Mothers who received a HIV positive diagnosis for the first time at or after 28 weeks gestation or during labour and delivery
- Mother on ART for less than 12 weeks prior to delivery

Birth testing should be offered where this is feasible:

- DNA PCR results can be returned the same day e.g., where on site point of care is available.
- ART regimens recommended for neonates as per national guidelines are available and can be initiated immediately.
- Follow-up of the newborn is done to ensure no lost to follow-up.

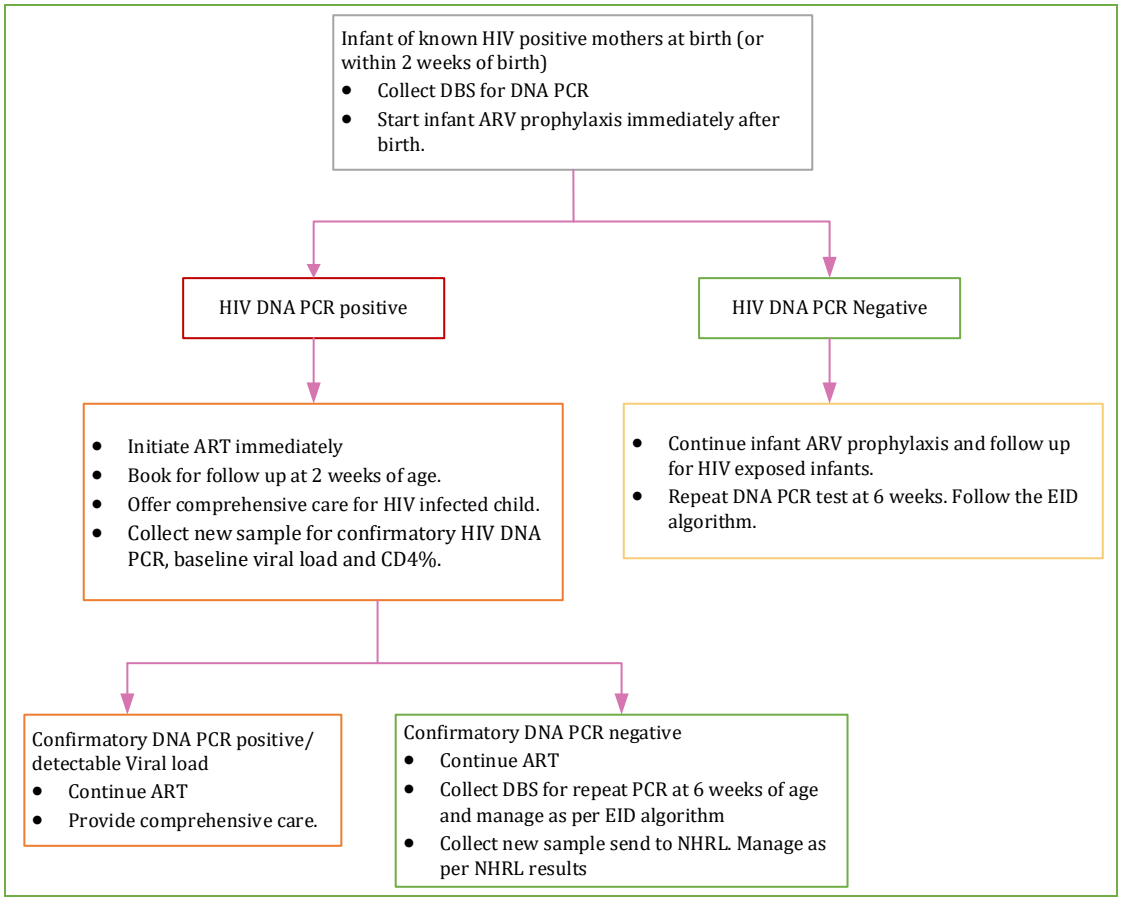


Figure 2.2: Birth Testing Algorithm

2.4.1.3 Use of Point of Care testing for Children

Point-of-care testing occurs at the health facility where care is being provided, with results being returned to the patient or caregiver on the same day as sample collection. Point of care DNA PCR testing for early infant diagnosis of HIV can reduce the turnaround time for testing and return of results and allow immediate initiation of ART among infants. Point of care DNA PCR testing can be used to diagnose HIV infection as well as to confirm positive results.

2.4.2 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, adolescents, and adults, and (refer to Figure 2.3)
- An HIV-positive diagnosis will be made **using three consecutive reactive assays**. This three-test strategy as well as retesting aims to ensure that at least a 99% Positive Predictive Value (PPV) is maintained, and false positive misdiagnosis is avoided.
- Offer adequate information to all clients and obtain consent prior to the HIV test (verbal consent is adequate but should be documented by the health care worker in client records). For children below the age of 14 year who are not emancipated minors, a written consent from the guardian is recommended.
- Individuals 15 years and older and emancipated minors can provide self-consent.
- Clients who test positive should be linked to care and treatment. Counselling support, index and family testing should be offered to these clients.
- Clients who test negative should be counselled on HIV risk reduction behaviors and linked to combination HIV prevention services (such as VMMC, RH/FP, condoms, PrEP, etc.) depending on individual risk profile. Table 2.5 provides recommendations for re-testing those who test HIV negative.

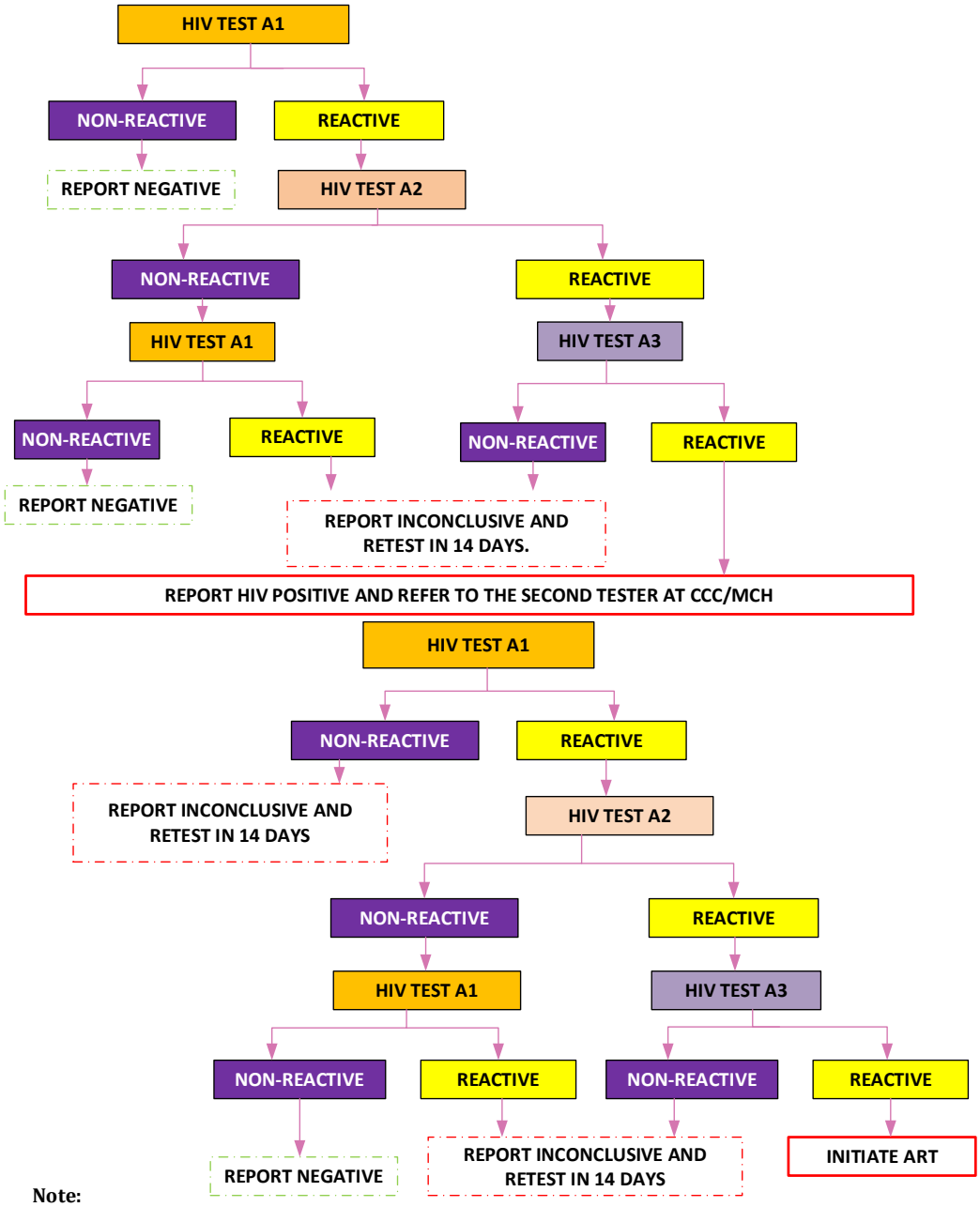
HIV testing algorithm for children >18months, adolescents and adults.

Figure 2.3 illustrates the serial testing algorithm. An HIV-positive diagnosis will be made using three consecutive reactive assays (Figure 2.3). All individuals are first tested on Assay 1 (A1). Anyone with a non-reactive test result (A1−) is reported HIV-negative. Individuals who are reactive on Assay 1 (A1+) will then be tested on a separate and distinct Assay 2 (A2). Individuals who are reactive on both Assay 1 and Assay 2 (A1+; A2+) will then be tested on a separate and distinct Assay 3 (A3). A positive HIV diagnosis is given when Assay 3 is reactive (A1+; A2+; A3+).

If Assay 3 is nonreactive (A1+; A2+; A3−), the status should be reported as HIV-inconclusive, and the individual should be asked to return in 14 days for retesting.

Individuals who are reactive on Assay 1 but non-reactive on Assay 2 (A1+; A2−) should be repeated on Assay 1. If repeat Assay 1 is non-reactive (A1+; A2−; repeat A1−), the status should be reported as HIV-negative. If repeat Assay 1 is reactive (A1+; A2−; repeat A1+), the status should be reported as HIV-inconclusive, and the individual asked to return in 14 days for retesting. **All clients with HIV positive results will be referred to a Comprehensive Care Clinic for retesting prior to initiation of ART**

NOTE: The three-test algorithm will be implemented after identification of the specific assay. Meanwhile, the current algorithm continues being in use (Annex 7). Guidance will be issued before implementation.



Note:

- The use of DNA PCR as a supplemental assay is no longer recommended
- For inconclusive HIV status, if reactivity remains the same after 14 days the individual should be reported as HIV-negative and advised to retest after 3 months

Figure 2.3: HIV Testing Services Algorithm

Results interpretation

RESULTS	INTERPRETATION
A1-	HIV-NEGATIVE
A1+; A2+; A3+	HIV-POSITIVE
A1+; A2-; Repeat A1+	HIV-INCONCLUSIVE (retest after 14 days). If reactivity remains the same after 14 days, the individual should be reported as HIV-negative
A1+; A2-; Repeat A1-	HIV-NEGATIVE
A1+; A2+; A3-	HIV- INCONCLUSIVE (Retest after 14 days). If reactivity remains the same after 14 days, the individual should be reported as HIV-negative

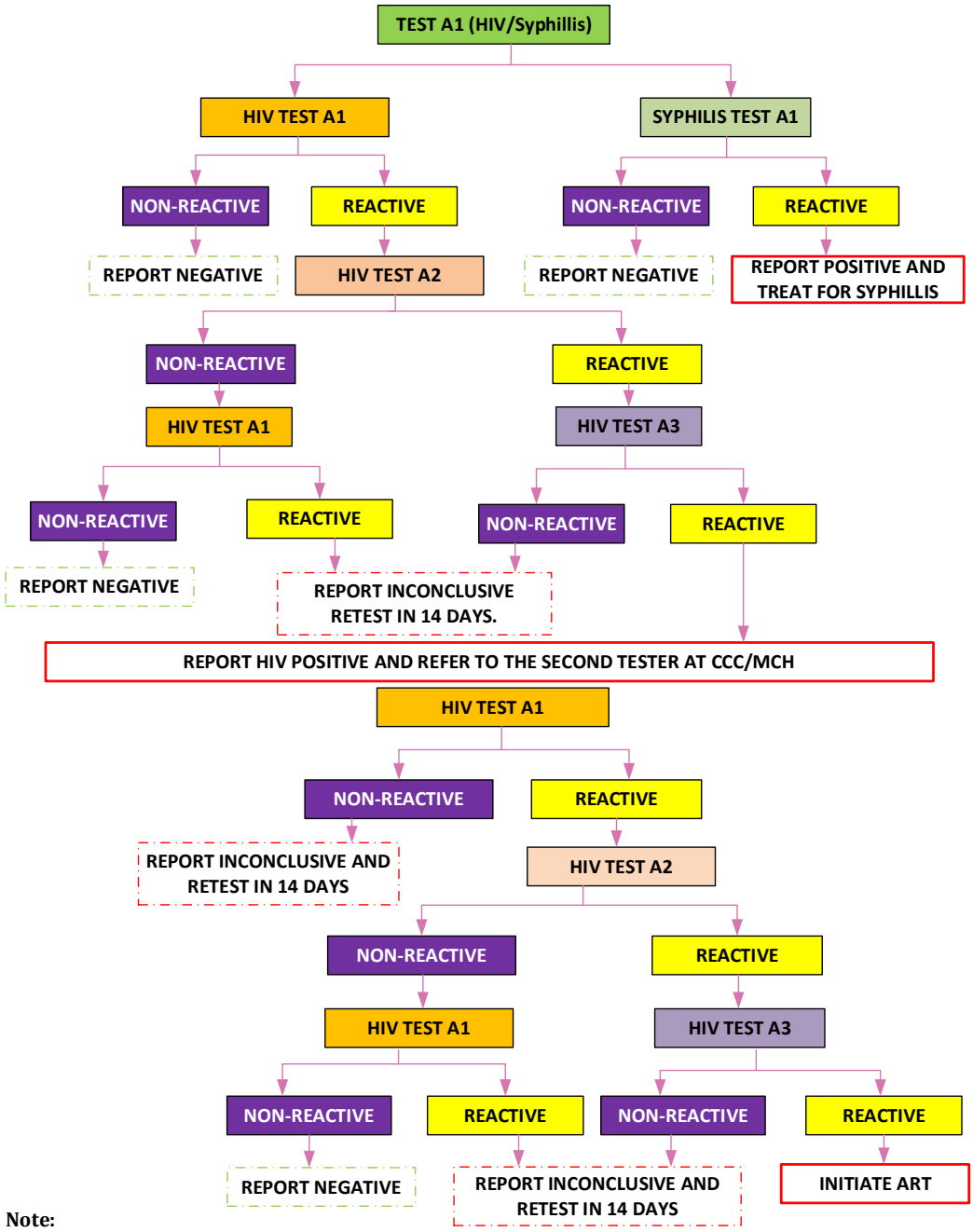
2.4.3 HIV testing for Pregnant Women

For pregnant women, the HIV/syphilis dual test should be used as the A1 test (Figure 2.4). The dual test kit is recommended for:

- Pregnant women during their first ANC, unless the woman is known to be living with HIV.
- For those who test negative for both HIV and Syphilis repeat testing should be conducted in the third trimester using the HIV and syphilis dual test.
- Partners accompanying pregnant women for the first-time during ANC

HIV/Syphilis dual test should not be used for retesting women on ART or with known positive HIV status, or women diagnosed with syphilis during pregnancy.

See Figure 2.4 for the full algorithm when considering HIV and syphilis (TP) results concurrently.



Note:

- The use of DNA PCR as a supplemental assay is no longer recommended
- For inconclusive HIV status, if reactivity remains the same after 14 days the individual should be reported as HIV-negative and advised to retest after 3 months

Figure 2.4 Dual HIV/syphilis Testing Algorithm

RESULTS	INTERPRETATION
A1 HIV-, Syphilis Test (TP) -	HIV negative, syphilis negative
A1 HIV-, Syphilis Test (TP)+	HIV negative, syphilis positive
A1 HIV+, Syphilis Test (TP)-	Syphilis negative and proceed with A2 for HIV
A1 HIV+, Syphilis Test (TP)+	Syphilis positive and proceed with A2 for HIV
A1 (HIV+); A2+; A3+	HIV-positive
A1(HIV+); A2-; Repeat A1+	HIV-inconclusive (retest after 14 days). If reactivity remains the same after 14 days, the individual should be reported as HIV-negative
A1(HIV+); A2-; Repeat A1-	HIV-negative
A1(HIV+); A2+; A3-	HIV- inconclusive (retest after 14 days). If reactivity remains the same after 14 days, the individual should be reported as HIV-negative

Table 2.4: Approaches to Improve Linkage to Treatment and Prevention Services

key area	Action
Information	• Quality post-test counselling should include information about the nature and availability of additional HIV-related services, description of the next steps in treatment and prevention 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 treatment and prevention (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. • For children, HIV status should be disclosed to children by age 12 years and the process can start when a child is as young as 7 years old. The health care provider or the parent/caregiver/guardian can disclose to the child with appropriate guidance and training. The aim of disclosure to children is to start to involve them in the management of their own health and reduce stigma associated with HIV
Barriers to Linkage	• During post-test counselling, identify and address any barriers to linkage

Table 2.4 Cont.

Systems to Facilitate Linkage	• The HTS provider is responsible for linkage into care. • Same day enrolment into care is expected. monitor linkage to treatment initiation within 14 days of diagnosis, however allow follow up of clients to 90 days of a HIV-positive diagnosis • For HIV negative clients link to HIV prevention services based on assessed risk • Linkage should be done to on-site treatment and prevention 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 cancer 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 monthly • Discuss linkage at MDT meetings.

2.5 Retesting recommendations for HIV negative persons

Retesting in this context refers to testing that occurs later after the initial test is negative.

The purpose of retesting is to:

- Monitor the effectiveness of HIV prevention interventions
- identify and treat new HIV infections as early as possible when prevention efforts fail.

The following are the recommendations for HIV retesting in different populations and settings in Kenya:

Table 2.5: Recommendations for Retesting HIV Negative Clients

Scenario/population	Recommendation for retesting
General population	All general population to be screened every 2 years using the approved NASCOP HTS screening tool and those eligible get tested
Key populations (FSW, MsM, TG, PWID)	Re-test every 3 months
Negative partner in discordant	Retest HIV negative partner at the initiation of ART for the HIV positive partner, at 6months and 12 months once viral suppression is achieved. Retest annually if the positive partner remains virally suppressed.
Pregnant women	Test in first trimester or first contact; Re-test in the third trimester and, during labour and delivery.
Breastfeeding mothers	Re-test 6 weeks after delivery, at 6 months then every 6 months until complete cessation of breast feeding. For mothers considered to be at high risk of HIV infection, retesting postnatally should be done every 3 months
Persons who had a most recent (e.g., less than one month) high risk exposure to HIV	Test at initial presentation and re-test at 4 weeks, after which National testing guidelines apply
STI symptomatic patients or patients with symptoms suggestive of acute HIV	Test at initial presentation and re-test at 4 weeks, after which national testing guidelines apply
Individuals on Pre-exposure prophylaxis (PrEP)	Test at initiation of PrEP; Retest at month one, and then every 3 months

2.6 Inconclusive HIV status

An HIV-inconclusive test status means that individuals had discrepant results on the test (for example, first test reactive, second test nonreactive, third test reactive) and so could not be given an HIV-positive or HIV-negative diagnosis.

Inconclusive results are rare, but they may occur when

i) cross-reactivity exists between kits or patient-related factors,
ii) the tester or test kit makes an error; and/or
iii) individuals are seroconverting and in the window period, when infection cannot be determined.

The window period is the time from exposure to HIV infection to when the body produces enough HIV antibodies to be detected by an HIV antibody test. This time can vary across different types of tests, where some tests may be able to detect antibodies earlier than another test, which can lead to discrepant test results.

All people with an inconclusive HIV status should be encouraged to return in 14 days for retesting. Receiving inconclusive results could be confusing and stressful for clients and may be difficult for the provider to explain. During post-test counselling, the provider needs to take time to explain carefully what an HIV-inconclusive status means, stating that it is neither HIV-positive nor HIV-negative, and that retesting in 14 days is needed to establish the correct diagnosis. Because definitive diagnosis cannot be made on the day of testing, and immediate referral to HIV care or ART initiation is not appropriate, providers need to help clients make a clear plan for follow-up and schedule an appointment for retesting. Also, clients should be informed about prevention options and how to stay HIV-negative, as well as about the availability and benefits of ART.

Those suspected of having an acute HIV infection1 – for example, if they report or present with symptoms associated with acute HIV infection – should be followed up closely. This is a period of high infectiousness due to high viral load, and clients need to be informed how to protect their partners. Individuals at high ongoing risk of HIV can be informed about PrEP and encouraged to discuss options depending on their final HIV status when they come back for retesting.

2.7 Approach to Patients on ART with a Discrepant HIV Test Result

HIV testing should not be performed to patients who are already enrolled into HIV care and on ART. However, some patients self-refer for HIV antibody testing without disclosing that they are known HIV positive and on ART. Figure 2.5 provides recommendations on managing patients who have a non-reactive antibody test while on ART.

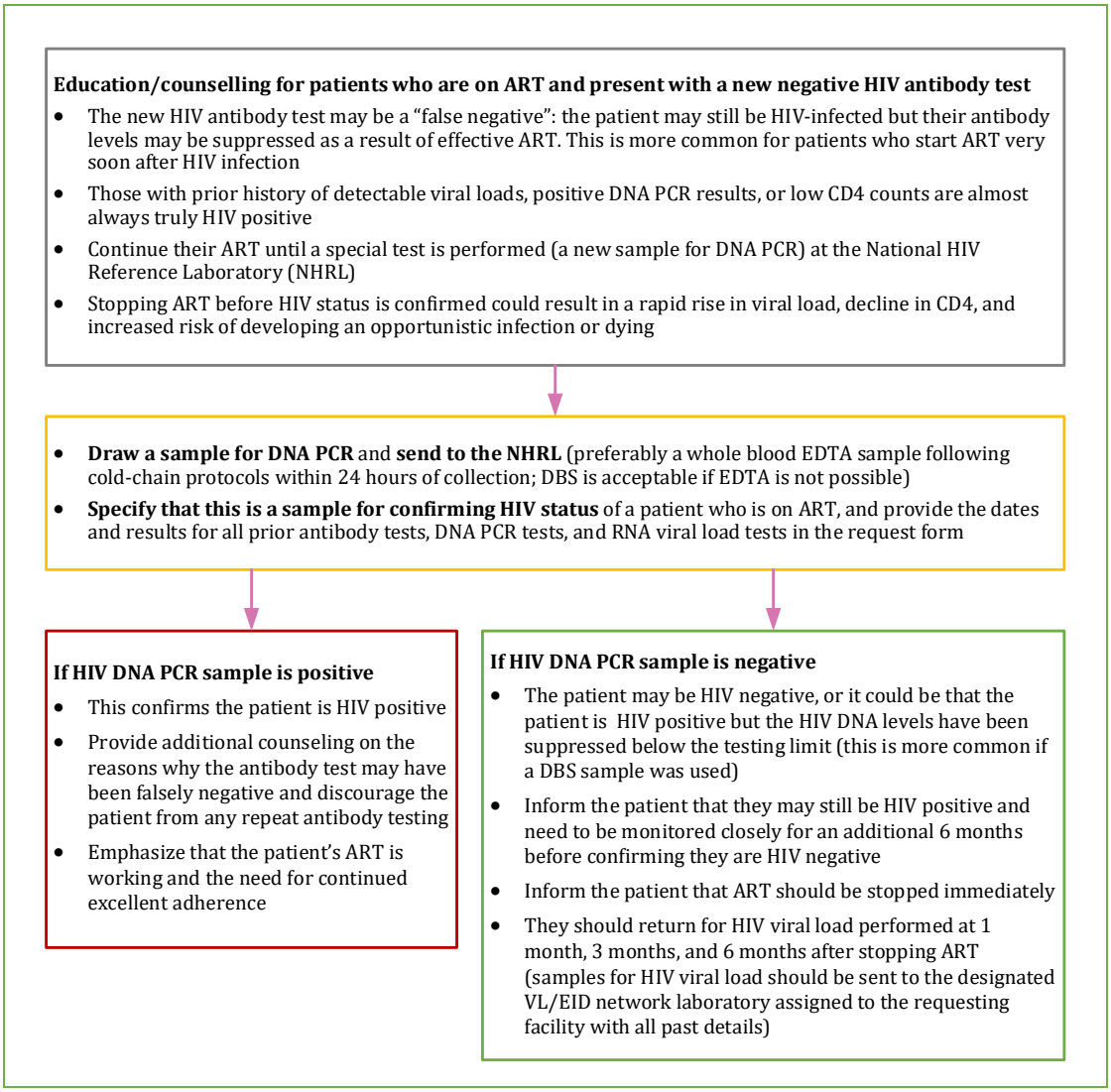


Figure 2.5: Managing Patients on ART Who Present with a New Negative HIV Antibody Test

3. Initial Evaluation and Follow up

3.1 Introduction

All PLHIV are eligible 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.

In order to provide targeted services based on clinical presentation, during the initial evaluation all PLHIV should be categorized as presenting with advanced HIV disease (AHD) or as presenting well (Table 3.3). Patients with advanced disease require more intensive evaluation for and management of OIs, and once ART is started, they are at higher risk of developing immune reconstitution inflammatory syndrome (IRIS, Annex 16).

Similarly, after at least 6 months on ART, PLHIV should be categorized as being either established or not established on ART (clinically, virologically, and psychosocially) to best meet the specific needs of each patient for treatment and follow-up and improve patient outcomes through provision of targeted differentiated care. Differentiated care minimizes inconvenience and unnecessary frequent follow-up, thus reducing costs and time related to clinic visits. It also allows resources to be focused on those patients who require additional attention.

3.2 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.

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.

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

History	Details for History taking
Current and past medical history	• Presenting complaints/current symptoms ○ Also inquire about symptoms due to co-existing HIV-related and non-HIV-related disease and co-morbidities that will require immediate intervention • History of TB and TB contacts Complete 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)
	  ○ Document history of TB
	• Current medications,
	  ○ Establish current medications (prescription, non-prescription, and herbal) likely to interact with ARVs
	  ○ Document ARV exposure history including previous or current ARV use (including for PMTCT, PEP, PrEP, and ART)
	• Drug allergies, especially sulpha allergy
	• History of hospitalizations
	  ○ Establish reasons for hospitalizations
	• Family history of chronic disease or cancer
	Establish nutritional history and adequacy of nutritional intake and household food security

Psychosocial history	• Education, employment, family, marital status
	• Establish possible presence of mental health concerns
	  ○ Including past treatment for mental illnesses and any current symptoms of depression
	• Assess for disclosure and presence of self-stigma
	  ○ Encourage disclosure to trusted close relations and sexual partners
	• Substance use screening including alcohol, tobacco, miraa (khat), marijuana, narcotics, injection drug use (use the CRAFFT screening tool for adolescents and the CAGE-AID screening tool for adults to screen for alcohol and drug use disorders – see Tables 4.15 and 4.16)
	• Establish and document social support structures
	• Link to additional facility and community support resources, including psychosocial support groups, peer mentors, harm reduction services for PWIDs, etc.
	Elicit and begin to address possible barriers to adherence

Table 3.1 Cont.

Sexual and reproductive history	**History**
	● History of STIs
	● Current symptoms of STIs
	● Sexual practices
	  ○ Determine HIV status and disclosure to sexual partner(s)
	  ○ ART status of sexual partner/s
	● Pregnancy history and age of all living children
	● Menstrual history, family planning and plans for pregnancy
	● History of cervical cancer screening
	● Vaccination history (including COVID-19 vaccine)
	Discuss:
	● Secondary prevention and avoidance of re-infection with STIs
	● Pregnancy intention and contraception needs
	Encourage contact tracing and HIV testing for sexual partners and all children < 15 years of age of HIV-infected women or whose mothers' HIV status is unknown

Vital signs, and anthropometric measurements	● Measure and record weight, height, MUAC (in children and pregnant women), temperature, pulse rate, BP, respiratory rate, and pulse oximetry ● Calculate BMI as: Weight (kg)/ Height^2(m); Use z-scores for children ● Monitor growth trends for children
General examination	Examine the following: ● 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, pruritic papular eruptions (PPE), folliculitis, fungal infections, molluscum, and KS) ● Assess developmental milestones for children
Systemic examination	● Central Nervous System ● Mental State Examination (for mental status) ● Abdomen ● Respiratory ● Cardiovascular ● Genitourinary/ anorectal system (for ulcers, discharge, condylomata/warts, prostate examination for men ≥ 45 years of age). Speculum examination with cervical cancer screening for females

Table 3.1 Cont.

Summary	List differential diagnosis and management plan for each problem (including investigations, treatment, referrals, and follow-up) • Assign and document the WHO Clinical Stage and manage presenting illnesses • Growth and developmental milestone must be assessed and used for WHO staging in children *Differentiate between patients with advanced disease versus those who are clinically well, to guide acuity of follow-up*

3.3 Initial Laboratory Evaluation of PLHIV

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	• Positive status should be reconfirmed prior to ART initiation for all patients • Refer to current HIV testing algorithm
	CD4 cell count	• For all patients (CD4% for children ≤ 5 years old) • If CD4 ≤ 200 cells/mm3 in PLHIV >5 years, then laboratories should automatically perform a serum cryptococcal antigen (sCrAg) on the same sample to screen for cryptococcal infection • TB-LAM should also be conducted
	Viral load (HIV-1 RNA)	• Baseline viral load (VL) is recommended for infants after 1st PCR test is positive. Specimen for baseline VL can be drawn at the time of initiating ART; obtaining a VL should not delay ART initiation
	Serum Cryptococcal Antigen (sCrAg)	• Obtain serum CrAg If CD4 ≤ 200 cells/mm3 in patients >5 years as reflex testing by the laboratory • If positive, manage as per the cryptococcal meningitis screening algorithm (Figure 4.1)

Table 3.2 Cont.

Others	Hb (preferably full blood count if available)	• All patients especially if on AZT •
	Pregnancy Test	• Pregnancy status should be determined for all women of reproductive age (based on history of last menstrual period, and if uncertain, irregular, or delayed then a urine pregnancy test should be performed)
	TB- LAM	• Conduct TB-LAM on a urine sample if CD4 ≤ 200 cells/mm3 in PLHIV >5 years, and if CD4% ≤ 25% in children < 5 years • Seriously ill patients
	Urinalysis (for protein & glucose)	• All patients
	Creatinine	○ All patients, especially those starting TDF. Calculate Creatinine Clearance (CrCl), (Annex 15)
	Syphilis serology (VDRL, TPHA, or RPR)	• All patients with a history of being sexually active
	Glucose	• All patients
	Plasma lipid profile	• All patients
	HBsAg	• All adolescent and adult patients (plus children who did not complete routine childhood immunizations)
	HCV antibody	• PWID or for patients with history of injection drug use
	ALT	• Not recommended as 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 or HCV infection, hepatotoxic drugs such as fluconazole, etc.)
	HPV testing	• For women of reproductive age between 25-49 years conducted at baseline and every two years (refer to cancer screening guidelines)

It is not possible for ALL facilities providing ART to offer all the laboratory tests recommended for HIV treatment. If a facility does not have on-site capacity to carry out any test, arrangements should be made to transport specimens to a local or regional reference laboratory.

3.4 Management of Patients Who Present with Advanced HIV Disease

The World health organization (WHO) defines AHD for adults, adolescents, and children five years and older as having a CD4 cell count of less than 200 cells/mm3 or WHO clinical stage III or IV disease. All children younger than five years living with HIV who are not already receiving ART and not clinically stable are considered to have AHD.

Advanced HIV Disease can occur in various settings including PLHIV newly presenting to care, those returning to care after treatment interruption and those on ART who have experienced treatment failure.

PLHIV with AHD have immune suppression with reduced ability to fight opportunistic infections (OI), other infectious and non-infectious diseases, and are therefore at increased risk of morbidity and mortality. AHD is also associated with increased health-care costs, use of more health-care services and more frequent monitoring needs. Leading causes of mortality among adults with AHD include immune reconstitution inflammatory syndrome, tuberculosis (TB), severe bacterial infections, cryptococcal disease, histoplasmosis, toxoplasmosis, and Pneumocystis Jirovecii pneumonia amongst others.

CD4 testing criteria to diagnose AHD and determine eligibility for package for care:

- New clients initiating ART:
  - CD4 testing should be conducted as a baseline test for ALL PLHIV

- Patients who are treatment experienced:
  - PLHIV ≥5 years of age and who had previously initiated ART and are reinitiating after >3 months).
  - Individuals who have documented persistent unsuppressed viral load (two viral load VL >1,000 within 3-6 months).

Package of Care for AHD

All PLHIV presenting with Advanced HIV Disease (AHD) should be offered a package of care that includes timely initiation of ART, screening, diagnosis, prophylaxis, and management of opportunistic infections.

Table 3.3 provides a summary of definitions of well versus advanced disease and package of care for each at enrolment.

Table 3.3: Differentiated Care Based on Initial Patient Presentation

Adults, adolescents, and children ≥ 5 years who Present with Advanced HIV Disease: WHO Stage 3 or 4, or CD4 count ≤ 200 cell/mm³ All children younger than five years at enrollment into care	
Package of Care	● Standard Package of Care (Chapter 4) ● Intensive management of presenting illnesses and malnutrition ● Priority for identification, management, and prevention of OIs, including. ○ GeneXpert ultra for TB diagnosis for all PLHIV with presumptive TB (Figure 8.1) ○ TB-LAM (Figure 8.2), in addition to GeneXpert ultra, for PLHIV with presumptive TB who ▪ Have CD4 ≤ 200 cells/mm³ and if CD4% ≤ 25% in children < 5 years ▪ Have signs of severe illness, or ▪ Are currently admitted to hospital ○ Cryptococcal antigen screening for adolescents and adults with CD4 ≤ 200 cells/mm³ or clinical suspicion of meningitis (any age) (Figure 4.1) ○ Cotrimoxazole Preventive Therapy (CPT) ○ TB Preventive Therapy (TPT) ● Immediate ART initiation unless they are suspected to have TB, TB meningitis, or cryptococcal meningitis;(Table 6.1) ● Close monitoring for development of immune reconstitution inflammatory syndrome (Annex 16)
Focus of ART Preparation Counselling	● Immediate ART start is required to prevent further damage to the immune system. ● Starting ART soon will decrease risk of disease progression, including 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 until confirmed viral suppression. ● More frequent visits or hospitalization may be required to stabilize acute medical conditions and address psychosocial and other concerns ● Referral for management of co-morbidities or concurrent infections may also be needed

Management of Opportunistic Infections in Patients with AHD

Cryptococcal Disease (CM)

Cryptococcal disease is one of the most important opportunistic infections among people living with AHD and is a major contributor to mortality.

Early diagnosis and treatment of cryptococcal meningitis is key to reducing mortality from cryptococcal disease. Health-care professionals should have a low threshold for suspecting cryptococcal meningitis among people with advanced HIV disease.

Screening, prevention and treatment of cryptococcal meningitis is described in **Section 4.33.**

Tuberculosis (TB)

TB is the most frequent life-threatening OI and a leading cause of death among PLHIV. TB remains the leading cause of mortality among PLHIV, despite substantial scale-up of ART, accounting for 30% of the AIDS-related deaths reported.

Screening, prevention and treatment of TB is described in **Chapter 8.**

Table 3.4: Management of patients who are presenting well: WHO Stage 1 or 2, and CD4 count > 200 cell/mm3

Adults, adolescents, and children ≥ 5 years who Present Well: WHO Stage 1 or 2, and CD4 count > 200 cell/mm³	
Focus of ART 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 • ART will reduce the risk of transmitting HIV to others
Frequency of Follow-up	• Weekly follow-up until ART initiation, and then at week 2 and 4 after ART initiation, and then monthly until confirmed viral suppression • Additional visits as required to address any medical or psychosocial concerns
Adults, adolescents, and children ≥ 5 years who Present Well: WHO Stage 1 or 2, and CD4 count > 200 cell/mm³	
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 • ART will reduce the risk of transmitting HIV to others

3.5 Follow-up of PLHIV after ART initiation

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, routine and as-needed laboratory monitoring.

3.5.1 First 6 months after 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. A reasonable follow-up schedule for most patients is 2 weeks and 4 weeks after ART initiation (Table 3.5 and 3.6).

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.

3.5.2 Differentiated Service Delivery for Patients beyond the 1st 6 months of ART

Follow up of patients beyond 6 months of ART is described in table 3.5. It also provides the criteria for determining if a patient is established on ART.

In summary:

- Patients who are not established on ART require closer follow-up.
- Patients who are established on ART require less frequent facility follow-up, with up to six months between clinical appointments

Table 3.5: Differentiated Follow-up of Patients Beyond the First 6 Months of ART

Patients NOT established on ART	
Patients with any of the following: • On treatment for < 6 months • Any active OIs (including TB) in the previous 6 months • Poor or questionable adherence to scheduled clinic visits in the previous 6 months. • Most recent VL ≥ 200 copies/ml • Children < 2 years	
Package of Care	• Standard Package of Care • Case management to address reason/s for not being established on ART
Focus of Counselling	• ART is the most important treatment to maintain good health and an active life • ART will reduce the risk of transmitting HIV to others
Frequency of Follow-up	• Every 1-3 months, based on clinical judgment • Additional visits as required to address any medical or psychosocial concerns • If VL is detectable at 3 months they will need additional assessments for and management of the reason/s for detectable viral load, with close follow-up until viral suppression is achieved (Chapter 5). • Patients with confirmed viral suppression can be followed up every 3-6 months based on patient preference and clinician judgment, with additional unscheduled visits any time the patient has a concern.

Table 3.5 Cont.

Patients Established on ART	
Patients established on ART must have achieved ALL the following ● On their current ART regimen for ≥ 6 months ● Currently no active Illness or in the previous 6 months (patients with well controlled chronic conditions should not be excluded) ● Adherent to scheduled clinic visits for the previous 6 months ● VL ≤200 copies/ml (LDL) within the last 6 months **Note:** ● **This definition should be applied to all populations, including those receiving second- and third-line regimens, those with controlled comorbidities, children above 2 years*, adolescents, pregnant and breastfeeding women, and key populations.** ● **The client's category can change at any time so there is a need for a reassessment at each visit. Clients should be categorized at every visit and managed based on their status.**	
Package of Care	● Standard Package of Care ● Re-assessment of criteria at every clinical visit
Location of Services	● Clinical review and ART prescription from any ART service delivery point; all facility levels ● 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 ● Reminders that any significant life event or change in daily routine could interfere with adherence
Frequency of Follow-up	● Clinic appointments to be made at 6 months intervals ● ART should be offered as refills lasting 3 months, (through fast-track pick-up at facility or through community-based distribution). Patients on injectable contraception should be provided FP through a fast-tracked process between clinic 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 may be arranged based on patient preference
* Children below 2 years are excluded as they require frequent dose adjustment	

3.6 Summary of clinical and laboratory monitoring of PLHIV on ART

Table 3.6 summarizes the recommended minimum routine follow-up schedule for PLHIV. Additional clinical and laboratory follow-up should be performed whenever clinically indicated

Table 3.6: Summary of Clinical and Laboratory Monitoring for PLHIV[1]

	Initial Visit	**ART preparation**	**Week (After ART)**		**Months (after ART)**					**≥ 6 months**
Appointment[2,3]		Every week[4]	2	4	2	3	4	5	6	Every 1-6 months depending on stability
History and physical exam[5]	✓	✓	✓	✓	✓	✓	✓	✓	✓	At each clinical visit
Adherence assessment and support[6]	✓	✓	✓	✓	✓	✓	✓	✓	✓	At each visit
TB Screening	✓	Every visit, using ICF screening tool								
CD4 count	✓	• Baseline, and then only if patient develops treatment failure (to assess for risk of OIs), or if defaults from care (off ART) for at least 6 months • For patients on prophylaxis using dapsone (documented CTX allergy), repeat CD4 every 6 months until CD4 >200 cells/mm^3 for two consecutive measures 6 months apart and VL undetectable, after which dapsone and CD4 monitoring can be discontinued								
HIV Viral Load		• For PCR positive HEIs: baseline at the time of ART initiation • Age 0-24 years: at month 3, then every 6 months • Age ≥ 25 years: at month 3, then month 12, then annually thereafter if suppressed • For all: before any drug substitution for patients on ART for at least 6 months with no valid VL, at month 3 after regimen modification, and then as per population group • Any patient with a detectable VL during routine monitoring, follow viral load monitoring algorithm (Figure 6.6)								
HIV Viral Load (pregnant/ breastfeeding)		• If on ART at time of confirming pregnancy: VL done at confirmation of pregnancy (regardless of when previously done), then every 6 months until complete cessation of breastfeeding • If starting ART during pregnancy or breastfeeding, VL at 3 months after initiation, and then every 6 months until complete cessation of breastfeeding								

Table 3.6 Cont.

CrAg	✓	Baseline for adults and adolescents with CD4 ≤ 200 cells/mm^3 (as reflex testing by laboratory), then only if there is 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)
Syphilis serology (VDRL, TPHA, or RPR)	✓	Baseline, then annually in those at risk and as part of routine ANC profile
Drug Resistance Testing		DRT recommended once treatment failure confirmed on a DTG- or PI-based 1st line regimen, or confirmed treatment failure on 2nd line or subsequent regimens
ALT		Not recommended for routine baseline or follow-up unless specific clinical indication
Cervical Cancer	All women should be screened for cervical cancer following the national guidelines. Using HPV screening conducted every 2 years for HIV positive women in their reproductive age (or annually if using VIA-VILI)	
HCV	Baseline for PWIDs or with a history of injection drug use	

Table 3.6 Cont.

[1] Recommended investigation should not delay ART initiation.

[2]This is the 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, **and after any regimen modification**, 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] Patients who are adherent and virally suppressed at month 3, may not need subsequent monthly appointments until month 6.

[4] All PLHIV qualify for ART and should be initiated as soon as possible including same day and within 2 weeks. For patients who do not start ART on the same day as enrolment into HIV care, they should be followed up every week until ART initiation to address whatever issues are delaying ART initiation, for ongoing management of acute medical issues and for treatment preparation and ART readiness assessment.

[4]Refer to table 3.1 for detailed history and physical examinations.

[5]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 determine nutritional status and calculate the BMI, and thereafter, weight should be measured at every visit.

[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 Chapter 5 for specific adherence preparation, monitoring and support procedures for each visit

Required laboratory tests are highly recommended for patient monitoring, but are not a pre-requisite for ART initiation.

Targeted laboratory tests may be necessary to identify and manage inter-current diseases or adverse drug reactions.

3.7 Differentiated Care for Children, Adolescents and Pregnant/ breastfeeding Women

Children, adolescents, pregnant and breastfeeding women, and key populations face unique challenges in retention and viral suppression and hence may benefit more from differentiated service delivery models adapted to their needs.

Children: Children's care is dependent on family and care giver dynamics. Family centered approaches to care where clinic visits for parents/caregivers and the child are synchronized, should be used. Assessment and categorization to determine establishment on ART should be conducted for pairs and follow-up tailored to their situations. Weight-based dose adjustments should be incorporated in both the facility and community models (e.g., by using portable weighing scales if out of the health facility) to determine optimal doses for ARVs at each review. Aligning appointments with school calendar should be considered to avert disruption of treatment and learning of the child.

Adolescents: Adolescents require psychosocial support, ongoing adherence assessments and counselling which should be aligned with clinic visits, community follow-up as well as school calendar. Considerations should be factored in during the clinical encounters with more focus to those with adherence and viral suppression challenges. Adolescents and Youth Friendly services that incorporate life skills and extracurricular activities should be integrated where feasible.

Pregnant/breastfeeding women: Pregnant and breastfeeding women who have been established on ART should have their HIV clinic appointments synchronized with Antenatal Care visits and with follow-up of the HIV-exposed infant. Those initiated on ART during pregnancy may need close follow up to support them in adherence, retention and achieving viral suppression. Breast feeding women and their babies will have their clinical visit aligned with the immunization clinics schedule. Psychosocial support groups are encouraged for both pregnant and breastfeeding mothers including peer to peer support.

3.8 ART Prescription, Dispensing, and Distribution for clients established on ART

Patients who are established on ART should be offered ART refills of up to 3 months. The refill of other associated commodities such as cotrimoxazole, TPT and condoms should be aligned to the ART refill schedule. Clients established on ART should receive their ART, CPT, family planning, and any other chronic medicines through a distribution system that minimizes the burden on them (travel costs, waiting times, inconvenience) and burden on the health facility (personnel time, space constraints, etc.). This must be on a voluntary basis (i.e., the client can choose to remain in standard care if they prefer).

The health facility is responsible for ART prescription, dispensing, and distribution for all patients enrolled into care. ART distribution for patients established on ART can take place at the health facility or through a community distribution system, depending on patient preference and health facility systems and resources. **The point of ART dispensing should be based on client ability to access treatment with ease.** Models for ART refills include:

- Facility-based
    - Fast track facility-based refills
    - Facility-based ART distribution groups
- Community-based
    - Community-based ART distribution groups
    - Community ART distribution points
    - Community pharmacy distribution

Facility-based Fast Track System for ART Refills

The facility-based fast track system for ART refills is a simple model implemented at the health facility. The client is still required to come to the clinic every 3 months for ART refill, however the refill appointments require minimal or no waiting time at the clinic. Refer to DSD operational manual for detailed information on community models.

Facility-based ART Distribution Group

Facility-based ART Distribution Groups are a model for ART distribution, whereby a group of PLHIVs meet at a designated location within their health facility for drug refills and dispense drugs to their peers within the group while ensuring peer support and treatment literacy. ART refills are done through the group every 3 months and each client is required to attend their clinical review appointment every 6 months.
This model may provide clients with psychosocial support if they are not already part of a support group. This may also be more convenient for clients who are in urban settings and would not wish to be enrolled in a community-based group. Facility-based groups can be peer or HCW led.

Community-based ART Distribution Models

Clients may receive ART refills through community-based distribution. All clients may also benefit from home visits such as for adherence monitoring and support, on a case-by-case basis.
Clients can receive their ART refill through community-based models such as:

- Community-based ART distribution groups
- Community ART distribution points
- Community pharmacy distribution

Before implementing a community-based ART distribution program, a health facility should work with the CHMT to design a program that meets the criteria listed in Annex 14, and the plan approved by the County HIV Technical Working Group before implementation. Refer to DSD operational manual for detailed information on community models.

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; Positive Health, Dignity and Prevention (PHDP) services; screening and providing support in cases of gender-based violence (GBV) or intimate-partner violence (IPV); HIV education/counselling; 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).

The standard package of care should always be applied using a patient- and family-centered approach in PLHIV management. Patient-centered care includes: considering the individual patient's health needs; eliciting and addressing the patient's concerns and expectations; involving the patient's (and their family and friends as appropriate) in decision-making, and; respecting the patient's values and preferences. Family-centered care identifies, engages and provides care to all HIV-positive family members, prevents new infections among family members at risk, and promotes family support and awareness.

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

Component of Standard Package of Care	Sub components
Antiretroviral therapy (ART)	• ART initiation • Adherence assessment, counselling and support • Monitoring (clinical and laboratory)
Positive health, dignity and prevention (PHDP); gender-based violence (GBV) and intimate-partner violence (IPV) screening; and HIV education/counselling	• Disclosure • Index testing • Condom use • Family planning • STI screening, prevention, and treatment • Adherence counselling and support • Pre-exposure prophylaxis for HIV-negative sexual partners • GBV/IPV screening and support • HIV education/counselling

Specific opportunistic infection screening and prevention	• Cotrimoxazole preventive therapy
	• Tuberculosis (TB)
	  ○ Intensified case finding
	  ○ TB 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 (NCD) screening and management	• Hypertension • Diabetes mellitus • Dyslipidemia • Chronic kidney disease • Other NCDs
Mental health screening and management	• Depression • Anxiety • Stress • Trauma • Alcohol and drug use/addiction • Self-care and wellbeing
Nutritional services	• Assessment • Counselling and education • Management and support
Prevention of other infections	• Immunizations • Malaria • Safe water, sanitation and hygiene

Table 4.1 Cont.

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 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) • Clinical assessment at every visit, treat infections early, identify, manage and report adverse drug reactions aggressively and refer appropriately where specialized care is required. • Screen for opportunistic infections and provide prophylaxis (cotrimoxazole, TB Preventive Therapy (TPT), deworm every 6 months (starting at 1 year of age) 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, HIV education/counselling, adherence, availability of support for child disclosure, and follow-up requirements • Adherence assessment, counselling and support • Provide age-appropriate psychosocial support for the family and child and refer to community-based support programs as appropriate • Ensure that the 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 • Enroll in Orphans and Vulnerable Children (OVC) program for social protection and other services.

Table 4.1 Cont.

Standard Package of Care for Adolescents Living with HIV
Clinical care ● Provide immediate linkage to HIV care ● Provide ART to all HIV-infected adolescents ● Perform clinical and laboratory assessment ● Clinical assessment at every visit, treat infections early and refer appropriately where specialized care is required ● Screen for opportunistic infections and provide prophylaxis (cotrimoxazole, TPT) ● Provide NACS and monitor growth and development ● Provide/refer for HPV vaccine **Adherence and psychosocial support** ● Perform a baseline and regular subsequent psychosocial assessment ● Assess for and support disclosure of HIV status to the adolescent (Annex 5) ● Enroll in age-appropriate psychosocial support groups ● Provide treatment literacy ● Provide life skills counselling ● Provide adherence counselling ● Support appropriate transition into adult HIV treatment and prevention
Prevention of HIV transmission ● Encourage index 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 IPV ● 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 for specialized care ● Link with youth community groups, targeting youth both in and out of school **Other services** legal centers, paralegal services, gender-based violence recovery centers, educational institutions, bursary/scholarship programs, income generating activities, constituency development funds, vocational training centers for skills development, etc.

4.1 Antiretroviral Therapy

ART is 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 as soon as possible (preferably within 2 weeks), once patient readiness has been determined. Other sections of these guidelines deal with initial evaluation and monitoring (Chapter 3), patient preparation and adherence support (Chapter 5), and specific recommended ART regimens (Chapter 6).

4.2 PHDP, GBV/IPV & HIV Education/Counselling

PHDP (Positive Health, Dignity and prevention) is a framework that emphasizes the health and rights of PLHIV, including reducing risk of onward transmission of HIV. Within PHDP are 7 core domains of services 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 Services

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 (Annex 5)*
Index testing and engagement	• HIV testing of sexual and drug injecting 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, and PrEP as appropriate
Condom use	• Risk reduction counseling • 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 for specific clinical guidelines)*
Sexually transmitted infections (STI)	• Screening for symptoms of STIs • Prevention of STIs *(See Section 4.4.1 for specific clinical guidelines)*

Treatment adherence	• Benefits/importance of:
	  ○ Adherence to clinical care
	  ○ Adherence to ART
	• Messaging on Undetectable=Untransmissible (U=U)
	(Chapter 5)

Pre-exposure prophylaxis	• Assess HIV-negative sexual partners for PrEP *(Chapter 11)*
Additional services that should be offered to PLHIV beyond the above components include screening for GBV and IPV and HIV education/counseling services.	

4.2.1 Screening for Gender-Based Violence (GBV)/Intimate-Partner Violence (IPV)

National data (KDHS 2014) shows that 45% of women and 44 % of men aged 15-49 years have experienced physical violence since age 15.; 14% of women and 6% of men age 15-49 report having experienced sexual violence at least once in their lifetime. To identify these survivors screening is recommended. WHO recommends that facilities should meet the minimum requirement before starting to routinely screening clients.

The minimum requirements are:

- A protocol or Standard Operating Procedure exists for providing post-GBV and Violence Against Children services
- A questionnaire, with standard questions where providers can document responses,
- Providers offer first-line support (LIVES)
- Providers have received training on how to ask about GBV and Violence Against Children
- Private setting, confidentiality ensured
- A system for referrals or linkages to other services within the facility is in place

If any of these minimum requirements is missing, GBV and Violence Against Children services are considered inadequate, and providers should ensure to have these systems in place before conducting routine enquiry or universal screening

All clients accessing HIV care services should be screened for any form of violence including IPV 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 various serious health problems. Many people have problems with their husbands, partners or other people in their lives. Sometimes the people who love us can hurt us. Has this ever happened to you?"

Has your partner ever:

1. Insulted you or made you feel bad about yourself?
2. Belittled or humiliated you in front of other people?
3. Did things to scare or intimidate you on purpose
4. Threatened to hurt you or someone you care about?
5. Slapped you or thrown something at you that could hurt you?
6. Kicked, dragged, beat you up?
7. Chocked or burned you on purpose?
8. Threatened to use or actually used a gun, knife or other weapon against you?
9. Physically forced you to have sexual intercourse when you did not want?
10. Did you ever have sexual intercourse you did not want because you were afraid of what he might do?
11. Forced you to do something sexual that you found degrading or humiliating?

If a survivor answers yes to any of these questions provide them with LIVES and do a mental assessment

Table 4.2a: Components of screening for GBV/IPV (LIVES)

Listen	Listen to the client closely, with empathy and without judging
Inquire	Assess and respond to the client's various needs and concerns
Validate	Show the client that you understand and believe them. Assure the client that they are not to blame
Enhance safety	Discuss a plan to protect the client from further harm if violence occurs again
Support	Support the client by helping them to access information, services and social support

Supportive messages that may be helpful include:

- "What happened to you is not your fault"
- "Many women/men are in the same situation as you"
- "You are not to blame."
- "Everybody deserves to feel safe at home if you feel like you are in immediate danger, we can involve the police or local administration "

Men, the elderly, and children suffer different forms of violence and should be assessed if there is any clinical suspicion. Key populations are particularly vulnerable to abuse, including MSM, transgender, and prisoners. For children art and play therapy is used during history taking and psychological assessment.

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 Chapter 5 of these guidelines.

In addition, 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
- Behavior changes 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 Preventive Therapy (CPT)

CPT is no longer recommended as life-long prophylaxis, and is only recommended in the following sub populations, unless they have an allergy to sulfur drugs or develop toxicity from CPT:

- HIV exposed infants
- HIV infected children and adolescents <15 years of age
- PLHIV > 15 years of age:
    - Living in malaria-endemic zones*
    - Presenting with WHO stage 3 or 4 event, or meeting the criteria AHD
    - Suspected treatment failure
- All Pregnant and Breast-feeding women

For HIV exposed and infected infants, CPT should start at 6 weeks of age. CPT is effective in AHD, and preventing specific OIs for patients with low CD4 counts (PCP and toxoplasmosis), as well as reducing the risk of common bacterial infections, sepsis, diarrhea illness and malaria.

**Refer to the National Guidelines for the Diagnosis, Treatment and Prevention of Malaria in Kenya for the current Kenya Malaria endemicity map*

Table 4.3: Co-trimoxazole Preventive therapy

Sub-Population	Starting/Restarting criteria	Ending criteria
HIV exposed Infants	All infants, starting 4-6 weeks after birth	Child is confirmed HIV-negative
HIV-infected children and adolescents ≤ 15 years old	All children	Attains 15 years of age
PLHIV > 15 years old	Suspected treatment failure WHO Clinical Stage 3 and 4	Clinically stable: ○ On ART for at least 12 months ○ Showing no signs or symptoms of WHO Clinical Stage 2,3 or 4
HIV-positive Pregnant and breastfeeding women	All	Clinically stable: ○ On ART for at least 12 months ○ Showing no signs or symptoms of WHO Clinical Stage 2,3 or 4 ○ Not pregnant or breastfeeding

Table 4.4: 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

Note: If CrCl 15-30 ml/min then use 50% of normal recommended dose; if CrCl < 15 ml/min then CTX should be avoided

During pregnancy, CPT should be initiated irrespective of the gestational age and should continue throughout pregnancy and breastfeeding. Additional intermittent preventive therapy (sulfadoxine-pyrimethamine (SP)) for malaria is not required for 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, rash may develop with severe exfoliation of the skin and Stevens-Johnson syndrome. Rash severity should be assessed, with management based on severity (Table 4.5)
- Desensitization is effective in the majority of patients with mild to moderate rash (Table 4.6a). The rapid desensitization regimen (Table 4.6b) can be used in situations where treatment for PCP is needed

Table 4.5: Management of Drug-Associated Skin Rash

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 super-infection); **patient should NEVER be re-challenged with CTX or other sulfa-containing drugs;** document and report adverse event and issue patient alert card

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

Table 4.6a: 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
Note: For children, continue up until they have reached their recommended weight-based dosage	

Table 4.6b: 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
Note: The rapid desensitization protocol should not be used for children because the cumulative dosage will be too high	

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.

Note:

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 with absolute CD4 count ≤ 200 cells/mm3 (or CD4 % ≤ 25% for children ≤ 5 years old), and should be discontinued once a patient achieves a sustained CD4 count of > 200 cells/mm3 (or > 25% for children ≤ 5 years old) for at least 6 months.

Dapsone is NOT recommended during breastfeeding.

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 TB Preventive Therapy (TPT) unless they have a specific contraindication. All patients who receive a full course of TPT should have this clearly documented in their file (Section 8.2)

For PLHIV who have presumptive TB, GeneXpert ultra is the preferred testing platform to confirm the diagnosis, with TB-LAM used as an adjunct bedside test when indicated, while awaiting GeneXpert ultra-results. All PLHIV qualify for ART, including patients with HIV/TB co-infection.

Chapter 8 provides specific guidelines for ICF, TPT, use of GeneXpert ultra and TB-LAM, and ART for patients with TB/HIV co-infection.

4.3.3 Cryptococcal Meningitis (CM) Screening and Treatment

All adult and adolescent PLHIV with a baseline CD4 count of ≤ 200 cells/mm^3 should be screened for cryptococcal infection (Figure 4.1). This should 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 cryptococcal screening if clinically suspected. For patients who are symptomatic for meningitis but screen serum CrAg negative, alternative diagnoses for sub-acute meningitis should be explored, such as TB meningitis. All patients with clinical meningitis should be assessed and managed at a facility that can perform lumbar punctures.

Whenever performing CSF CrAg for patients with symptomatic meningitis, CSF GeneXpert ultra for TB should be performed at the same time, as well as urine for TB-LAM.

Fluconazole use during first trimester of pregnancy increases the risk of birth defects. All pregnant women who screen positive with serum CrAg should be offered a lumbar puncture (irrespective of symptoms) to determine if they have cryptococcal meningitis. If the CSF CrAg is positive, they should be treated with 2 weeks of amphotericin B for induction (without fluconazole), while consulting *Uliza!* Hotline (0726 460 000; ulizanascop@gmail.com) to discuss consolidation/maintenance. Pregnant women with negative CSF CrAg should start ART immediately (without pre-emptive fluconazole therapy) and be monitored for symptoms of CM.

Table 4.7 provides detailed guidance on the use of amphotericin, fluconazole, flucytosine (once available), and therapeutic lumbar punctures for the treatment of symptomatic cryptococcal meningitis

Table 4.7: Treatment of Cryptococcal Meningitis

Target population	Regimen	Induction (2 weeks)[1,2]	Consolidation (8 weeks)	Maintenance	When to start ART
Adults	Preferred	Ampho B 1.0 mg/kg/day + Fluconazole 1,200 mg/day	Fluconazole[6] 800 mg/day	Fluconazole 200 mg/day for at least 1 year and until CD4 count > 200 cells/mm^3 for two measures 6 months apart AND VL is undetectable	Defer ART until after completing 5 weeks of CM treatment and symptoms have resolved
	Alternative	Fluconazole[3,4,5,6] 1,600 mg daily	Fluconazole[6] 800 mg daily		
Children and adolescents	Preferred	Ampho B 1.0 mg/kg/day + Fluconazole 12 mg/kg/day (up to max 800 mg/day)	Fluconazole 6-12 mg/kg/day up to 800 mg/day	Fluconazole 6mg/kg/day up to 200 mg/day	
	Alternative	Fluconazole[3,4,5] 12 mg/kg/day (up to max 1,600 mg/ day)	Fluconazole 12 mg/kg/day up to 800 mg/day	Fluconazole 6mg/kg/day up to 200 mg/day	

[1]Amphotericin B should always be used for induction when available. If it is not possible to complete 2 weeks of induction with ampho due to availability, toxicity or monitoring, then use a shorter duration of ampho and complete the 14-day induction period with the alternative regimen

[2]Once available, flucytosine may become part of the preferred and alternative induction regimens, given 100mg/kg per day divided into four doses per day

[3]Fluconazole requires a dose adjustment for impaired renal function; when CrCl ≤ 50 ml/min then use 50% of the standard recommended dose

[4]Fluconazole should not be used with rifabutin-based TB treatment

[5]When using high-dose fluconazole check ALT after one week of treatment and based on symptoms thereafter

[6]Fluconazole is contraindicated in the first trimester of pregnancy. Amphotericin can be used. Please consult expert or National or Regional TWG.

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 Ampho B given with 1 litre of 5% dextrose. Add one to two tablets of 8 mEq KCl orally twice daily. An additional one 8 mEq KCl tablets twice daily may be added in the second week. Include magnesium supplementation at 250 mg tablets of magnesium trisilicate twice daily (or 4 mEq tablets of magnesium chloride 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 Ampho B. Darrows or Ringer's solutions can also be used

Note: Avoid KCl replacement in patients with pre-existing renal impairment or hyperkalemia

Managing hypokalaemia and raised creatinine levels

- Obtain a routine baseline and twice weekly potassium and creatinine:
  - If K < 3.3 mmol/L, administer 1 L of normal saline with KCl 40 mmol in normal saline or 1-2 tablets of 8mEq KCl every 8 hours. Add magnesium. Monitor potassium daily
  - If creatinine level increases > 2-fold from baseline, omit dose of Ampho B, increase hydration to 1 L every 8 hours. 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 1,600 mg/day to complete induction. Monitor creatinine daily

Therapeutic lumbar punctures are a critical component of the management of CM and should be standard of care:

- For all patients with symptomatic CM: perform daily therapeutic lumbar punctures:
  - If opening pressure is ≤ 40 cm: draw off enough CSF to reduce pressure to 20 cm
  - If opening pressure is > 40 cm: draw off enough CSF to reduce pressure by 50%
  - Continue daily LPs until pressure is normal for 3 consecutive days
  - Restart LPs if symptoms return

If measuring intracranial pressure is not possible (even using a giving set and tape measure), then perform daily therapeutic LPs until severe headache subsides, removing 10-20 ml of CSF each time

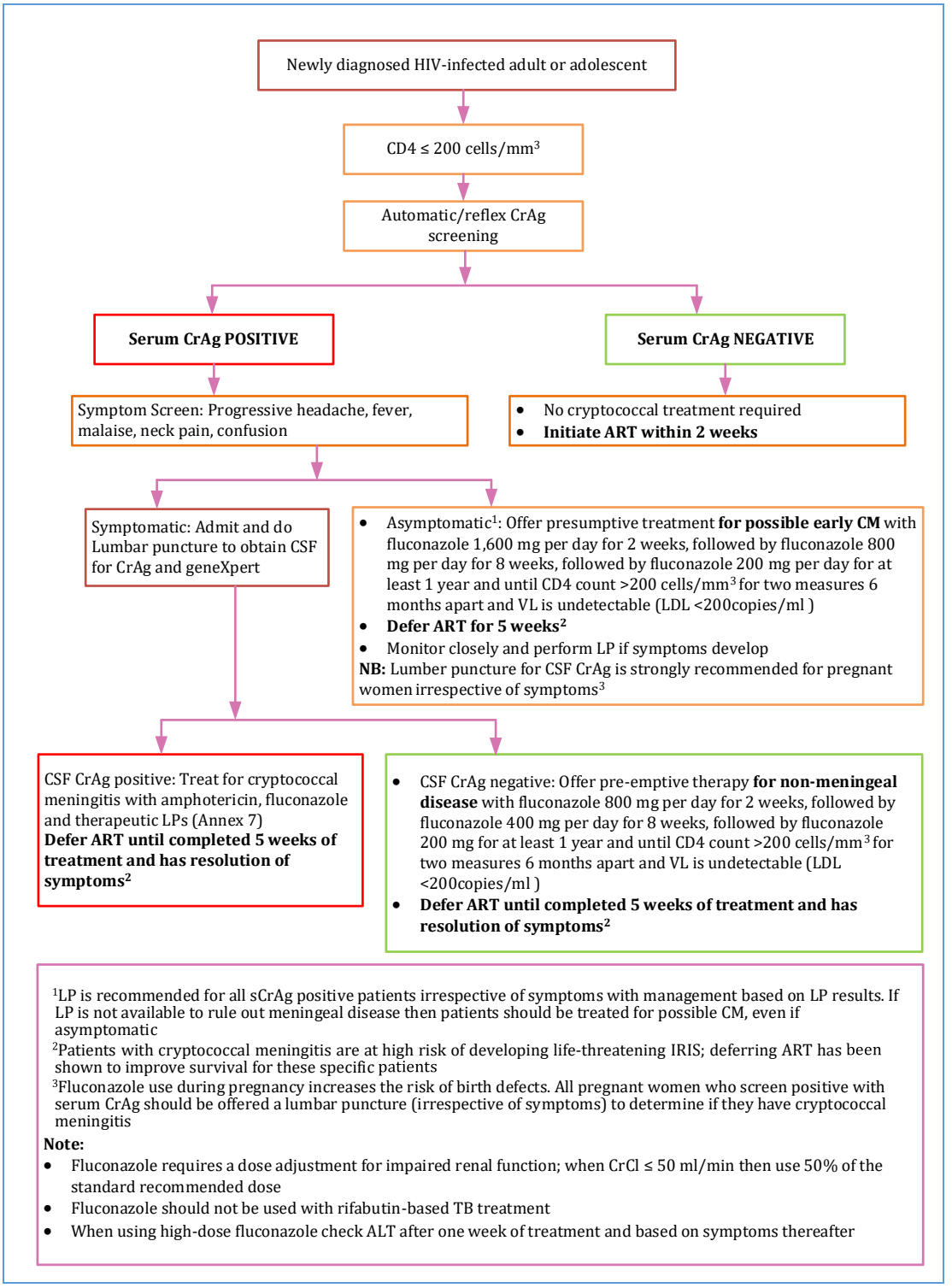


Figure 4.1: Routine Screening for Cryptococcal Meningitis for HIV-infected Adults and Adolescents

4.4 Reproductive Health Services

4.4.1 Sexually Transmitted Infections

Screening for syphilis using VDRL, TPHA, or RPR should be performed as a baseline investigation for all adolescent and adult PLHIV. Pregnant women should be screened for Syphilis during the first ANC visit and 3rd trimester.

All PLHIV should be assessed for symptoms of STIs using the National Algorithms for Treating Common STI Syndromes (Kenya National guidelines for management and control of STIs, 2018. Annex 4). Sexual partners should be treated as well.

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 STI guidelines), with presumptive treatment every quarter.

4.4.2 Family Planning and Pre-Conception Counselling

Pregnancy status should be determined for all women of reproductive age at every visit (based on history of last menstrual period and, if uncertain, irregular, or delayed, then a urine pregnancy test should be performed).

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 (defined as condoms plus another form of effective contraception) should be provided immediately with follow-up appointments scheduled to ensure no interruption in contraception provision. Table 4.8 outlines contraception options for PLHIV based on the ARVs they are using.

Table 4.8: Contraceptive Methods for PLHIV Based on WHO 2018 Medical Eligibility Criteria

Contraceptive Method		ARVs Being Used						Anti-TB
		NRTI (any)	NNRTI		PI/r (any)	INSTI		Rifampicin or Rifabutin
			EFV or NVP	ETR		RAL	DTG*	
IM medroxyprogesterone (DMPA; Depo Provera)		1	1	1	1	1	-	1
Norethisterone enanthate (NET-EN; norethindrone)		1	2	1	2	1	-	2
Implants		1	2	1	2	1	-	2
Combined oral contraceptive (pill)		1	2	1	2	1	-	3
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 2018 MEC Guidelines, however, drug interactions between DTG and hormonal contraception have not been identified

For patients who intend to become pregnant, the key pre-conception messages and services are presented in Table 4.9.

Table 4.9: Pre-Conception 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 fertility calendar app)
	• 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)
		  ○ Syphilis screening
		  ○ Cervical cancer screening
		• STI symptom screening
		• Nutritional assessment, counselling, and support
		• Folic acid supplementation
		• Standard VL monitoring (Figure 6.6)
		• PrEP for the HIV-negative partner

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 (Chapter 11) • In situations where viral suppression is challenging, consider specialist referral for additional options such as sperm washing and artificial insemination	
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 (Chapter 11) • Discuss self-insemination during the peri-ovulatory period, where appropriate/as preferred • In situations where viral suppression is challenging, consider specialist referral for additional options such as artificial insemination	

4.4.3 Maternal Healthcare

Maternal healthcare begins with preconception counselling (Table 4.9), and continues throughout pregnancy and breastfeeding. The standard package of antenatal and postnatal services in the context of HIV is described in Chapter 7 of these guidelines.

4.5 Non-communicable Diseases Screening and Management

4.5.1 Metabolic Disorders

Screening, prevention and management of specific NCDs 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.

The modifiable risk factors for cardiovascular disease include tobacco use and exposure to tobacco smoke, unhealthy diets, overweight/obesity, physical inactivity, harmful use of alcohol, hypertension, diabetes, hyperlipidemia, infections such as rheumatic fever and HIV. Advancing age, sex, race/ethnicity and family history are non-modifiable risk factors associated with cardiovascular diseases

HIV and other chronic diseases require health systems that support chronic care and adherence; their management should be integrated at the health facility, including at the primary care level.

Lifestyle modifications are always the first line of prevention and management for hypertension, diabetes mellitus (DM), and dyslipidaemia (Table 4.10). These are recommended for all patients to prevent these NCDs and should be integrated into routine HIV treatment and prevention. Recommendations for screening, diagnosis, and initial management of hypertension, type 2 DM, dyslipidaemia, and chronic kidney disease (CKD) are provided in Tables 4.11-4.14.

For comprehensive guidelines on prevention, diagnosis and management of diabetes and cardiovascular diseases, refer to *Kenya National Clinical Guidelines for the Management of Diabetes* and *Kenya National Guidelines for Cardiovascular Diseases Management*, respectively.

Table 4.10: Lifestyle Modifications to Prevent and Manage Cardiovascular Disease in PLHIV

Smoking Cessation

- Smoking cessation has multiple short-term and long-term benefits, including
  - Reduced premature aging/wrinkling of skin
  - 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)
  - Reduced risk of cancers: lung, bladder, breast, mouth, throat, esophagus
  - Better response to ART (better viral suppression)
  - Reduced risk of developing TB or dying from TB
- Tobacco dependence treatment and cessation programs should combine behavioral/counseling support with pharmacotherapy treatment where necessary and available. For further details on cessation interventions, refer to the Kenya National Guidelines for Tobacco Dependence Treatment

  Refer to Table 4.18 for tips to assist a client to quit smoking

Dietary Changes and Weight Loss

- 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 flavoring, and fried foods
- Increase intake of whole grains, vegetables, fruit, and beans
- Increase intake of fish
- Consume less than 5 g (just under a teaspoon) of salt per day

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 4.11: 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

Additional Investigations for patients with hypertension

- Urinalysis: to assess for kidney disease and diabetes
- Creatinine, Na, K: to assess for kidney disease
- Blood glucose: to assess for diabetes
- Full blood count: anaemia may indicate chronic kidney disease
- Lipid profile: dyslipidemia is a cardiovascular risk factor
- ECG: to assess for cardiac pathology including cardiomegaly, ventricular dysfunction, ischemic heart disease, etc.

Management (treatment target is BP < 140/90 mmHg)

- If baseline BP is 120-139/80-89 (pre-hypertension)
  - Lifestyle modification, along with monthly BP monitoring

- If baseline BP is 140-159/90-99
  - Lifestyle modification (Table 4.9) for up to 6 months, along with monthly BP monitoring
  - If does not meet treatment target with lifestyle modifications, then add drugs to lifestyle modification
    - 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 blocker 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); or, losartan 50 mg OD (maximum dose is 100 mg OD), with referral to a physician if available
    - Introduce one drug at a time. If the target blood pressure is not reached within one month after initiating therapy, the dosage of the initial medication should be increased. Titrate to maximum recommended dosage (if tolerated) before adding an additional drug
    - 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 physician
    - **Note: Calcium-channel blockers have known drug interactions with PIs and NNRTIs and should be used with caution (Annex 13).** ACE-I and thiazide diuretics do not have significant interactions with ARVs

- **If baseline BP ≥ 160/100 mmHg**
  - **Initiate lifestyle modifications and introduce anti-hypertensive medications concurrently**

Table 4.12: 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%, or oral glucose tolerance test ≥ 11.1 mmol/L
- Abnormal results should be repeated to confirm the diagnosis, particularly for patients without symptoms of diabetes (such as polyuria, polydipsia, polyphagia, weight loss)

Management (treatment target is HbA1c ≤ 7.0% or FBS 4-7 mmol/L)

- For patients with pre-diabetes (abnormal results but does not meet criteria above for diabetes) monitor FBS or HbA1c every 3 months and encourage lifestyle modifications (Table 4.10)
- For patients with diabetes, monitor HbA1c (or FBS if HbA1c is not available) every 3 months
- Lifestyle modification (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)
    - **Note:** DTG may increase metformin plasma levels: monitor blood glucose levels; dose reduction of metformin may be required, and maximum daily dose of metformin should be 1g
  - 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 sulphonylureas (gliclazide)) and/or specialist consultation. Some patients may require insulin.
  - At every visit: A thorough history (to elicit features of hypoglycemia, 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)

  Note: patients with DM are at increased risk of developing TB

Table 4.12: Dyslipidemia 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
• Dyslipidemia is defined as high fasting total cholesterol (>5.2 mmol/L), LDL (>3.4 mmol/L) or triglycerides (>2.2 mmol/L)
Management

• Lifestyle modification for 3-6 months (Table 4.10)
• If the patient is on an ARV known to cause or exacerbate dyslipidemia (primarily LPV/r & EFV) then consider a single-drug substitution to a more lipid-friendly drug (such as ATV/r or DTG) as the treatment of choice before adding a lipid-lowering drug. Rule out treatment failure before making single-drug substitutions (Figure 6.4)
• If patient does not meet treatment target with lifestyle modifications, then add drugs
  ○ Atorvastatin: starting dose of 10 mg OD (maximum dose 20 mg once daily if patient is on a PI/r; maximum dose 80 mg once daily if not on a PI/r)
  ○ Simvastatin and lovastatin are contraindicated in the presence of 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 and monitored annually
Diagnosis
• Impaired renal function is defined as creatinine clearance < 90 ml/min, or dipstick proteinuria ≥ 1 (see Annex 15 for CrCl calculations) • Abnormal results should be repeated to confirm diagnosis • Chronic kidney disease is defined as evidence of kidney damage that persists for at least three months
Management
• Management depends on the cause of the renal impairment; additional investigations and/or specialist consultation may be required • Consultations with a physician is recommended • Treat dehydration promptly and aggressively • If on TDF-containing regimen, substitute with another ARV if CrCl<50 ml/min (see Section 6.5), with the exception of patients with HBV/HIV co-infection (Table 9.3 for renal dose adjustments of TDF and 3TC for patients with HIV/HBV co-infection) • Avoid nephrotoxic drugs (e.g., aminoglycosides and NSAIDS) • Evaluate for and treat hypertension • All NRTIs except ABC require dose adjustments for renal impairment, depending on the severity (Table 6.6 for specific dose adjustments). NNRTIs, PIs, and INSTIs do not require dose adjustments for impaired renal function **Note: DTG may cause a small rise in serum creatinine levels but this does NOT represent a decline in renal function, close monitoring is recommended.**

Patients at higher risk for renal disease and for developing TDF-associated renal toxicity include those with: pre-existing renal disease, hypertension, diabetes mellitus, severe wasting (weight below 60 kg in adults), age > 45 years, WHO stage 3 or 4, CD4 < 200 cells/mm3, high HIV viral load, and concomitant nephrotoxic agents.

Glomerular disease directly related to HIV infection, commonly known as HIV-associated nephropathy (HIVAN) is an important cause of chronic kidney disease among PLHIV.

Prevention, early identification, and management of kidney disease is important to reduce the burden of dialysis and other complications.

4.5.2 Cancer Prevention, Early Detection and Management among PLHIV

PLHIV have a substantially higher risk for many cancers, mainly due to a weakened immune system which impairs control of oncogenic viral infections. A high prevalence of these infections and other modifiable risk factors (such as smoking, alcohol use, unhealthy diet and physical inactivity) contributes to the elevated risk. PLHIV are far more likely than the general population to be diagnosed with Kaposi Sarcoma, non-Hodgkin lymphoma and other cancers (cervical, anal, liver, lung and oral/throat) hence the importance of prioritizing screening and early diagnosis programs in this group.

4.5.2.1 Specific Interventions for Cancer Control in PLHIV

Four interventions are important for cancer control among PLHIV:

- **Achieve viral suppression:** uncontrolled viral replication is a major risk factor for cancer. All PLHIV should initiate ART, and be supported and monitored to achieve long-term viral suppression in order to reduce risk for cancer, and to improve treatment outcomes for many cancers
- **Primary prevention through avoidance of modifiable risk factors**
  - Smoking cessation
  - Avoidance of harmful use of alcohol
  - Regular physical activity
  - Healthy diets
  - Vaccination: vaccination against Human Papillomavirus for girls 9-14 years old are eligible in Kenya, Hepatitis B Vaccine for newborns and high-risk groups
- **Secondary prevention through screening and early diagnosis**
  - Screening: application of simple tests to detect cancer in asymptomatic individuals
    - Cervical cancer: all women LHIV who have been sexually active up to 49 years old (25-49 years in the general population), through either visual inspection with acetic acid (VIA) or PAP smear annually, or HPV testing every 2 years
    - Breast cancer: mammogram annually from 40-55 years; mammogram every two years from 56-74 years; screening for younger women can be performed on an individual basis based on family history or other risk factors. Clinical breast exam can be used where mammogram is not available
    - Prostate cancer: serum prostate specific antigen (PSA) annually for men 40 years and above; digital rectal examination can be used if PSA is not available, and for all men with urinary symptoms
    - Colorectal cancer: fecal occult blood testing of stool (guaiac or FIT) annually for everyone 45-75 years old, or colonoscopy every 10 years
    - Oral cancer: visual examination for everyone above 40 years with history of tobacco use, known HPV infection or immunosuppression
  - Early diagnosis: prompt diagnosis of cancer in symptomatic individuals
    - Breast: lump, asymmetry, skin changes, nipple changes, blood-stained discharge
    - Cervix: post-coital bleeding, excessive vaginal discharge
    - Colon and rectum: change in bowel habits, unexplained weight loss, anemia, blood in stool
    - Oral: white or red lesions, growth, ulceration
    - Naso-pharynx: nosebleed, permanent blocked nose, deafness, lymph nodes in upper neck
    - Larynx: persistent hoarseness of voice
    - Stomach: upper abdominal pain, indigestion, weight loss
    - Skin: irregular growths, lesions, or non-healing sores
    - Bladder: painful or frequent urination, blood in urine
    - Prostate: difficulty (long time) in urination, frequent nocturnal urination
    - Retinoblastoma: white spot in the pupil, convergent strabismus (in a child)
    - Testis: swelling of one testicle

- **Tertiary prevention**: Cancer management, prevention of complications and treatment of side effects and secondary cancers

Note: For screening, diagnosis, and management recommendations refer to national guidelines for prevention and management of cancers. 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. Depression and alcohol/drug addiction are the most significant and are reviewed in this section. For any patient with other suspected mental health disorders, such as anxiety, psychosis or post-traumatic stress disorder, consider formal screening and/or referral to a specialist.

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 upon enrollment 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?*

All patients who answer "yes" to either or both of the questions above, and all patients with a detectable viral load after 3 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 4.15).

Table 4.15: 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 program)	**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 6.4)
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 6.4) **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 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 temporary. Patients on EFV who develop any persistent symptoms of depression should be switched to another ARV after ruling out treatment failure (Figure 6.4).

Supportive Counselling for Depression

Patients with mild depression should receive supportive 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
- Counseling on self-management
  - Continuing ART as prescribed
  - Continuing activities that they used to find interesting/pleasurable
  - Maintaining a regular sleep cycle
  - Keeping physically active
  - Participating in community/social events
  - Returning to clinic if any thoughts of self-harm occur
- Addressing psychosocial stressors
  - Explore potential stressors in the patient's life
  - Assist in problem-solving to reduce stressors
  - Assess for and manage intimate partner violence
- Reactivation of or referral to social networks, including peer support groups
- Regular follow-up until symptoms improves and are stable

Pharmacological Management of Depression

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

Fluoxetine is an antidepressant and does not have significant drug interactions with ARVs.

- Starting dose for an adult is usually 20 mg once taken daily 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.
- 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.
- If/when the patient is ready to discontinue antidepressant therapy it should be discontinued as a weekly taper (e.g., if the maintenance dose is 60mg then taper to 40mg, then 30mg, then 20mg, then 10mg and then stop), with close monitoring for recurrence of symptoms.

4.6.2 Alcohol and Drug Use/Addiction

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 year 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 3 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 screening tool (Table 4.16). For adults, use the CAGE-AID screening tool (Table 4.17). Anyone who screens positive on these tools should have further assessment and management by clinical staff, ideally with experience in managing alcohol and drug use disorders. Table 4.18 gives some general guidance on management of addictions. The National Protocol for Treatment of Substance Use Disorders in Kenya provides more in-depth guidance.

Table 4.16: CRAFFT Screening Interview for Adolescents

CRAFFT Screening for Alcohol and Drug Use Disorders for Adolescents		
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 **C**ar driven by someone (including yourself) who was "high" or had been using alcohol or drugs?		
2. Do you ever use alcohol or drugs to **R**elax, feel better about yourself, or fit in?		
3. Do you ever use **A**lcohol or drugs while you are alone?		
4. Do you ever **F**orget things you did while using alcohol or drugs?		
5. Do your **F**amily or **F**riends ever tell you that you should cut down on your drinking or drug use?		
6. Have you ever gotten into **T**rouble while you were using alcohol or drugs?		

Table 4.17: 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 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 felt you should **C**ut down on your drinking or drug use?		
2. Have people ever **A**nnoyed you by criticizing your drinking or drug use?		
3. Have you ever felt bad or **G**uilty 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 (**E**ye opener)?		

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 National Protocol for Treatment of Substance Use Disorders in Kenya provides additional resources for assessments and interventions.

Table 4.18: 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
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

As indicated in the introduction of this section on mental health (Section 4.6), the following are key areas of concern in mental ill health and there needs to be a high index of suspicion in order to identify these often-debilitating conditions that negatively affect an individual's ability to cope with the tasks of daily living. The last to items in this section contribute towards building resilience which positively affects an individual's mental health enabling them to positively interact with their environments and live more meaningful lives.

4.6.3 Anxiety

Anxiety and other anxiety related disorders are mental health conditions that are often characterized by experiences of one or several of the following:

- Feelings of nervousness
- Fear, or worry that interfere with the ability to sleep or otherwise function
- A lack of appetite
- Tremulousness and or frank trembling
- Sweating and clamminess of hands
- Other symptoms may include a racing heart (rapid heartbeat), difficulty breathing, headaches, difficulty falling asleep, and difficulty concentrating.

Concerns around anxiety, especially within the context of living with HIV or caring for persons living with HIV may reveal themselves during the history taking. These manifestations need to be taken seriously and addressed with sincerity and compassion.

Many of these may require basic reassurance and support or even just a listening ear during the evaluation session. These will go a long way in alleviating many patient's anxieties and concerns. A quick screening tool can be used to assess whether the anxiety demonstrated or identified may require further attention.

The Generalized Anxiety Disorder Assessment (GAD-7) is a seven-item instrument that is used to measure or assess the severity of generalized anxiety disorder (GAD). Each item asks the individual to rate the severity of his or her symptoms over the past two weeks.

Over the **last 2 weeks,** how often have you been bothered by the following problems	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	+1	+2	+3
2. Not being able to stop or control worrying	0	+1	+2	+3
3. Worrying too much about different things	0	+1	+2	+3
4. Trouble Relaxing	0	+1	+2	+3
5. Being so restless that it is hard to sit still	0	+1	+2	+3
6. Becoming easily annoyed or irritable	0	+1	+2	+3
7. Feeling afraid as if something awful might happen	0	+1	+2	+3

Figure 4.2: Generalized Anxiety Disorder Assessment (GAD-7)

The following cut-offs correlate with level of anxiety severity:

- Score 0-4: Minimal Anxiety
- Score 5-9: Mild Anxiety
- Score 10-14: Moderate Anxiety
- Score greater than 15: Severe Anxiety

Treatment options can then be explored including referral to psychologists, psychiatrists for possible psychotherapy and medication if required

4.6.4 Stress and stress management

This is a feeling of emotional or physical tension. The symptoms include ache and pains, palpitations, exhaustion, insomnia, headache, dizziness or shaking, digestive problems, weak immune system, muscles tension or jaw tension.

Many patients may experience these symptoms individually or in clusters and they interfere with the lives they are living. Sources of stress may be from difficulties in understanding issues around HIV, from addressing different concerns within themselves, from their significant others, from

their workplaces. These issues could be social, financial or environmental concerns and may be severe enough to negatively impact their lives. The stress may be so severe as to be observed by anyone interacting with the individual and may manifest in their behaviour and the symptoms they complain about. It is important for the health care worker to be calm, and assured as they address the patient's concerns around stress. Further, a screening tool can be used to assess the need for referral to more specialized mental health workers to provide much needed support.

4.6.5 experiences of Trauma

Trauma results from exposure to an incident or series of events that are emotionally disturbing or life-threatening with lasting adverse effects on the individual's functioning and mental, physical, social, emotional, and/or spiritual well-being. Past traumatic experiences in PLHIV must be addressed for their wellbeing.

Assessing for Trauma- Primary Care PTSD Screen for DSM-5 (PC-PTSD-5)

The Primary Care PTSD Screen for DSM-5 (PC-PTSD-5) is a screening tool designed to identify persons with probable PTSD. Results of the screening should be considered "positive" if the respondent answers "yes" to any 3 items in the questions listed below. Those screening positive should have further assessment with a structured interview for PTSD, preferably performed by a mental health professional who has experience in diagnosing PTSD.

"Sometimes things happen to people that are unusually or especially frightening, horrible, or traumatic." For example:

1. A serious accident or fire
2. A physical or sexual assault or abuse
3. An earthquake or flood
4. A war
5. Seeing someone be killed or seriously injured
7. Having a loved one die through homicide or suicide

"If you have ever experienced this type of event, please answer the following in the past month, have you"

- Had nightmares about the event(s) or thought about the event(s) when you did not want to?
- Tried hard not to think about the event(s) or went out of your way to avoid situations that reminded you of the event(s)?
- Been constantly on guard, watchful, or easily startled?
- Felt numb or detached from people, activities, or your surroundings?
- Felt guilty or unable to stop blaming yourself or others for the events(s) or any problems the event(s) may have caused?

4.6.6 Psychosis

Psychosis is a mental disorder characterized by a disconnection from reality.

Psychosis may occur as a result of a psychiatric illness such as schizophrenia. In other instances, it may be caused by a health condition, medication or drug use.

Signs and Symptoms of psychosis

- Marked behavioural changes
- Neglecting usual responsibilities related to work, school, domestic or social activities
- Agitated, aggressive behaviour, decreased or increased activity
- Fixed false beliefs not shared by others in the person's culture
- Hearing voices or seeing things that are not there
- Lack of realization that one is having mental health problems

Treatment may include medication and talk therapy.

4.6.7 Self-Care

Overall, in the context of mental health, taking up self-care strategies will help individuals live both more responsibly, and more satisfactorily as this helps boost both physical and mental health.

Self-care strategies include the following;

- Getting regular exercise
- Eating healthy, regular meals and staying well hydrated
- Making sleep a priority. Many people struggle with this but just getting regular sleep with a constant waking and sleeping time contribute tremendously to good self-care as well as good, well rested physical and mental health
- Taking up a relaxing activity
- Setting goals and priorities.

This allows for being realistic in one's expectation in life and formulating realistic strategies to achieve one's goals

Practicing gratitude

Reminding oneself that things that one is grateful for. The more specific one is, the easier it is to even be grateful for them. Listing them down is a good way of getting such clarity

Focusing on positivity

The calls for appreciating the good and positive things that have happened, are going on and are planned for in one's life. The things to look forward to. This strategy also calls for the identification and challenging of negative and unhelpful thoughts. Good friends and counsellors, as well as other health workers with mental health skills can assist in this.

Staying connected

This is extremely important. Increasingly in the present world disconnection is leading to more and more physical and mental ill health. Staying connected with family and friends as well as spiritual support systems enable one to better manage their lives as they work towards being as mentally healthy as possible.

4.6.8 Wellbeing

According to the WHO, mental health is a state of well-being in which an individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and is able to make a contribution to his or her community.

Support structures for wellbeing:

The support structures for wellbeing are available at different levels of implementation which are:

- Individual counselling
- Group therapy
- Networks of organizations providing support to different categories of populations in different age sets such as adolescents, men, women etc.

Health workers in facilities should take the initiative to set up/ maintain these structures and establish referral systems for clients in need of these services. Referral for PLHIV should include services that address issues that potentially could affect the mental health of PLHIV such as social and financial issues.

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 (timed with routine clinic visits, preferably monthly for the first year of life, and then quarterly up to 14 years old, and then every 3-6 months)
  - Anthropometric (Tables 4.19, 4.20 and 4.21 provide interpretation and required actions for anthropometric results for children and adults)
  - Biochemical (investigations as listed in Table 3.2 for baseline and Table 3.5 for follow-up investigations)
  - Clinical (physical examination as described in Table 3.1 for initial evaluation)
  - Dietary (24-hour 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) including exclusive breastfeeding
  - 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)
  - Counsel on critical nutrition practices

Messages: Critical Nutrition Practices (CNPs)

1. Have periodic nutritional status assessments
2. Increase energy intake through a balanced diet
3. Maintain high levels of sanitation and food hygiene
4. Practice positive living behaviors
5. Carry out physical activity or exercises
6. Drink plenty of clean, safe water
7. Seek prompt treatment for all opportunistic infections and manage diet-related symptoms
8. Manage drug-food interactions and side effects

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; Table 4.10 provides specific nutritional recommendations for patients with non-communicable diseases
- Exclusive breastfeeding for the first 6 months of life; complementary foods for children aged 6 - 24 months with continued breastfeeding to prevent malnutrition (Table 7.7 provides complementary feeding recommendations)
- Micronutrient supplements to prevent vitamin and mineral deficiencies
- Food security and linkage to HIV sensitive social protection 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 4.19: Interpretation of MUAC Results for Children and Pregnant/Lactating Women

MUAC Level by Age (cm)			Classification	Action to Take
6-59 months	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 4.3)
> 23			Normal	Education and counselling

Table 4.20: Interpretation of Z-scores for Children

Ratio	Indicator		Z-score	Severity
Weight/Age	Underweight		< - 3	Severe
Height/Age	Stunting		- 3 to - 2	Moderate
Weight/Height	Wasting*		> - 2 to - 1	Mild
			> - 1	Normal

*Children with weight/height z-score of -2 or less should be supported with therapeutic/supplementary foods

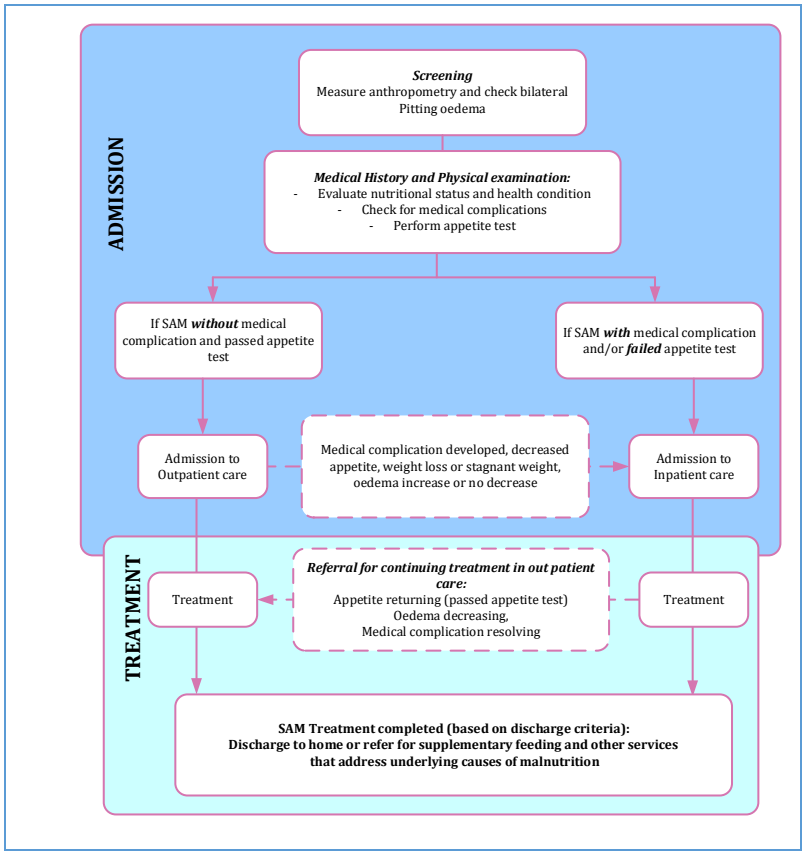


Figure 4.3: Management of Severe Acute Malnutrition in Children

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
- ✓ 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 of 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

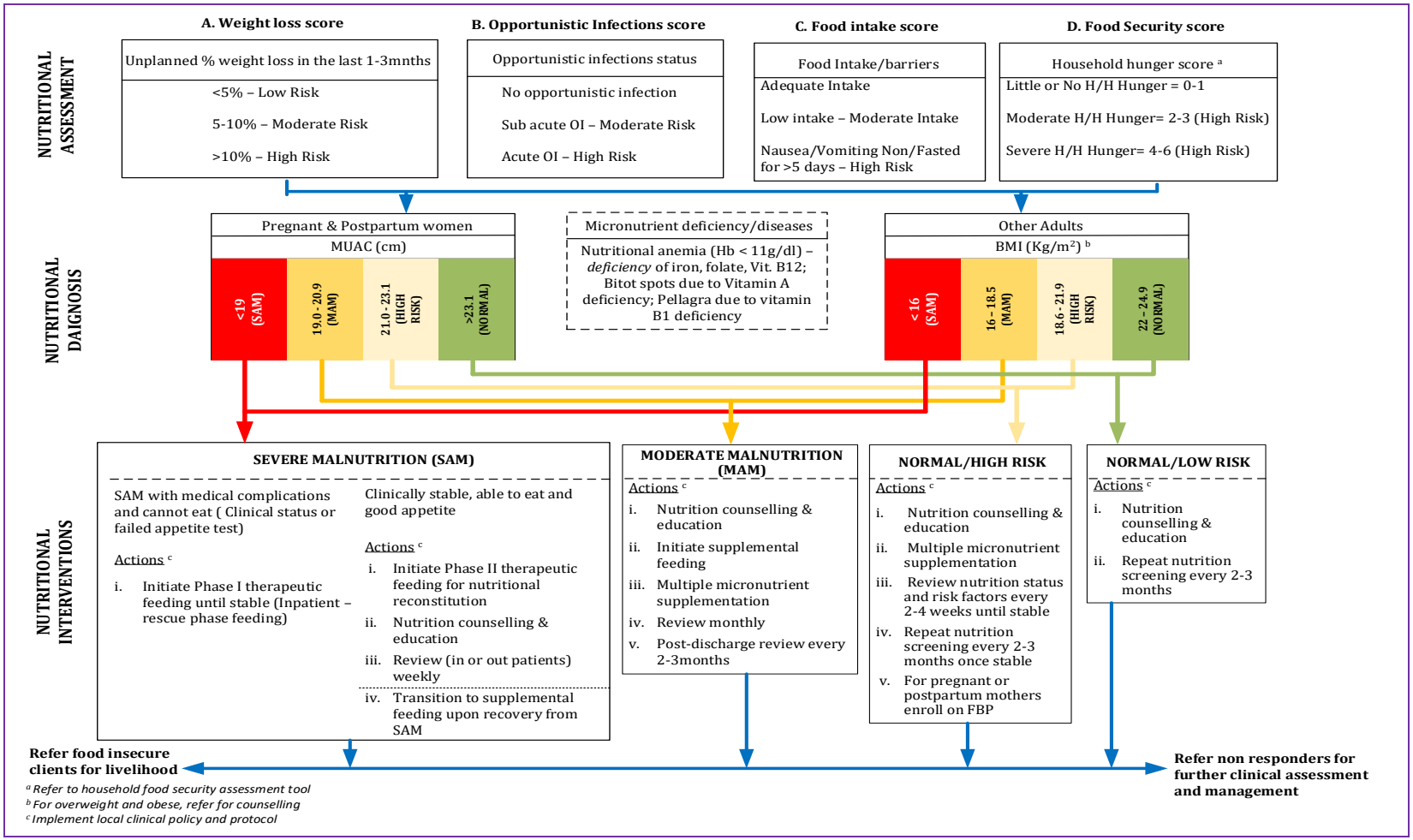


Figure 4.4: Management of Malnutrition in Adults with HIV

Table 4.21: 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 • Screen for TB
16.0–18.4	Mild/moderate malnutrition	• Nutritional counselling and supplementary feeding • Screen for TB
18.5–25.0	Normal/ recommended	Nutritional counselling, consistent exercise 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

4.8 Prevention of Other Infections

4.8.1 Immunizations

All children, regardless of HIV status, should be immunized following the full KEPI schedule, with a few exceptions for infants with severe immunosuppression (Table 4.22). For infants living with HIV and HEIs, an earlier dose of measles vaccines should be given at 6 months of age.

Table 4.22: Kenya Expanded Program on Immunizations 2016 Schedule

Age	Vaccines
Birth	OPV[1], BCG[2]
6 weeks	OPV[3], Pentavalent (DPT-HepB-HiB), Pneumococcal (PCV10), Rotavirus
10 weeks	OPV[3], Pentavalent (DPT-HepB-HiB), Pneumococcal (PCV10), Rotavirus
14 weeks	IPV, Pentavalent (DPT-HepB-HiB), Pneumococcal (PCV10)
6 months	Measles/Rubella (MR) - for HIV exposed and infected infants; Vitamin A
9 months	Measles/Rubella (MR); Vitamin A; Yellow Fever[4]
18 months	Measles/Rubella (MR); Vitamin A
10 years (girls only)	HPV (2 doses at 6 months apart in the general population; 3 doses for PLHIV, at month 0, 1-2, and 6)
11-12 years	Tdap (tetanus, diphtheria and pertussis)

[1]Give OPV to all infants at birth or within the first two weeks of life. If missed in the neonatal period and the child has symptoms of advanced HIV disease (WHO Stage 3 or 4) or severe immunosuppression (CD4% < 25%) then defer BCG until virally suppressed on ART and with immune system recovery

[2]Give BCG to all infants at birth or within the first two weeks of life. If missed in the neonatal period and the child has symptoms of advanced HIV disease (WHO Stage 3 or 4) or severe immunosuppression (CD4% < 25%) then defer BCG until virally suppressed on ART and with immune system recovery. Do not give BCG vaccine to babies born to smear positive mothers. Investigate to rule out TB, give TPT then vaccination done two weeks after completion of TPT

[3]If HIV+ with symptoms of advanced HIV disease (WHO Stage 3 or 4) or severe immunosuppression (CD4% < 25%) then use IPV instead of OPV

[4]Yellow fever vaccine is only routinely used in certain counties as specified by National Vaccines and Immunization Program; defer yellow fever vaccine if symptoms of advanced HIV disease (WHO Stage 3 or 4) or severe immunosuppression (CD4% < 25%), until virally suppressed on ART and with immune system recovery

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 Immunization Program and NASCOP.

Recommended vaccinations for adolescents and adults living with HIV are listed in Table 4.23.

Table 4.23: Vaccinations in Adolescents and Adults Living with HIV

Infection	Vaccine	Live (Y/N)	Course	Comments
COVID-19	Various	N	Variable	Follow national guidelines on dosing for the specific vaccine available
Hepatitis B	Subunit	N	4 doses (at 0, 1, 2 and 6 months)	Use double dose if non-adjuvanted; use standard dose if adjuvanted
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
Human Papillomavirus (HPV)	Virus-like particles	N	3 doses (at months 0, 1-2, and 6)	All girls at 9-14 years old
Influenza	Inactivated	N	1 dose	Annually
Hepatitis A	Inactivated	N	2 - 3 doses	3 doses if CD4 count < 350 cells/mm^3 at 0, 1 and 6 months. If CD4 count > 350 cells/mm^3, give 2 doses at 0 and 6 months. For those at continued risk, one booster dose every 10 years
Additional Vaccines for Special Circumstances				
Yellow fever	Live attenuated	Y	1 dose	Use only in patients <60 yrs of age **and** CD4 > 200 cells/mm^3
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

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 (CPT) for protection against malaria infection (Table 4.3: Co-trimoxazole Preventive therapy)
- 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
- 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
  Note: SP should not be given to women who are taking CPT
- PLHIV on CPT who develop fever should not be treated for an unconfirmed presumptive diagnosis of malaria. 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. **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

Diarrheal 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 for protection against some GI infections (Table 4.3: Co-trimoxazole Preventive therapy)
- Hand washing 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.
- Training on 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 and population benefits of ART 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), continued during initial evaluation, and thereafter during the entire follow-up period 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 at the time of HIV diagnosis. This is particularly important with the current 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, the stage of ART initiation, and the follow-up stage 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 each visit. This is particularly important during the first few months of HIV care.

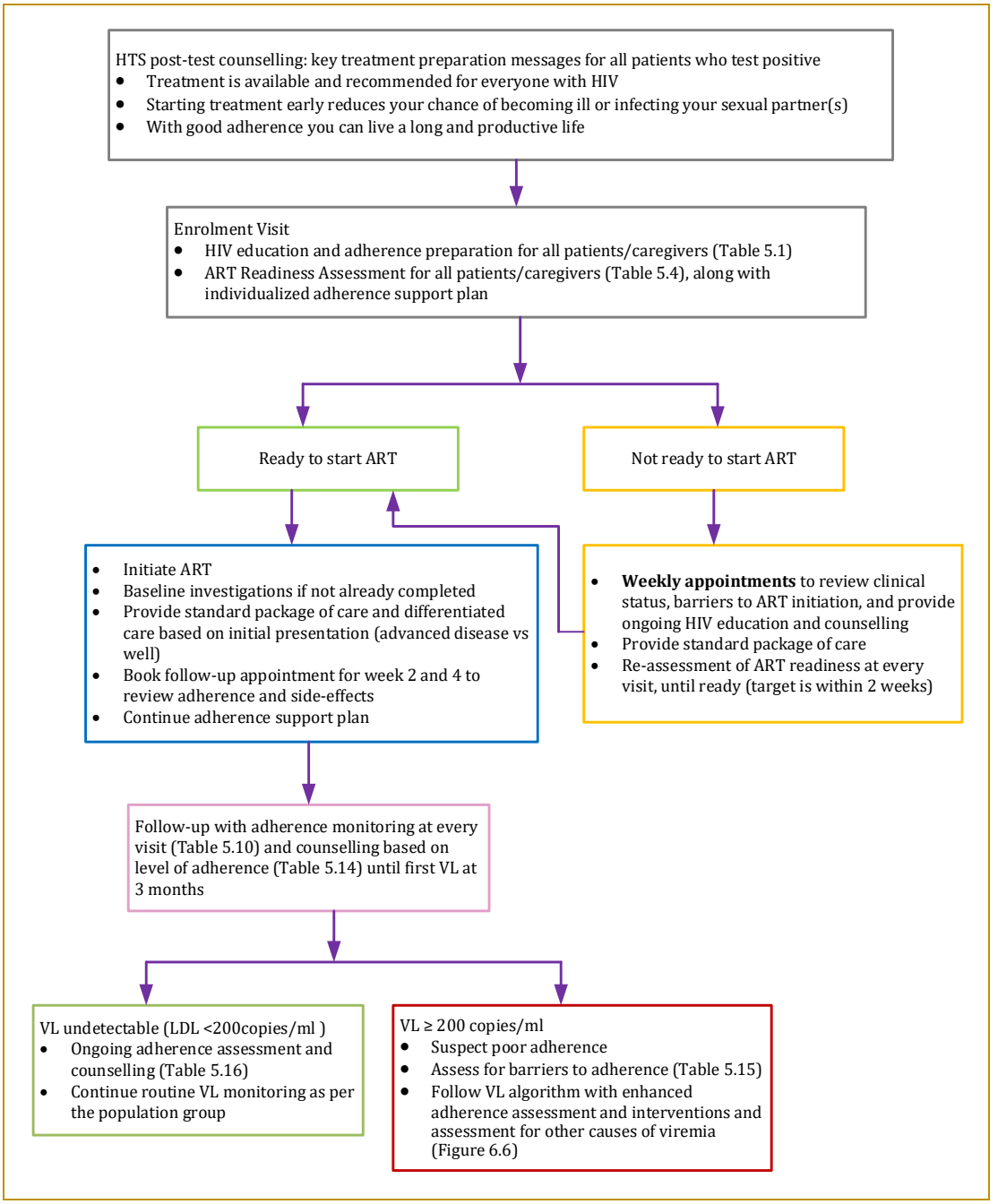


Figure 5.1: Adherence Preparation, Monitoring and Support until Viral Load after 3 Months on ART

Adherence Preparation, Monitoring and Support

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 resistance mutations, when the viral load is still high.

For these reasons, adherence preparation, monitoring and support must be emphasized during the first few months of ART until the patient achieves full virological suppression, after which adherence monitoring and support can continue at lower intensity.

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.

ART can be initiated concurrently with the first adherence counselling session, even during the enrolment visit, especially for infants and for pregnant women. This may also apply to patients with a good understanding of HIV and ART and strong motivation for immediate ART initiation.

Each member of the multidisciplinary team should have the requisite training to 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 are assured and providers are adequately trained. It should also be incorporated into health talks, peer support group activities, and group counselling sessions.

Before commencement of a counseling session, the counselor should ensure that adequate space is available to conduct the counseling, that confidentiality can be maintained, and that tools such as psychosocial assessment forms, treatment literacy flip charts, PHDP flip charts, and tools to document the counseling sessions are available.

Persons living positively (adolescent and adult peer educators who can share personal experiences when needed) should be engaged to support patient education as indicated in the operational guidance below.

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 offer peer-led patient support:

- 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

- Supporting HIV self-testing
- Providing HIV testing services
- Acting as peer linkage supporters
- 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., salaries; stipends; transportation allowances)
- Priority consideration for employment opportunities

5.1 Undetectable = Untransmittable (U=U)

ART adherence resulting to durable viral suppression eliminates risk of sexual transmission of HIV and is key to HIV epidemic control. Adoption of the Undetectable equals Untransmittable (U=U) campaign is posed to revolutionize HIV treatment among PLHIV and fortify treatment-for-prevention strategies. Multiple studies have showed that durable viral suppression of <50 copies/ml eliminates risk of sexual transmission of HIV. (Table 5.17 Viral load cut-offs)

The framework of U=U offers a unique opportunity to dismantle HIV stigma and discrimination, emphasizes the critical importance of antiretroviral therapy (ART), daily adherence, and continuous engagement in medical care for PLHIV.

Definitions:

- **Durably Undetectable:** 2 consecutive viral load results of <50 copies/ml
- **Untransmittable:** The finding established by various clinical trials and observational studies, that people who maintain an undetectable viral load have minimal HIV virus in their blood and other body fluids secretions that they have "effectively no risk" of passing HIV to others through sex.

5.1.1 Benefits of U=U

- Diminish stigma associated with having HIV
- Reduce barriers to HIV testing and treatment
- Increase interest in starting and staying on ART
- Improve self-esteem by removing the fear of being contagious
- Support healthy sexuality regardless of HIV status
- Reduce sex partners' concerns

5.1.2 Considerations for implementation of U=U within clinical settings

- Viral load monitoring as per the recommended intervals for various populations
- Continuous adherence monitoring and support at all clinical visits
- STI screening at all visits
- Messaging on U=U should be provided for all PLHIV as part of treatment literacy

5.1.3 Messaging to Patients on U=U

- *Keeping your HIV undetectable helps you live a long and healthy life*
- *To get your HIV to an undetectable level and to keep it undetectable, take antiretroviral medicines as prescribed*
- *It may take up to 6 months of taking HIV treatment medicines to bring your HIV viral load down to an undetectable level*
- *If you are durably suppressed and you are taking your medications as prescribed, you can be sure you will not pass HIV through sex*
- *People who keep their HIV at an undetectable level will not pass HIV to others through sex*
- *If you stop taking HIV medicines, your HIV can rebound to a detectable level within 1 to 2 weeks, and you may pass HIV to your sex partners*
- *Keeping your HIV at durably suppressed level helps you safely conceive a child with your partner*

5.1.4 How patients can discuss U=U with others

- Counsel patients to share information about the research on U=U as follows:
    - *In recent research studies that involved thousands of couples, no one who was on HIV treatment and whose HIV was durably undetectable passed HIV to their HIV-negative sex partner*
- Advise patients that they can share the following personal information with current or potential sex partners:
    - W*hen they last had a viral load test and if their viral load was undetectable*
- Individuals should tell their partner(s) that their HIV is undetectable only if they have taken HIV medicines consistently since their last test with an undetectable viral load

5.1.5 Counselling patients about other prevention combination interventions

- **PrEP:** PrEP is a safe and effective daily pill that prevents HIV infection. The partner without HIV may decide to take PrEP if they:
    - Are unsure that their partner's HIV viral load is undetectable, especially if their partner has only recently started ART
    - Have more than 1 sexual partner
    - Feel more secure with the added perception of protection provided by PrEP
- **PEP:** After a possible HIV exposure (e.g., Occupational exposure or if a sex partner with HIV has not consistently taken ART and is not virally suppressed), the immediate initiation of emergency PEP can prevent HIV infection
- **Condom use:** Condoms protect against other STIs, such as gonorrhea, chlamydia, and syphilis, and help prevent pregnancy.

Counsel patients to find a prevention strategy that works for them:

- If an individual who does not have HIV is unsure if their partner has an undetectable level of virus or is anxious about acquiring HIV, care providers should encourage that person to choose a prevention strategy that works for them, whether that is use of PrEP, emergency PEP, condoms, or a combination of these strategies
  Note: Care providers should emphasize that no one should ever be compelled to have sex without condoms

5.1.6 Application of U=U in other settings

- **Breastfeeding:** Studies demonstrate that ART greatly reduces the risk of transmission through breast milk. However, research has not established that people whose HIV is undetectable do not transmit virus during breastfeeding. Prophylaxis should be provided to HIV exposed infants during the breastfeeding period as per the guidelines regardless of the viral load status
- **Injection drug use:** Studies demonstrate that ART greatly reduces the risk of transmission through sharing of injection drug use. However, research has not established that people whose HIV is undetectable do not transmit virus through needle sharing. All people who inject drugs should only use their own needles and not share needles or other paraphernalia with others
- **Needle stick injuries:** Research has not established that people with undetectable viral load do not transmit HIV to people who are stuck by needles containing their blood. HIV PEP should be provided as per the guidelines

5.2 ART Adherence Preparation and Support

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

5.2.1 Treatment Preparation as Part of HIV Testing Services

With the current 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

5.2.2 ART Treatment Preparation

ART treatment preparation involves HIV education and counselling, including identifying likely barriers to adherence, a discussion of strategies and support systems to overcome possible barriers to adherence, and an individualized adherence plan, as summarized in Table 5.1. The education and counseling sessions should be documented in patient charts.

Table 5.1: Treatment Preparation and Adherence Counselling Guide

HIV Education

• Ask the patient what they know about HIV
• Ask the patient what they know about treatment for HIV
• Correct/clarify as needed, ensuring you cover:
  ○ Modes of transmission and importance of testing partners/children
  ○ HIV effect on the immune system and health
  ○ HIV viral load and its relationship to health and to HIV transmission
  ○ Goals of ART
  ○ Relationship between adherence and viral suppression, treatment failure, and drug resistance
  ○ Consequences of drug resistance
• Ensure the patient understands by asking them to explain it back to you

Barriers to Adherence
• Ask the patient what they think will be most difficult about taking ART every day • As the patient what they think will be most difficult about attending all clinic appointments • Discuss common reasons patients have trouble with excellent adherence and identify which may be most relevant for them, including:

Table 5.1 Cont.

• **Patient Factors** ○ Stigma and non-disclosure (having to hide their ARV pill-taking) ○ Lack of support systems ○ Alcohol or drug use ○ Depression or other psychiatric illness ○ Loss or grief ○ Cognitive disorders ○ Change in daily routine ○ Chaotic lifestyle; no consistent daily routine ○ Forgetting to take pills ○ Feeling better so does not think the ART is needed any more ○ Feeling too sick to take ART ○ Age (adolescents - impulsive, more susceptible to social pressure; children – caregiver dependent)	• **Provider/System Factors** ○ Side effects (many patients have side effects when they first start their ART, including nausea, headaches, and difficulty sleeping. These side effects almost always resolve with continued use) ○ Pill burden ○ Poor patient-provider relationship ○ Inadequate HIV education ○ Cost of care (direct and indirect) ○ ARV supply-chain limitations (stock-outs, or low stock levels resulting in small refill quantities)
Individualized Adherence Plan	
• Ask the patient what they can do to ensure excellent adherence • Ensure the adherence plan incorporates details of the patient's specific ART regimen: ○ Number of pills, frequency, food requirements/restrictions ○ Common side effects ○ Important drug interactions • Work with the patient to make an individualized adherence plan, which may include: ○ Disclosing their HIV status to a close friend or family member who can help support their treatment; bringing their treatment buddy to clinic with them or to a session with a counsellor to learn more about HIV ○ Disclosing their HIV status to household members so they do not have to hide pill-taking ○ Combining pill taking with a consistent activity in their daily routine ○ Keeping the ARVs in a place that they are likely to see every day ○ Setting a daily alarm on their phone/watch/clock ○ Connecting with a support group for additional counseling/education/support ○ Getting treatment for alcohol or drug use ○ Getting treatment for depression or other psychiatric illness • Discuss what to do if: ○ Develops side effects ▪ Discuss common and serious adverse events for their specific regimen ▪ Encourage patient to return to clinic for any side effects rather than stopping ART ○ Forgets to take a dose: take it late rather than skipping the dose completely ○ Travels without their ART: go to the nearest health facility or call clinic for guidance • Ask the patient to summarize their individualized adherence plan	

Table 5.1 Cont.

Ongoing Support at Subsequent Visits
● Review the patient's HIV knowledge ● Review the patient's motivation to take ART ● Elicit any concerns the patient may have about their ART, side effects, visit schedule, or health ● Review the ART dosing schedule and ask about any missed pills ● Explore barriers to adherence that were previously identified or new ones that have developed ● Explore any recent or expected changes in their life or daily routine ● Discuss their individualized adherence plan and if any changes are required

HIV Education and Counselling

HIV education 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 5.2), 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 for each patient individually (Table 5.4).

Table 5.2: Components of HIV Education (see Annex 8 for detailed content guide)

Component	Questions to be Covered
HIV	• What is HIV • How is HIV transmitted • Why should partners and family members be tested for HIV
Viral load	• What is viral load • How often is viral load measured • What do viral load measurements mean, including the goal of achieving viral suppression
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 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, TPT)
Nutrition	• Why is nutrition important • What can you do to improve your nutrition
Follow-up	• How often will you need to come for clinic visits? • What will we be checking for during your clinic visits

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 5.3).

Table 5.3: 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 treatment and prevention, and their general well-being. This teases out issues that need to be explored in detail during the counselling session e.g., disclosure, family planning, living circumstances etc. • 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 patient's 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 etc.

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
	• It is important to maintain a non-judgmental attitude, establish trust with parents/caregivers, and involve the child as they mature

Table 5.3 Cont.

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
	  ○ Support groups can be used for ART distribution to improve convenience to the patient
	• 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

SMS reminder system	• Enroll 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

5.2.3 Age-Specific Treatment Preparation and Support

Treatment preparation must be customized to the patient's age, gender, 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. Specific needs for children, adolescents, caregivers, pregnant and breastfeeding women and men should also be taken into consideration.

The HIV education and counselling sessions should be provided at every visit until the patient is ready and willing to start ART, as determined using the ART Readiness Assessment Form (Table 5.4). 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. 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. However, once the patient has initiated ART, continued HIV education, counselling and adherence support must be provided. The counselling sessions should preferably be conducted by the same counsellor, peer educator, social worker, nurse, community health volunteer, and/or clinician who is professionally certified to counsel based on a certified curriculum, and they possess the requisite competencies to provide quality counselling. In order to prepare children and adolescents for ART, the counsellor should be trained in providing psychosocial support to this age group.

Table 5.4: 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: is the caregiver 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. Has the Patient/caregiver provided accurate locator information and contact details?		
10. Patient/caregiver feels ready to start ART today?		

Table 5.4 Cont.

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 with TB: **defer ART until patient tolerates anti-TB medication; initiate ART as soon as possible preferably within 2 weeks; for TB meningitis delay ART for 4 to 8 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 5 weeks of CM treatment, 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, on a case-by-case basis**		

At each visit up until ART initiation, every patient should be assessed for readiness to start ART (Table 5.4), with the patient/caregiver allowed to make the final decision on whether and when to start ART.

Special Considerations when Counselling 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 5.2 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 5.5).

Table 5.5: 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	

In addition to the standard HIV Education and Adherence Counselling topics, unique issues need to be addressed for caregivers, children and adolescents (Table 5.6).

Table 5.6: Unique Considerations for Caregivers, Children and Adolescents

Caregiver Barriers to Adherence
• Frequently changing or multiple simultaneous caregivers
• Loss or grief
• 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 stage and emotional state
• Child refusal to swallow medicine (do not allow refusal to take medicines: all activities should be stopped 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). Treatment preparation and support sessions should be customized to the patient's age (Tables 5.7-5.9).

Table 5.7: Treatment Preparation and Support for Children (≤ 9 years) and Caregivers

Visit	Standard of Care
At enrolment into care	Use the 5As (Assess, Assist, Advice, Agree, Arrange) • Perform a psychosocial assessment at enrolment to evaluate for possible psychological, emotional and social adherence boosters and barriers • Assess growth and developmental milestones (Annex 3) to rule out growth retardation, developmental challenges such as autism, deafness and any other physical challenge. Any child with developmental challenges should be referred for appropriate care • Identify the primary caregiver as soon as possible after diagnosis of HIV in a child. In the absence of a caregiver, link the child to a community health volunteer or a peer educator while a more permanent solution is sought, and link with Department of Children and Social Protection • The child and their caregiver, if also infected, should be enrolled in the same clinic, and have appointments booked on the same clinic day for family-centered care • Provide HIV education and counselling to caregiver (and child as appropriate for age, Table 5.5) as outlined in Table 5.2 • Identify and establish appropriate adherence support interventions (Table 5.3), including linkage to pediatric and caregiver support groups • Discuss benefits of disclosure of HIV status of the child and formulate a disclosure plan for children aged 5 years and above (Annex 5) • Conduct readiness assessment to initiate ART (Table 5.4); ART should be initiated same day or the date of initiation agreed upon • Review ART dosing and timing (including having the caregiver demonstrate how they measure and administer the ART) • Conclude the session by agreeing on a treatment and follow-up plan • Where ART is initiated book the child to return within two weeks. Those unwilling to initiate should return weekly for further counselling on barriers to initiation • Identify referral needs and link as appropriate • Document session in the patient's chart
Two weeks after ART Initiation	• Review and reinforce the messages delivered at enrolment; confirm the caregiver's understanding of key messages • Review ART dosing, timing and reminders (including having the caregiver demonstrate how they measure and administer the ART) • Explore any barriers to adherence • Revisit benefits of disclosure and the individualized age-appropriate disclosure plan • Identify referral needs and link as appropriate • Document the session in the patient's chart
Four weeks after ART Initiation, and further follow-up visits	• Review and reinforce the messages delivered in previous sessions; confirm the caregiver's understanding of key messages • Review ART dosing, timing and reminders (including having the caregiver demonstrate how they measure and administer the ART) • Explore any barriers to adherence • Revisit benefits of disclosure and the individualized age-appropriate disclosure plan • Identify referral needs and link as appropriate • Document the session in the patient's chart

Table 5.8: Treatment Preparation and Support for Adolescents (10-19 years)

Visit	Standard of care
At enrolment into care	Use the 5As (Assess, Assist, Advice, Agree, Arrange) • Perform a psychosocial assessment at enrolment to evaluate for possible psychological, emotional and social adherence boosters and barriers • Assess growth and developmental milestones to rule out growth retardation, developmental challenges such as autism, deafness and any other physical challenge. Any adolescent with developmental challenges should be referred for appropriate care • Identify the primary caregiver as soon as possible after diagnosis of HIV in an adolescent. Adolescents older than 15 years and emancipated minors may not have or may not want the presence of a caregiver. In this case, the clinical team should explore alternative options to support the adolescent until they are ready to disclose to their caregivers/guardian or identify someone to disclose to. The alternative options include adolescent mentors, peer educators, social worker, nurses or community health volunteers as may be appropriate. An adolescent can have both private and joint sessions with the caregiver when deemed appropriate • The health provider should explore Sexual and Reproductive Health (SRH) understanding, fears and needs of the adolescent and prioritize interventions as appropriate. SRH counseling should be introduced in a one-to-one session with the adolescent. The care giver can be excused from the sexual and reproductive health session to enable adolescent to open up during the session • The adolescent and their caregiver, if also infected, should be enrolled in the same clinic, and have appointments booked on the same clinic day for family-centered care • Provide HIV education and counselling to caregiver (and adolescent as appropriate for age, Table 5.5) as outlined in Table 5.2 • Identify and establish appropriate adherence support interventions (Table 5.3), including linkage to adolescent and caregiver support groups • Discuss with the caregiver the benefits of disclosure of HIV status to the adolescent (if not aware of status) and formulate a disclosure plan for adolescents (see Annex 5 for age-appropriate disclosure) • Conduct readiness assessment to initiate ART (Table 5.4); ART should be initiated same day or the date of initiation agreed upon • Review ART dosing and timing (including having the adolescent and/or caregiver demonstrate how they measure and administer the ART) • Conclude the session by agreeing on a treatment and follow-up plan • Where ART is initiated, book the adolescent to return within two weeks. Those unwilling to initiate should return weekly for further counselling on barriers to initiation • Identify referral needs and link as appropriate • Document session in the patient's chart

Table 5.8 Cont.

Two weeks after ART initiation	• Review and reinforce the messages delivered at enrolment; confirm the adolescent's and/or caregiver's understanding of key messages • Review ART dosing, timing and reminders (including having the adolescent and/or caregiver demonstrate how they measure and administer the ART) • Explore any barriers to adherence, including issues related to the school environment • Review support systems (including adolescent support group) • Revisit benefits of disclosure and the individualized age-appropriate disclosure plan • Review SRH needs • Identify referral needs and link as appropriate • Document the session in the patient's chart
Four weeks after ART initiation, and further follow-up visits	• Review and reinforce the messages delivered in previous sessions; confirm the adolescent's and/or caregiver's understanding of key messages • Review ART dosing, timing and reminders (including having the adolescent and/or caregiver demonstrate how they measure and administer the ART) • Explore any barriers to adherence, including issues related to the school environment • Review support systems (including adolescent support group) • Revisit benefits of disclosure and the individualized age-appropriate disclosure plan • Review SRH needs • Link to psychosocial support group • Identify referral needs and link as appropriate • Document the session in the patient's chart

Table 5.9: Treatment Preparation and Support for Adults

Visit	Standard of care
At enrolment into HIV care	Use the 5As (Assess, Assist, Advice, Agree, Arrange) • Perform a psychosocial assessment to evaluate adherence boosters and barriers e.g., mental, emotional and social status assessments; refer for appropriate care if mental disorder diagnosed • Identify a treatment buddy (family member, friend, peer educator, community health volunteer, etc.) and involve them in HIV education and adherence counselling • Provide HIV education and counselling to patient • Identify and establish appropriate adherence support interventions (Table 5.3), including linkage to a support group • Discuss benefits of disclosure of HIV status to a trusted family member/friend; how to disclose; and establish a disclosure plan • Discuss importance of child and sexual partner testing as well as assisted partner notification services (aPNS) • Discus prevention methods such as condoms, PrEP, PEP, STI screening and treatment • Conduct an assessment of readiness to initiate ART (Table 5.4); ART should be initiated same day or the date of initiation agreed upon • Review ART dosing and timing • Conclude the session by agreeing on a treatment and follow-up plan • Where ART is initiated, book the patient to return within two weeks. Those unwilling to initiate should return weekly for further counselling on barriers to initiation • Document session in the patient's chart

Table 5.9 Cont.

Two weeks after ART initiation	• Review and reinforce the messages delivered at enrolment; confirm the patient's understanding of key messages • Review ART dosing, timing and reminders • Explore any barriers to adherence • Review support systems • Revisit benefits of disclosure, the disclosure plan and progress in aPNS • Document the session in the patient's chart
Four weeks after ART initiation, and further follow-up visits	• Review and reinforce the messages delivered in previous sessions; confirm the patient's understanding of key messages • Review ART dosing, timing and reminders • Explore any barriers to adherence • Review support systems • Revisit benefits of disclosure the disclosure plan, and progress in aPNS • Document the session in the patient's chart

5.3 Adherence Monitoring, Counselling and Support During the First 3 Months of ART

5.3.1 Adherence Monitoring

Once ART has been initiated, adherence should be assessed non-judgmentally by a trained provider during each visit (Table 5.10). 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.

Adherence monitoring requires a combination of interventions. At every clinical visit, the MMAS-4 should be administered as well as pill counts. MMAS-8 should be administered any time a healthcare worker suspects adherence problem (e.g., patients with suspected or confirmed treatment failure; patient who misses an appointment).

Table 5.10: Adherence Monitoring Strategies

Adherence Monitoring Strategy	Technique	Frequency
Subjective (self-reported adherence)		
Morisky Medication Adherence Scale-4	Use Table 5.11 to assess adherence using a standardized questionnaire, and take action as required	Every patient, every visit
Morisky Medication Adherence Scale-8	Use Table 5.12 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)
Adherence Monitoring Strategy	**Technique**	**Frequency**
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 5.13 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 viral load monitoring algorithm (Figure 6.6). Undetectable VL is the best confirmation of adequate adherence	Age 0-24 years: at 3 months after ART initiation and then every 6 months Age ≥ 25 years: at month 3 after ART initiation and month 12 then annually For pregnant and breastfeeding women: at first ANC visit if already on ART, or 3 months after ART initiation if starting ART during pregnancy, and then every 6 months

Table 5:10 Cont.

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: perfect adherence.

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 5.11: 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 5.15) • 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 5.15) • Engage treatment supporter in adherence counselling sessions • Implement DOTs • Follow up in 1-2 weeks

Table 5.12: 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 5.15) • 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 5.15) • Engage treatment supporter in adherence counselling sessions • Implement DOTs • Follow up in 1-2 weeks

Table 5.13: 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 5.15) • 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 5.15) • Engage treatment supporter in adherence counselling sessions • Implement DOTs • Follow up in 1-2 weeks

5.3.2 Adherence Counselling and Support During the First 3 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 in the context of rapid ART initiation. 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 5.14 summarizes adherence counselling and support for patients from the time of ART initiation until the 3-month viral load results are available. For patients who have inadequate or poor adherence, Table 5.15 describes the assessment for barriers to adherence.

Table 5.14: Adherence Counselling and Support During the First 3 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 5.2, 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 already • Encourage introduction of additional standard support systems (Table 5.3), 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 5.15)** • Review patient/caregiver HIV knowledge (Table 5.2, 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 5.3), including supporting disclosure as needed, assigning a case manager and considering DOTs

Table 5.15: Assessment for 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 during pregnancy and breastfeeding • 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 or 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

Table 5.15 Cont.

Psychosocial circumstance	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.)
	● Any recent losses, grief
	● Changes in relationships with family members/friends
	● Screen the patient/caregiver for alcohol and substance abuse (Tables 4.15 and 4.16)
	  ○ 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 intimate partner violence (Section 4.2.1)
	● 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) and manage/refer as required ● Screen for other psychiatric conditions such as anxiety, post-traumatic stress disorder or psychosis, or refer to a mental health worker for assessment
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?

5.4 Adherence Monitoring, Counselling and Support for Patients with Suppressed Viral Load < 200 copies/ml

Once a patient has confirmed viral suppression (with VL < 50 copies/ml or below the Lower Detection Limit (LDL)) 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 5.16). These patients should also be educated on and assessed for qualification as "stable patient" services such as less frequent facility visits, fast-track or community-based ART distribution, etc. (Table 3.5).

Table 5.16: Adherence Counselling and Support for Patients with Viral Load < 50 copies/ml

No adherence concerns (based on adherence assessment or healthcare team opinion)	
Counselling: Group or individual, every visit (can be done by any member of the healthcare team, including the clinician)	• 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 (preferably by someone trained on adherence counselling)	• **Assess for and address potential barriers to adherence (Table 5.15)** • Review patient/caregiver HIV knowledge (Table 5.2, 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 the patient already has in place • Encourage introduction of additional standard and enhanced support systems (Table 5.3), including supporting disclosure as needed, assigning a case manager and considering DOTs

Table 5.17 Viral Load Monitoring Cut-Offs

Clinical Definition	Category	Lab Value	Interpretation	Guidance
• **Suppressed**	• LDL	• <50 Copies/ml	• Treatment Goal	• Continue Management
	• Low Risk LLV	• 50 – 199 Copies/ml.	• Stable Client, Untransmissible	• Continue management, remind client of treatment goal • Enroll in DSD
• **Unsuppressed**	• High Risk LLV	• 200-199 Copies/ml	• Increased risk of progression to treatment failure	• Step down from DSD, institute EAC, repeat VL after 3 months of excellent adherence
	• Suspected Treatment Failure	• ≥1000 Copies/ml	• Client at increased risk of morbidity and mortality	• Enroll Client in specialized clinic if available • Conduct EAC • Refer to VL algorithm

5.5 Adherence Monitoring, Counselling and Support for Patients with Unsuppressed Viral Load ≥ 200 copies/ml

Treatment failure should be suspected whenever a patient has been on ART for at least 3 months and has: a viral load ≥ 200 copies/ml; a decline in CD4 count or; any new or worsening clinical condition. Treatment failure is confirmed as per the viral load monitoring algorithm (Figure 6.6). Poor adherence is often the most important factor in developing treatment failure, though 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 ≥ 1,000 copies/ml after 3 months of excellent adherence**. For patients with high-risk persistent low-level viremia (VL 200 - 999 copies/ml after additional assessment and intervention), consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform).

5.5.1 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).

All patients with suspected or confirmed treatment failure should have a thorough assessment of potential barriers to adherence (Table 5.15).

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.

5.5.2 Enhanced Adherence Counselling

Adherence assessment and enhanced adherence counselling should begin as soon as a detectable viral load (≥ 200 copies/ml) is received, preferably within 2 weeks.

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.

At least three sessions of Enhanced Adherence Counselling, spaced 2-4 weeks apart, are recommended as the minimum number of sessions, but additional sessions can be added as needed (Table 5.18). If the adherence is evaluated as adequate, a repeat viral load is done after three months of excellent 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.

If adequate adherence cannot be achieved then consult with a senior clinician, discuss as an MDT, or consult the Regional or National TWG.

Table 5.18: Components of Enhanced Adherence Counselling Sessions (Annex 9A 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 common cognitive, behavioral, emotional and socio-economic barriers to adherence
	  ○ Stigma and non-disclosure
	  ○ Loss or grief
	  ○ 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
	• 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 • 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: consult with a senior clinician, discuss as an MDT, or consult the Regional or National TWG 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 < 200 copies/ml: continue current regimen with ongoing enhanced adherence; repeat VL after 6 months
	  ○ If VL ≥ 1,000: prepare patient for change of regimen (Figure 5.2)
	  ○ If VL is 200-999 copies/ml: perform another assessment for causes for viremia and address any issues identified; repeat viral load after an additional 3 months of excellent adherence

Table 5.18 Cont.

Other 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 involve 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
Home visits	• 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)
Monthly "high viral load" clinics	• Patients with suspected treatment failure should be booked for dedicated monthly high viral load clinics • Children and adolescents in school who are unable to attend clinic monthly may attend dedicated monthly clinics during mid-term and school holidays (at least every 6 weeks) • Comprehensive clinical and psychosocial evaluation should be conducted at each visit, appropriate investigations done and any opportunistic infections treated • Enhanced adherence counseling sessions should be conducted at each visit • Support groups for patients with viremia can be timed with "high viral load" clinic days
Special 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

Adherence support systems will need to be adapted to patients' specific needs and the context (Table 5.18). Special attention needs to be given to children, adolescents, pregnant and breastfeeding women, patients with mental health disorders and substance users.

5.6 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).

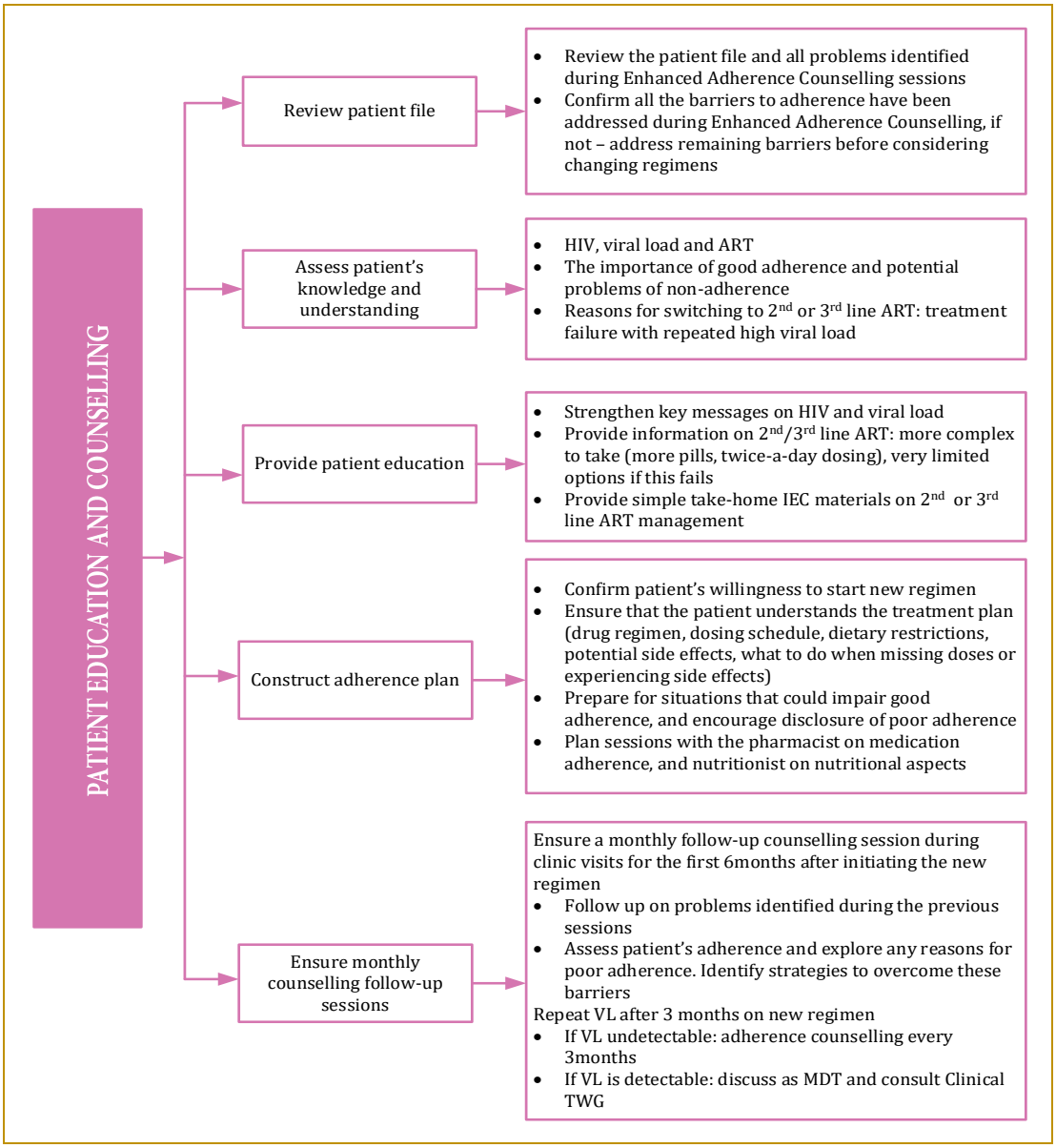


Figure 5.2: Adherence Counselling and Education for Patients Preparing to Initiate 2nd Line or 3rd Line ART

5.7 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).

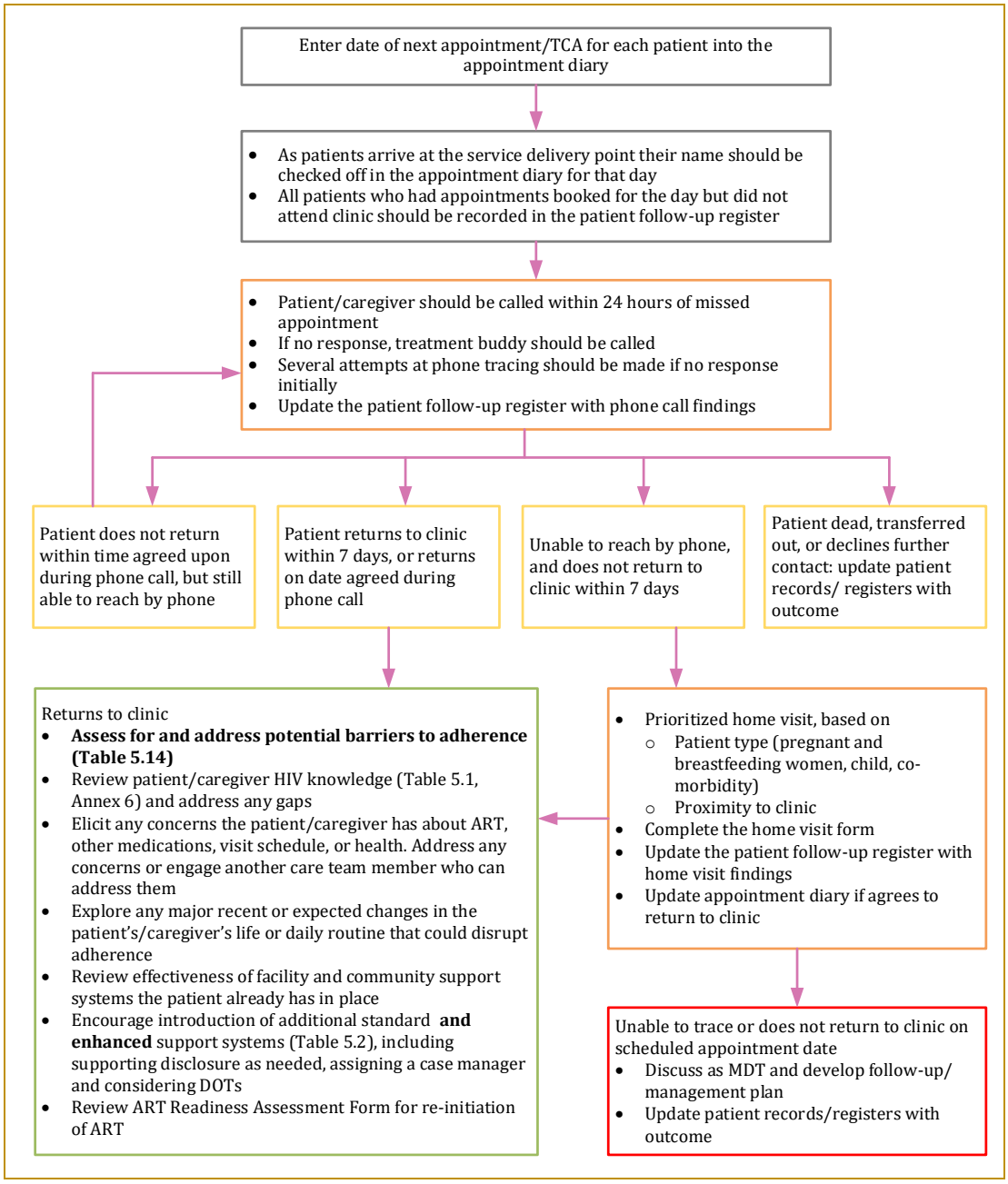


Figure 5.3: Identifying, Tracing and Supporting Patients who Default from Care

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

ART, while very effective in managing HIV disease, does not 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, reducing AIDS-related morbidity and mortality and the risk of sexual and vertical transmission of HIV.

6.1 Eligibility for ART

All individuals with confirmed HIV infection are eligible for ART irrespective of CD4 count, 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, and even on the same day as testing positive for HIV if they are ready.

ART Readiness Criteria (Table 5.4) can be used to help determine any issues that need to be addressed around the time of ART initiation. Same-day ART initiation (on the same day as testing HIV-positive) has additional benefits for HIV prevention (e.g., for pregnant and breastfeeding women, and the HIV positive partner in a discordant relationship), and is associated with improved retention, viral suppression, and survival. Special considerations for timing of ART initiation are listed in Table 6.1.

Table 6.1: Special Considerations for Timing of ART Initiation

Population	Timing of ART Initiation	Additional Notes
Pregnant and breastfeeding women	Support ART initiation on the same day as testing positive for HIV	Intensive adherence counselling, support and close follow-up required because of limited time for patient preparation
Infants (< 12 months old)	Support ART initiation on the same day as testing positive for HIV. Treatment should commence following a first positive PCR test. ALWAYS take a sample for a confirmatory PCR test as soon as the first positive PCR result is received, but do not delay ART initiation for the second PCR result	Intensive adherence counselling, support and close follow-up required because of limited time for caregiver preparation
Patients with strong motivation to start ART immediately	Support ART initiation as soon as the patient feels ready, preferably on the same day as testing positive for HIV	Intensive adherence counselling, support and close follow-up required because of limited time for patient preparation
Patients with newly diagnosed TB	Start anti-TB treatment immediately and initiate ART as soon as anti-TB medications are tolerated, preferably within 2 weeks. For TB meningitis delay ART for 4 to 8 weeks	Monitor closely for IRIS (Annex 16)
Patients with cryptococcal meningitis	Defer ART until after completing 5 weeks of CM treatment	Monitor closely for IRIS (Annex 16)
Patients for whom adherence will be particularly challenging	Start ART as soon as possible while implementing additional support systems (e.g., optional enrolment of a PWID into a MAT program; psychiatric treatment for a patient with mental illness; enrolment into an OVC program for orphans etc.)	A case manager should be assigned to all patients with complex adherence challenges
All other patients	Start ART as soon as possible, preferably within 2 weeks, and even on the same day as testing positive for HIV if they are ready	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 the PMTCT chapter in Tables 7.3 to 7.6.

All patients must have their weight documented at every visit. Children and adolescents less than 15 years must have correct weight-based dosing of ARVs confirmed at every visit.

Infants and children depend on their caregivers for adherence to medication. Caregivers should be adequately prepared for their role of administering ARVs to infants and children, including addressing anticipated challenges such as drug palatability. It can be helpful for more than one caregiver to be informed about a child's HIV status and receive instruction on administration of ART.

Caregivers should always be shown and then asked to demonstrate how to measure and administer ARVs. This should be done both at the time of prescribing the ART (by the clinician) and at the time of dispensing the ART. Clinicians should ensure that the caregiver accompanying a child for clinical review is the same caregiver responsible for day-to-day ART administration.

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

Age	Weight	Preferred Regimen	Dosing[2] (correct weight-based dosing must be confirmed at every visit)
Birth to 4 weeks	Any	AZT + 3TC + NVP[3]	Refer to Annex 10 for weight-based dosing
> 4 weeks to < 15 years	< 30 kg	ABC + 3TC + DTG[4]	Refer to Annex 10 for weight-based dosing
	≥ 30 kg	TDF + 3TC + DTG[5,6]	TDF/3TC/DTG (300/300/50mg): 1 tab once daily
≥ 15 years	Any	TDF + 3TC + DTG[5,6]	TDF/3TC/DTG (300/300/50mg): 1 tab once daily

1 Patients currently on first-line regimens that are not included in the indicated preferred (Table 6.2) or alternative (Table 6.3) regimens should be considered for regimen optimization as per Section 6.5.1

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 4 weeks of age should initiate on AZT+3TC+NVP irrespective of previous ART exposure; metabolism of other ARVs is not well known for this age group. As soon as these infants become 4 weeks old, they should switch to ABC/3TC+DTG (dosing included in Annex 10). Consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000, ulizanascop@gmail.com) in case of pre-term infants

4 Once adolescents reach 30 kg, if virally suppressed they should be considered for transition as per Figure 6.2

5 TAF may become the preferred NRTI once fixed-dose combinations are available

6 DTG/3TC dual therapy may be considered for HBV-negative patients once fixed-dose combinations are available

Table 6.3: Use of Alternative ARVs in First-Line Regimens [1]

Age	Weight	Scenario and ARV Affected	Alternative ARV to Use
Birth to 4 weeks	Any	NVP: Develops hypersensitivity reaction	Use RAL granules or LPV/r granules (over 2 weeks of age) or defer ART until 4 weeks of age, then start ABC+3TC+DTG
		AZT: Infant Hb < 9.5 g/dL	Defer ART until 4 weeks of age, then start ABC+3TC+DTG
> 4 weeks to < 15 years	< 30 kg	ABC: Develops ABC hypersensitivity reaction[2]	Use AZT (if Hb ≥ 9.5 g/dL); if Hb < 9.5 g/dL consults Regional or National HIV Clinical TWG (call Uliza Hotline 0726 460 000; ulizanascop@gmail.com)
		DTG: Unable to tolerate	Use LPV/r at standard weight-based BD dosing, if 4-in-1 available this is preferred
		DTG: Currently on rifampicin-containing anti-TB medications	Increase DTG dosing frequency to twice daily for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to once daily dosing[3]
	≥ 30 kg	TDF: Impaired renal function (CrCl ≤ 50 ml/min)	Use ABC[4,5] or TAF (once available)
		DTG: Unable to tolerate	Use EFV (for PWID use ATV/r)
		DTG: Currently on rifampicin-containing anti-TB medications	Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to TDF/3TC/DTG FDC OD [3]
≥ 15 years	Any	TDF: Impaired renal function (CrCl ≤ 50 ml/min)	Use ABC[4,5] or TAF (once available)
		DTG: Unable to tolerate	Use EFV (for PWID use ATV/r)
		DTG: Currently on rifampicin-containing anti-TB medications	Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to TDF/3TC/DTG FDC OD [3]

Table 6.3 Cont.

[1] For other scenarios that are not covered in this table, discuss as an MDT and consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform)

[2] ABC hypersensitivity reaction (AHR) is rare in the Kenyan population. Table 6.9 provides the definition and management of AHR

[3] The additional 2 weeks of higher-dose DTG is to counter the ongoing liver enzyme induction effect of rifampicin, which continues for a short period after TB treatment is completed

[4] TAF may become the preferred NRTI once fixed-dose combinations are available

[5] DTG/3TC dual therapy may be considered for HBV-negative patients once fixed-dose combinations are available

6.4 Dosing and Administration of Dolutegravir (DTG)

DTG is preferred in first line ART (in combination with other ARVs) for children, adolescents and adults. DTG is well tolerated, highly efficacious, has a high genetic barrier to resistance and fewer drug-drug interactions.

Table 6.4: Dosing and Administration of Dolutegravir

Recommended Dosing of DTG

- < 20 kg body weight: Use weight-based dosing with dispersible 10mg DTG tablets as per Annex 10
- ≥ 20 kg body weight: DTG 50 mg film-coated tablet once daily, preferably as a morning dose. It is also available as part of FDC. Those unable to swallow the film coated tablets whole refer to Annex 10
- For patients taking rifampicin: Increase DTG dosing frequency to twice daily for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to once daily. (The additional 2 weeks of higher-dose DTG is to counter the ongoing liver enzyme induction effect of rifampicin, which continues for a short period after TB treatment is completed)
- For patients with suspected or confirmed INSTI resistance (e.g., patients with prior history of failing a RAL-based regimen): use DTG twice daily
- DTG can be taken with or without food

Common Side Effects of DTG

- The most common side effects of DTG are headache, nausea and diarrhea. These side effects usually resolve after continued use for 1-2 weeks. It is critical to inform patients / caregivers about these potential side effects and their temporary nature, and encourage them to continue their ART and consult a HCW if concerned.
- Some patients on DTG are more likely to develop insomnia. This may be reduced by taking DTG as a morning dose, or by taking DTG with a low-fat meal or on an empty stomach.
- DTG may cause a small rise in serum creatinine levels but this does NOT represent a true decline in renal function.
- Integrase inhibitors, including DTG, are associated with increased weight gain. Counsel patients about healthy eating and physical activity and the benefits of maintaining a healthy weight.
- All adverse events should be reported through the national pharmacovigilance mechanism. (http://www.pv.pharmacyboardkenya.org/)

Table 6.4 Cont.

Pregnancy Safety of DTG

- DTG is safe during pregnancy and breastfeeding. Pregnancy intention should be discussed with all women initiating ART regardless of regimen. Women who do not wish to become pregnant should be offered appropriate family planning counseling and methods.

Important Drug Interactions with DTG

- Rifampicin
  - Rifampicin lowers DTG levels: increase DTG to 50 mg twice daily for patients on rifampicin who are ≥ 20 kg in body weight. Children <20 kg taking DTG who require rifampicin should increase their weight-appropriate DTG dose to twice daily.
  - There are no significant drug interactions between DTG and other currently used anti-TB medications (including for MDR-TB)
- Mineral supplements, including: antacids containing calcium, zinc, magnesium or aluminum; iron supplements; prenatal vitamins (which contain iron and calcium)
  - These supplements decrease the absorption of DTG: administer DTG at least 2 hours before or 6 hours after taking any of these supplements
  - Dose separation is not required for calcium and iron supplements (including prenatal vitamins) if DTG is taken with a meal
  - It is critical to educate patients about this important drug interaction because many patients get these supplements and antacids over-the-counter without informing their healthcare provider
- Carbamazepine, phenobarbital, phenytoin
  - These anticonvulsants decrease DTG levels: use a different anticonvulsant if available
  - If DTG must be co-administered with these drugs then increase to DTG to twice daily, although there is little data to guide this
  - If valproic acid is available this can be used with DTG without dose adjustment
- Metformin
  - DTG increases levels of metformin; the levels of DTG are not affected: use a lower dose of metformin (often 50% of usual dose) and monitor glycemic control. Use a maximum daily dose of metformin 1 g
- Other drug-drug interactions with DTG
  - See Annex 13C

6.5 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 3.5; 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 optimizing therapy for patients who have undetectable viral load, managing adverse drug reactions or toxicity, drug-drug interactions, co-morbidities and treatment failure.

6.5.1 Optimizing Therapy for Patients who have suppressed viral load on First Line ART

Patients who are virally suppressed on first line ART may benefit from regimen optimization even if they are currently tolerating their regimen well and have no drug-drug interactions requiring a change. Regimen modifications may be done for age/weight transitions among children and adolescents <15 years and to simplify a regimen, prevent long-term toxicity and improve cost-effectiveness. Dolutegravir has been shown to have superior tolerability and efficacy compared to efavirenz and lopinavir and is now preferred as part of first line ART for children, adolescents and adults. While most adults in Kenya have switched over to a DTG-containing regimen, proactive switching of children is now also recommended with the availability of a pediatric dispersible dolutegravir tablet.

Children and adolescents with suppressed viral load on first line ART and not on the recommended first line regimen as per Table 6.2 should be considered for optimization as per Figures 6.1 and 6.2, such as when children grow and enter a new weight band. This also includes PLHIV who recently initiated non-standard therapy (less than 3 months ago, before the first VL is due). Decisions on regimen modification should be made following discussion with the patient/caregiver.

Always discuss the possibility of new side effects when changing to a new ARV, particularly side effects common to all ARVs (headache, nausea, diarrhea) and any side effects specific to the new ARV. Reassure patients that most side effects resolve with continued use after 1-2 weeks.

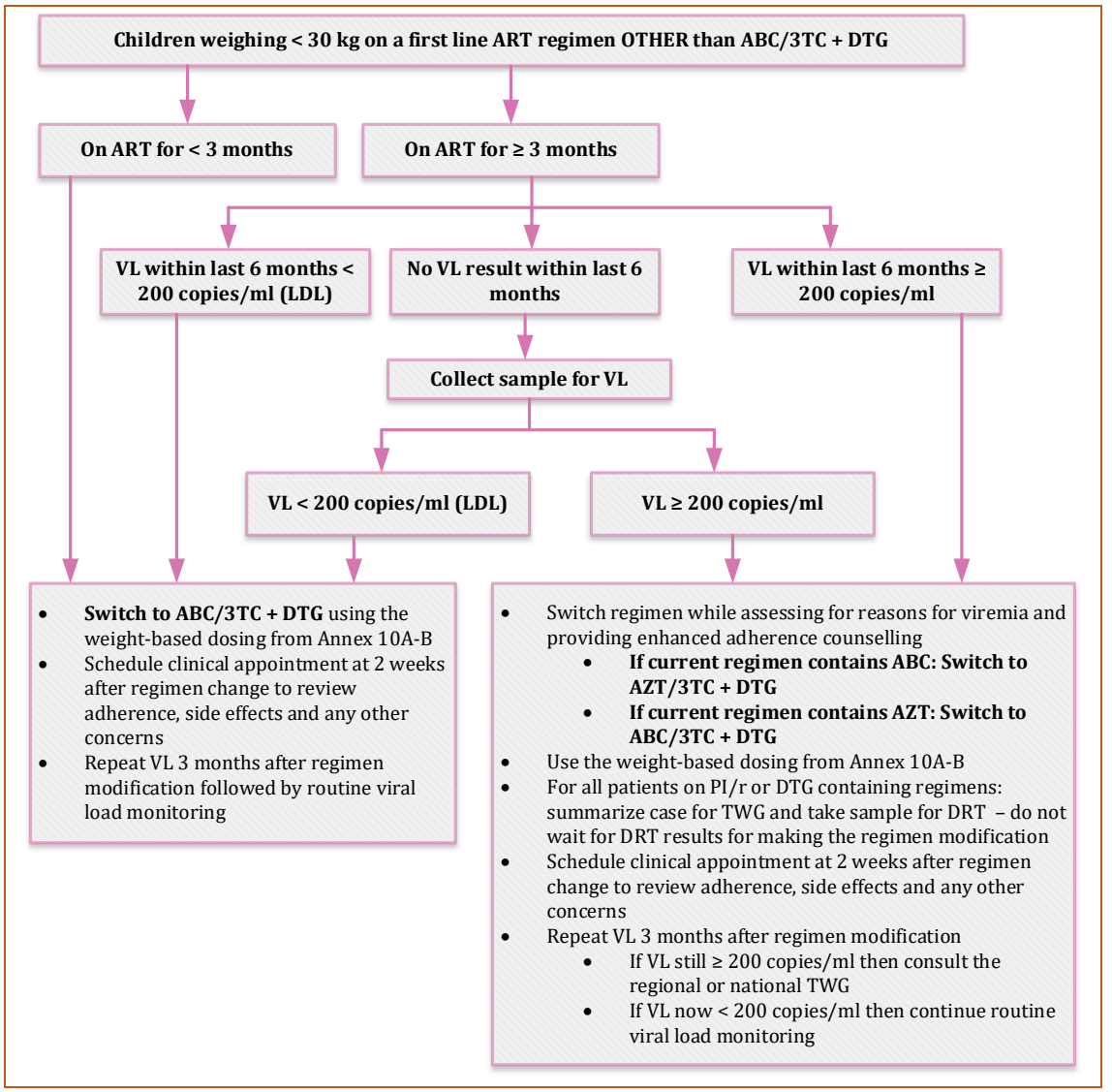


Figure 6.1: Optimizing ART Regimens for Children and adolescents <15 years Weighing < 30 kg on First Line ART

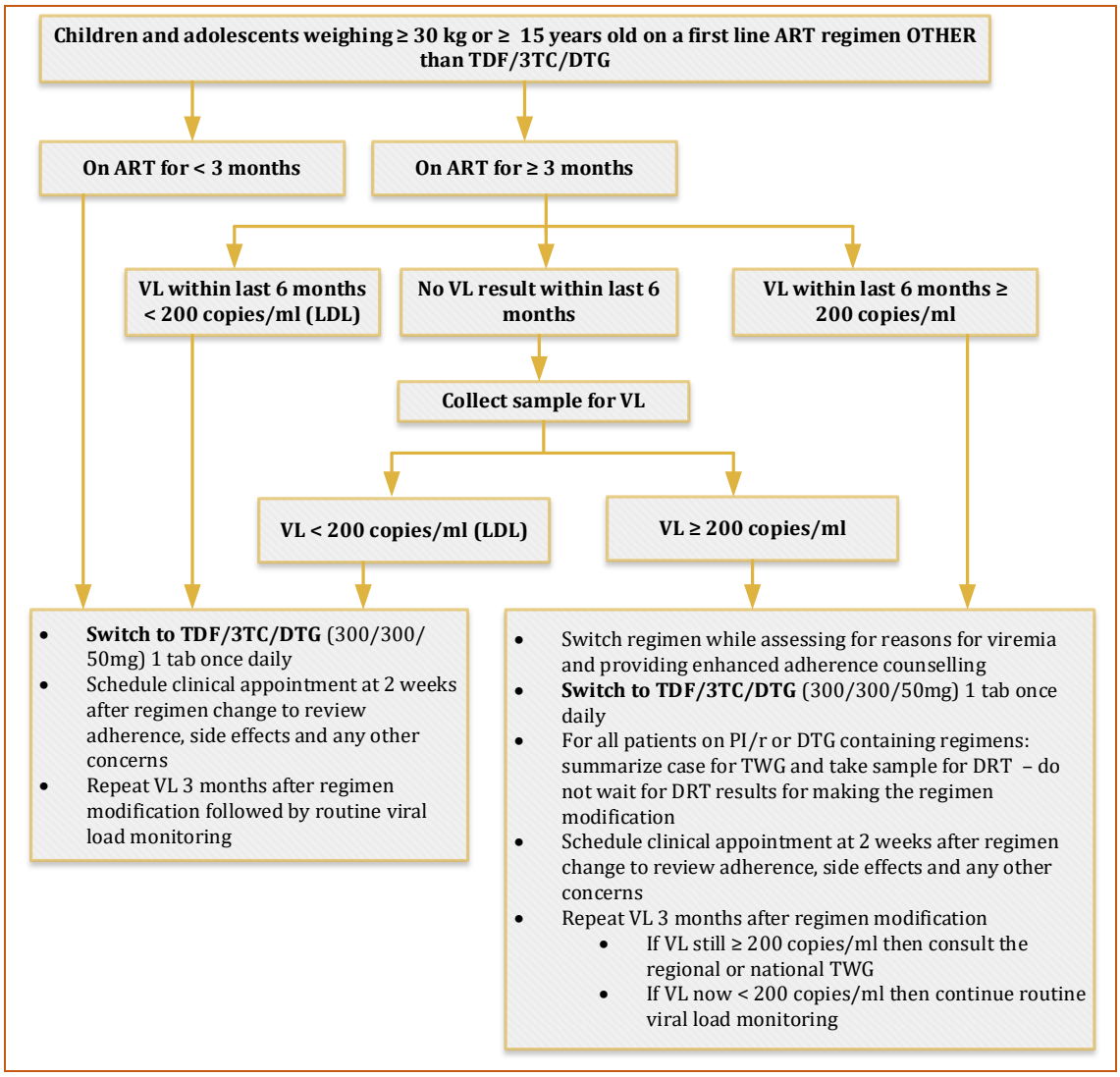


Figure 6.2: Optimizing ART Regimens for Children and Adolescents Weighing ≥ 30 kg or ≥ 15 years old on First Line ART

6.5.2 Changing ARVs Due to Adverse Drug Reactions

Patients starting ART should be educated on the potential side effects of ART and all other prescribed medication. 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 (http://www.pv.pharmacyboardkenya.org/). Pharmacovigilance is particularly important for monitoring ADRs associated with any new ARVs that enter the national supply chain, as rare ADRs may appear in routine care, which were not observed in the highly selected patients participating in clinical trials.

The most common significant ADRs associated with ARVs that may require a drug substitution are summarized in Table 6.5. General principles for managing ADRs are outlined in Figure 6.3. Managing specific ADRs is described in Tables 6.6 to 6.9.

Table 6.5: Common Significant Adverse Drug Reactions

ARV Agent	Adverse Drug Reaction	High Risk Situations/Comments
NRTIs		
ABC	ABC hypersensitivity reaction (see Table 6.9)	Do not re-challenge
AZT	Anaemia, neutropenia (See Table 6.7)	Risk factors: CD4 count < 200 cells/mm^3; BMI < 18.5 (or body weight < 50 kg); anaemia at baseline; concurrent use of other drugs with similar ADR (cotrimoxazole, gancyclovir, ribavirin)
	Lactic acidosis	Risk factors: Pregnancy; obesity
	Lipoatrophy	Risk factors: Low CD4 count
TDF	Renal dysfunction (See Figure 6.5)	Risk factors: Underlying renal disease; age > 60 years; BMI < 18.5 (or body weight < 50 kg); diabetes; hypertension; concomitant PI use or nephrotoxic drug Avoid in patients with CrCl< 50ml/minute unless no suitable alternative such as required to treat HIV/HBV co-infection if TAF is not available
TAF	Weight gain	Risk factors: women; concomitant use of INSTIs Provide advice on healthy eating and physical activity to maintain a healthy weight (Table 4.9)
NNRTIs		
All NNRTIs	Rash (NVP>>EFV>ETR)	Manage rash as per Table 4.4
EFV	CNS side-effects	Risk factors: Pre-existing psychiatric disorder
	Gynaecomastia	Switch from EFV to an alternative, and consult if gynecomastia does not improve
NVP	Hepatotoxicity (See Table 6.8)	N/A.
PIs		
All PIs boosted with RTV	GI intolerance (LPV/r>DRV/r>ATV/r)	Consult for recommendation on alternative regimen (R-TWG or Uliza Hotline 0726 460 000, https://nhcsc.nascop.org/clinicalform)
	Dyslipidaemia (LPV/r>DRV/r>ATV/r)	Risk factors: Obesity; sedentary lifestyle; diet high in saturated fats and cholesterol
ATV/r	Hyperbilirubinemia	This only requires drug substitution if cosmetic effect of jaundice is likely to interfere with patient adherence
DRV/r	Rash/hypersensitivity	Risk factors: sulfa allergy
INSTIs		
All INSTIs	Weight gain	Risk factors: women; concomitant use of TAF Provide advice on healthy eating and physical activity to maintain a healthy weight
	Rash/hypersensitivity	Consult (Uliza Hotline 0726 460 000, https://nhcsc.nascop.org/clinicalform)
DTG	Insomnia	Give in the morning; if no improvement then try giving with low fat meal or on empty stomach

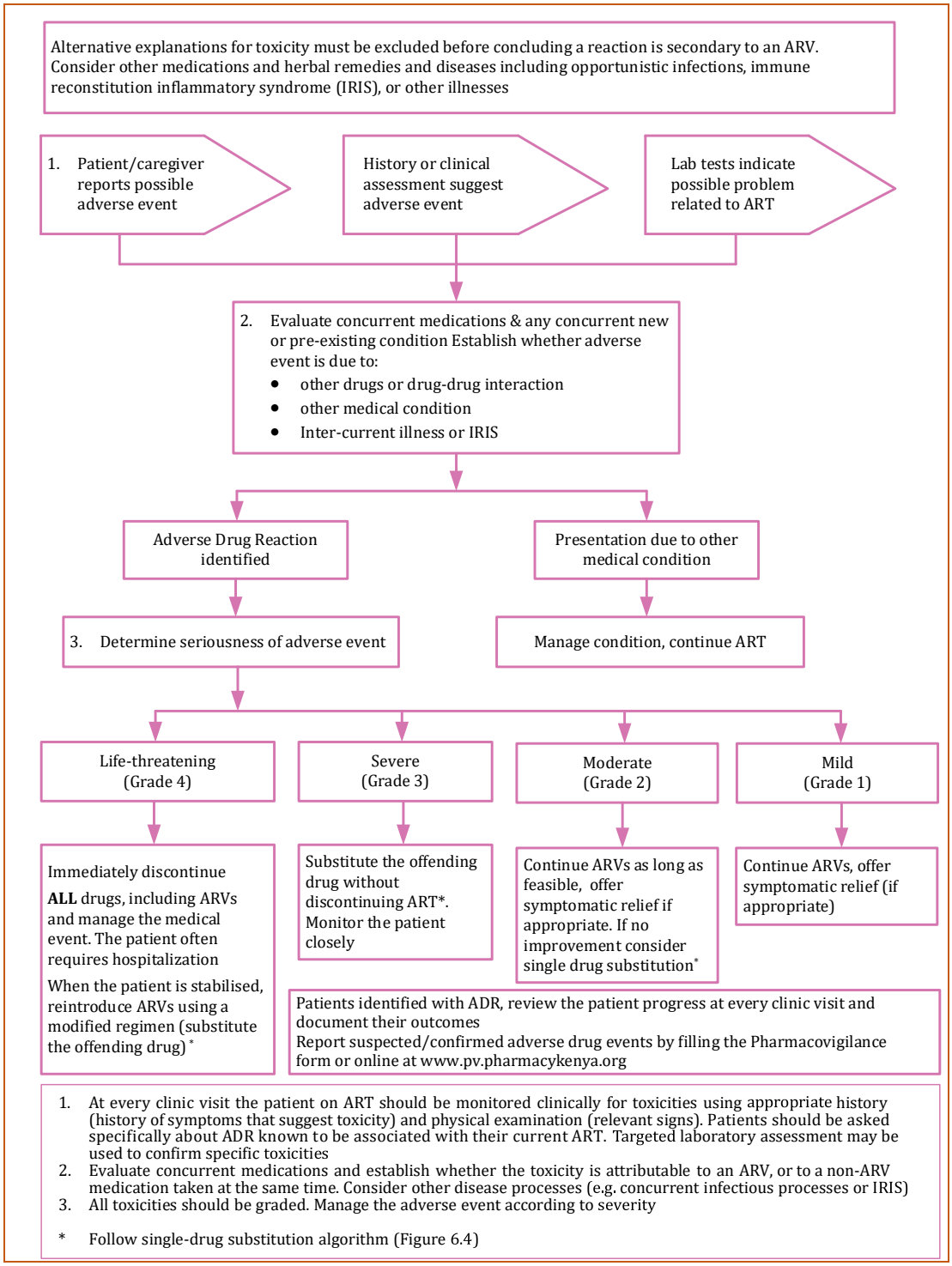


Figure 6.3: General Principles for Managing Adverse Drug Reactions

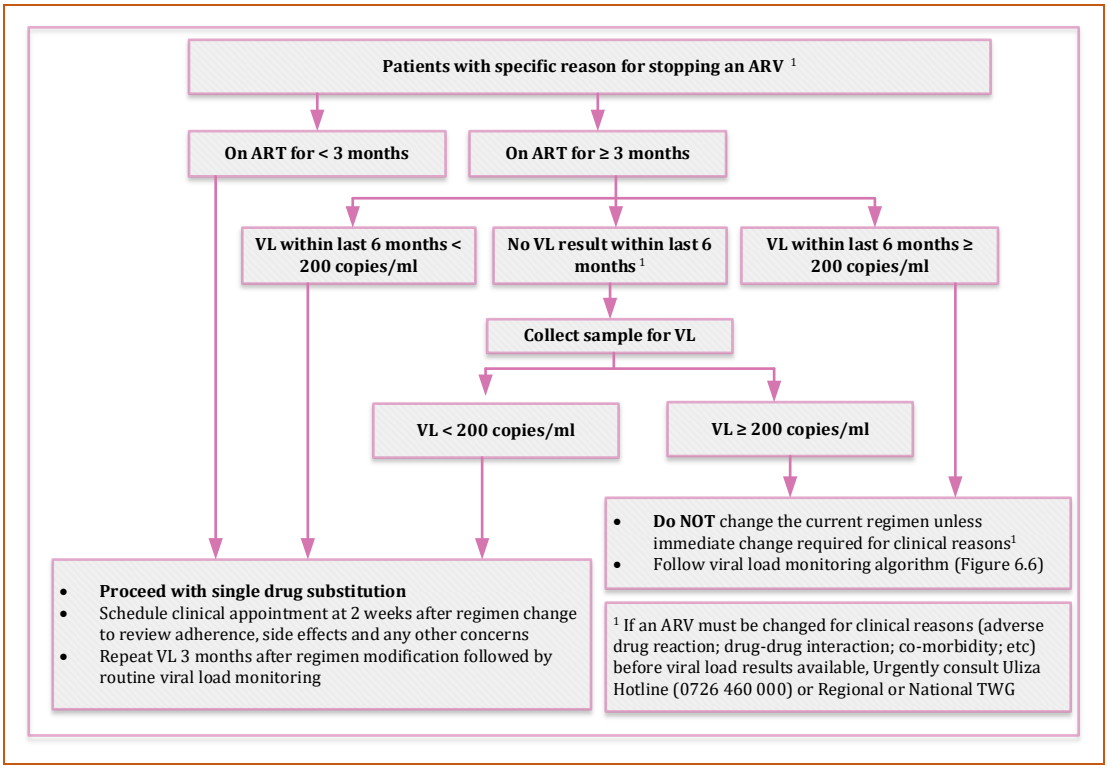


Figure 6.4: Managing Single Drug Substitutions for ART

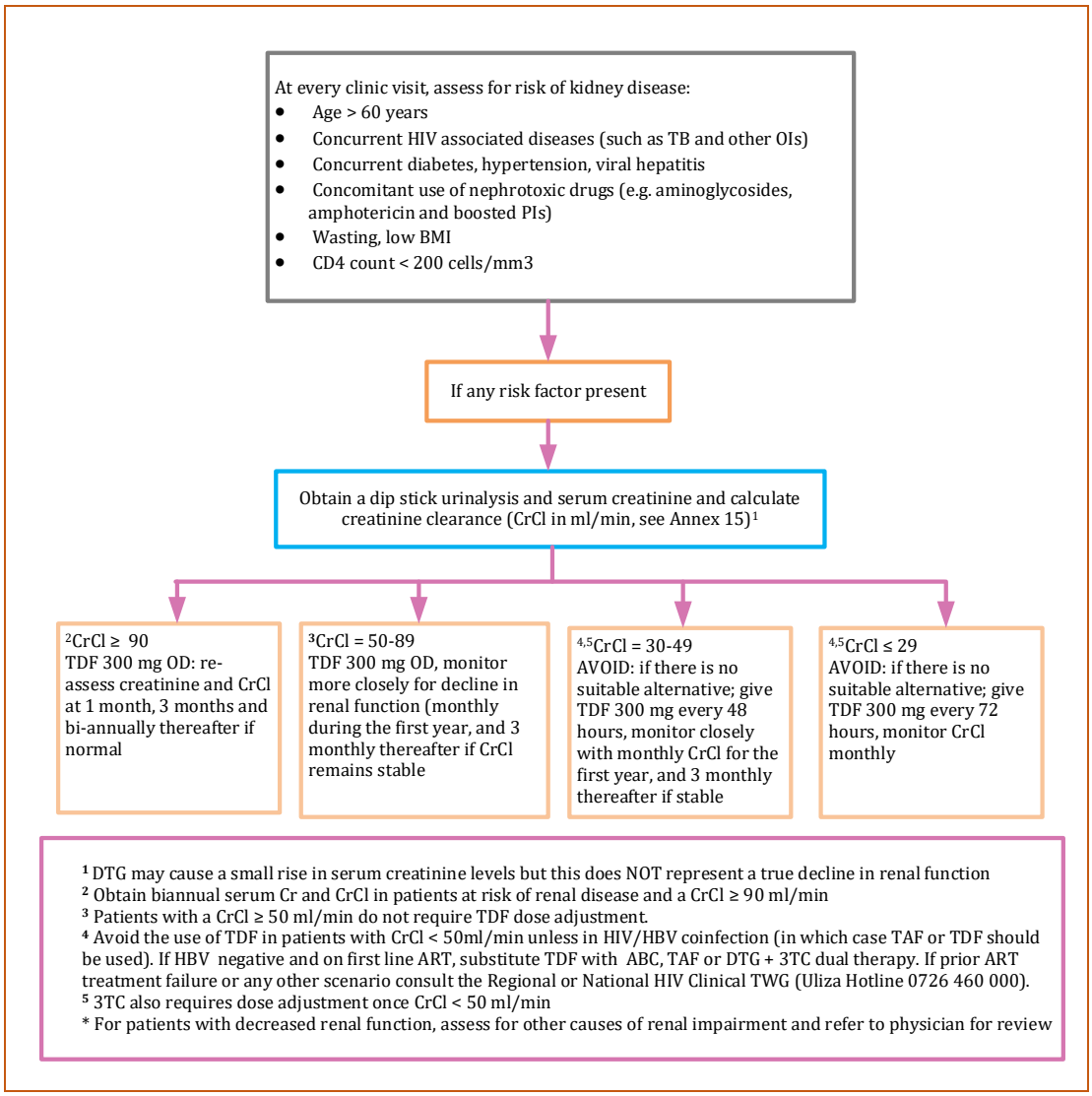


Figure 6.5: Managing TDF-Associated Kidney Toxicity

Table 6.6: ARV, CTX and Fluconazole Adjustments in Renal and Hepatic Impairment[1]

Drug	CrCl (ml/min) 15 - 50	CrCl (ml/min) <15	Haemodialysis	Liver impairment
ABC	No change			Reduce adult dose to 200 mg BD for moderate to severe liver impairment. AVOID in severe hepatic impairment
AZT	No change	300 mg/day	300 mg/day	Reduce dose by 50% or double interval of administration in moderate to severe impairment
TDF[2]	AVOID unless HBV+[2]	AVOID unless HBV+[2]	300 mg every 7 days	No change
TAF	No change	AVOID unless HBV+[2]	No dose adjustment- Administer after dialysis	No change
3TC	150 mg OD	150 mg OD	75 mg OD	No change
LPV	No change			No change, use with caution in moderate to severe impairment
RTV				
ATV				
DRV				
RAL	No change			No change in mild to moderate impairment. Use with caution in severe impairment
DTG				
EFV	No change			Use with caution in mild to moderate liver impairment. AVOID in severe impairment
NVP	No change			AVOID
ETV	No change			Use with caution in severe liver impairment
CTX	If CrCl > 30 ml/min then no dose adjustment required; if 15-30 ml/min then use 50% of normal recommended dose; if CrCl < 15 ml/min then CTX should be avoided			Use with caution in mild to moderate liver impairment. AVOID in severe impairment
Fluconazole	If CrCl ≤ 50 ml/min then use 50% of normal recommended dose (no dose adjustment required for CrCl > 50 ml/min)			Use with caution

[1] Patients with evidence of renal or hepatic impairment should have access to regular monitoring of renal and liver function

[2] TDF and renal impairment:

- In acute kidney injury (AKI), interrupt TDF administration until the cause of AKI is established and corrected.
- Avoid the use of TDF in patients with CrCl < 50ml/min unless in HIV/HBV coinfection (in which case TAF or TDF should be used). For patients with HBV co-infection, the benefit of TDF or TAF for treating HBV often outweighs the risks of renal impairment, so more severe levels of renal impairment are tolerated. See Table 9.3 for TDF and TAF dose adjustments for patients with HBV/HIV co-infection. These patients should be managed in consultation with an experienced clinician
- If HBV negative and on first line ART, substitute TDF with ABC, TAF or DTG + 3TC dual therapy, following the single drug substitution algorithm (Figure 6.4). If prior ART treatment failure or any other scenario consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform)

Table 6.7: Management of AZT-Associated Bone Marrow Suppression

Test	Result	Action
Hb (g/dL)	> 8.5 (and decrease from pre-AZT baseline)	Retain AZT, repeat Hb at week 1, 2, 4 and 12 (if accessing follow-up Hb is difficult then consider substituting to an alternative ARV immediately)
	≤ 8.5	Switch from AZT to an alternative ARV
Neutrophils (x 10^9/L)	1.0 – 1.5 (and decrease from pre-AZT baseline, if available)	If receiving cotrimoxazole consider withholding unless essential. Retain AZT, repeat at week 1, 2, 4 and 12 (if accessing follow-up neutrophils is difficult then consider switching to an alternative ARV immediately)
	≤ 1.0	Switch from AZT to an alternative ARV

Note:

- 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
- AZT-associated bone marrow suppression occurs early in the course of treatment, usually within 3 months of initiating ART
- 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 6.8: 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 Consult senior clinician for next step

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

Table 6.9: Diagnosis and Management of Abacavir Hypersensitivity Reaction

Diagnosis
Within 3 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 diarrhea • Extreme fatigue and/or body pain preventing normal activities AND: there is not a more 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 • Issue an Adverse Event alert card
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

6.5.3 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, antacids, multivitamin/mineral supplements, methadone, several anti-fungal, anti-convulsant, calcium-channel blockers, some anti-depressants, some statins, and some anti-malarial. Annex 13 provides common drug-drug interactions and management recommendations. It is recommended practice to check for interactions whenever a new medicine is started.

6.5.4 Changing ARVs Due to Treatment Failure

Viral load is the test of choice for monitoring response to ART and identifying treatment failure. **First VL should be performed 3 months after ART initiation for all PLHIV.**

Treatment failure should be suspected when a new or recurrent HIV-associated condition indicating severe immunodeficiency (WHO stage III or IV condition) develops after at least 6 months on ART. Treatment failure should always be confirmed with VL testing.

Frequency of routine VL monitoring for specific populations is:

- Age 0-24 years old: at 3 months after ART initiation and then every 6 months
- Age ≥ 25 years old: at 3 months after ART initiation, then at month 12 and then annually
- Pregnant or breastfeeding: at confirmation of pregnancy (if already on ART) or 3 months after ART initiation (if ART initiated during pregnancy/ breastfeeding), and then every 6 months until cessation of breastfeeding
- Before making any drug substitution (if no VL results from the prior 6 months)
- Three months after any regimen modification (including single-drug substitutions), and then as per population group
- For any patient with a detectable VL follow the viral load monitoring algorithm (Figure 6.6)

Interpreting Viral Load Results and Defining Treatment Failure (Figure 6.6)

The goal for ART is to achieve sustained viral suppression defined as below the Lower Detection Limit (LDL), < 50 copies/ml is considered as suppressed. See Table 5.17

Persistent low-level viremia (PLLV) is defined as having between 200-999 copies/ml on two consecutive measures. These patients are at increased risk of progression to treatment failure, development of resistance and death and therefore require a similar case management approach as patients with VL ≥ 1,000 copies/ml, and consultation with the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform).

Treatment failure is suspected when a patient has a high VL ≥ 1,000 copies/ml after at least 3 months of using ART. Treatment failure is only confirmed when VL is ≥ 1,000 copies/ml after assessing for and addressing poor adherence or other reasons for high VL, and then repeating VL after at least 3 months of enhanced adherence to allow for viral re-suppression.

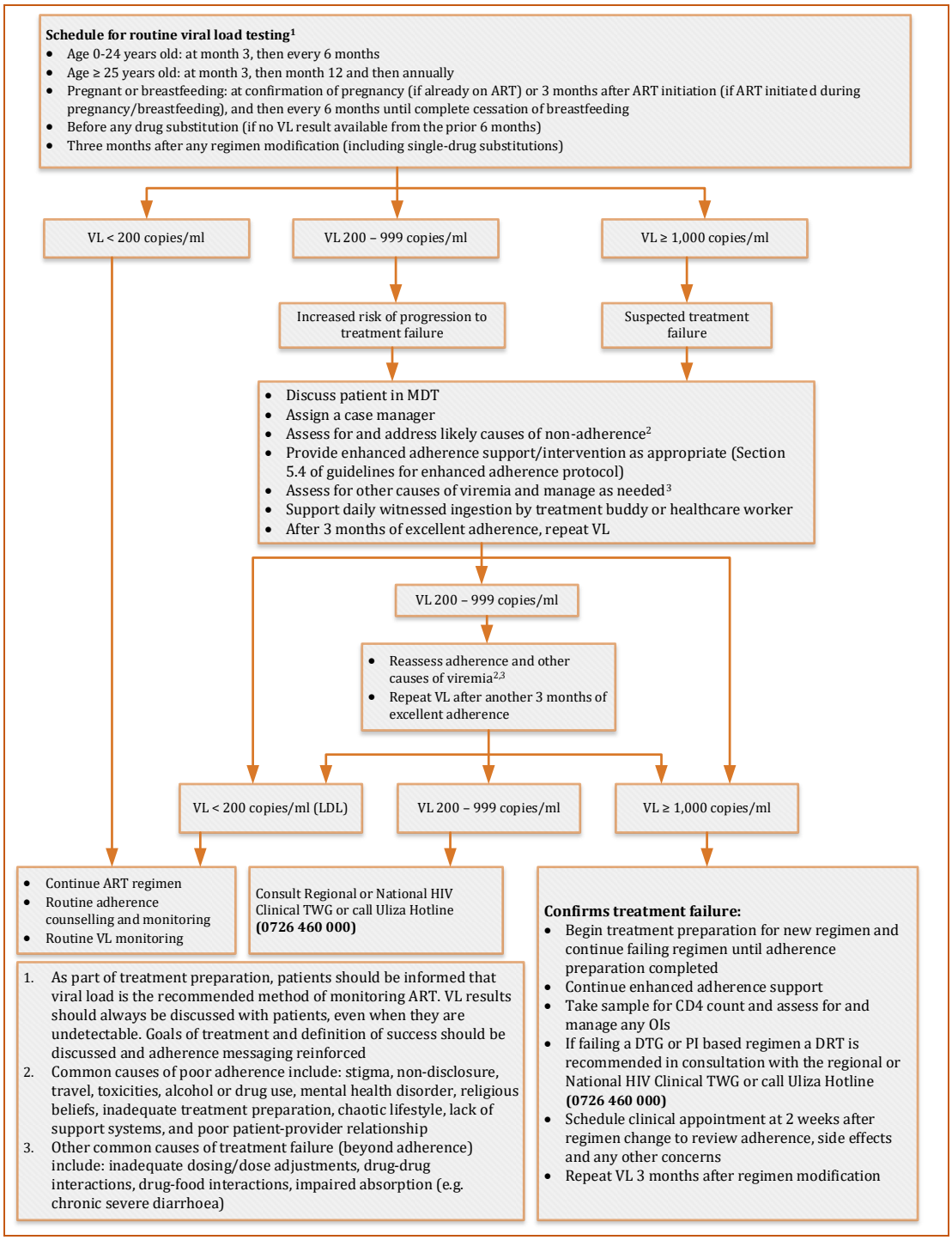


Figure 6.6: Viral Load Monitoring of Patients on ART (1st Line or 2nd Line)

Non-adherence is the most frequent cause of treatment failure. As per the viral load monitoring algorithm, **adherence issues must be addressed BEFORE confirming treatment failure.**

Daily witnessed ingestion by a treatment buddy or healthcare worker is recommended to confirm excellent adherence before repeating the VL. 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. **An exception to this may be when the regimen itself is the primary cause of poor adherence** (e.g., side effects from one of the ARVs are not manageable such as severe diarrhea with LPV/r that does not improve with symptom management), in which case the regimen may need to be modified to allow for perfect adherence. This should be done in consultation with the Regional or National HIV Clinical TWG.

Chapter 5 provides detailed guidance on adherence preparation, assessment, and support.

Table 6.10: Recommended Second-line ART Regimens in Infants, Children, Adolescents and Adults, excluding TB/HIV co-infection [1]

Weight/scenario	First-line ART	Second-line ART
< 30 kg	ABC (or AZT) + 3TC + DTG	DRT-based second-line[2,3]
	ABC + 3TC + LPV/r	Take sample for DRT and change to AZT + 3TC + DTG while awaiting DRT results; modify based on DRT results if indicated
	AZT + 3TC + LPV/r	Take sample for DRT and change to ABC + 3TC + DTG while awaiting DRT results; modify based on DRT results if indicated
	ABC + 3TC + EFV	AZT + 3TC + DTG
	AZT + 3TC + EFV	ABC + 3TC + DTG
≥ 30 kg or ≥ 15 years old	TDF (or ABC) + 3TC + DTG (or PI/r)	DRT-based second-line[2]
	TDF (or ABC) + 3TC + EFV	TDF + 3TC + DTG
	AZT + 3TC + EFV	TDF + 3TC + DTG
Pregnant and Breastfeeding women	TDF (or ABC) + 3TC + DTG	Take sample for DRT and change to TDF + 3TC + ATV/r while awaiting DRT results; modify based on DRT results if indicated
	TDF (or ABC) + 3TC + PI/r	Take sample for DRT and change to TDF + 3TC + DTG while awaiting DRT results; modify based on DRT results if indicated
	TDF (or ABC) + 3TC + EFV	TDF + 3TC + DTG
	AZT + 3TC + EFV	TDF + 3TC + DTG
HIV/HBV Co-infection	Always maintain TDF in order to treat the HBV as well as HIV	
TB/HIV Co-infection	Refer to Table 8.8: Recommended ART Regimens for Patients who Develop TB while **Failing** 1st Line ART	

Table 6.10 Cont.

1. If any drug in the recommended 2nd line regimen is contraindicated or previously not tolerated, consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform). Such patients may require DRT to select agents for the second-line ART. Additional drugs may be recommended on a case-by-case basis, including DRV/r, ATV/r, RAL, or ETR
2. Patients failing DTG-based or 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 HIV Clinical TWG (https://nhcsc.nascop.org/clinicalform) or call Uliza Hotline (0726 460 000) to determine the most suitable second-line regimen for the patient. The DRT results will be used to determine if there is true DTG or PI failure or if there is an underlying problem with non-adherence. Daily witnessed ingestion is recommended prior to performing DRT

Important Considerations for First-line Treatment Failure in Children

- Second-line ART in infants and children is more complex to manage. These children and their caregivers 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 the Regional or National HIV Clinical TWG. Some of these children will require HIV DRT to determine the most suitable second-line regimen

Important considerations for second-line ART Treatment Failure

- Patients failing second-line ART have limited options. ARVs 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 viral load monitoring algorithm (Figure 6.6)
    - After the first detectable VL (ε 50 copies/ml), assess for and address all causes of poor adherence, and assess for all other possible causes of viremia.
    - These patients should be discussed at an MDT session. Repeat the VL after 3 months of excellent adherence (preferably with daily witnessed ingestion of the ARVs by a treatment buddy, relative, CHV, etc.).
    - If the second VL is still ε 50 copies/ml then continue the failing second-line regimen while reassessing adherence and other causes of viremia, implementing adherence support systems as needed, and then repeat the VL after another 3 months.
    - If viremia continues then consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform) using the national case summary form (Annex 9B). These patients will likely 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
    - Assigning 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 6.11: Possible Third-line ART in Children, Adolescents and Adults

	Possible 3rd Line Regimen	Comment
Children	DTG + 3TC + DRV/r	Third line ART selection is based on DRT results Note that the Regional or National HIV Clinical TWG may recommend reusing some of the ARVs the patient has already failed, even when resistance is present
	DTG + AZT + 3TC + DRV/r	
	DTG + ABC (or TDF) + 3TC + DRV/r	
	ETV + 3TC + DRV/r	
Adults	DTG + 3TC + DRV/r	
	DTG + AZT + 3TC + DRV/r	
	DTG + TDF + 3TC + DRV/r	
	DTG + TDF (or AZT) + 3TC	
	ETV + 3TC + DRV/r	

7. Prevention of Mother to Child Transmission of HIV/Syphilis/Hepatitis B

Routine antenatal care (ANC) offers an important opportunity to provide high quality combined HIV prevention through targeted health education and counselling; HIV testing for the woman, partners and family members; linkage to HIV prevention and treatment; and to discuss and plan for future conception and contraception needs. Prevention of mother-to-child transmission of HIV (PMTCT)/Syphilis/Hepatitis B 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 importance of at least 8 ANC visits, details of ANC services (including health checks and treatment of any illness, medical tests including HIV, syphilis testing and hepatitis B, monitoring of maternal and fetal 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 including PrEP where appropriate, ART for those who are HIV positive, monitoring of ART and ARV prophylaxis and follow-up for HEIs) and triple elimination (preventing HIV/ syphilis/hepatitis B transmission from mother to child).
Counselling	• Pre-conception – Women in reproductive age who are known to be HIV positive should have pregnancy intention assessment visit at every visit. If they desire to become pregnant, pregnancy should be planned i.e., attain viral load suppression, immune reconstitution and have Iron and Folic Acid Supplementation (IFAS) administered prior to conception. • Women who are newly diagnosed with HIV and/or newly initiating ART require more intensive adherence counseling and HIV education, which may include a case manager and/or mentor mother • Birth preparedness: support the pregnant woman and her partner to develop an individual birth plan that includes place of delivery with skilled attendants, 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, lower abdominal pain, severe headache, swollen feet, convulsions and per vaginal bleeding. • Maternal, infant and young child nutrition (MIYCN): All pregnant women should receive information on proper nutrition during pregnancy and breastfeeding, safe infant feeding and optimal nutrition practices. Promote exclusive breastfeeding for the first 6 months irrespective of HIV status, followed by complementary feeding (Table 7.7). During pregnancy, provide iron, folate and multivitamins; monitor for anemia, advise on adequate caloric intake (HIV positive women require an additional 10% of recommended daily allowance (RDA))

Table 7.1 Cont.

Counselling	● HIV testing services ○ All pregnant women (unless known HIV positive) should be counselled and tested for HIV, syphilis and Hepatitis B during their first ANC visit and if negative, repeat HIV and syphilis testing in the third trimester. ○ All pregnant and breastfeeding mothers with continued HIV risk (Key populations) should be counseled and tested for HIV every 3 months until post-cessation of breastfeeding. ○ Pregnant and breastfeeding mothers should be educated and offered a self-test kit for their sexual partner(s) ○ At Labour and delivery, HIV testing should be done for all women with unknown HIV status or that previously tested negative, even if tested during the third trimester ○ All breastfeeding mothers (unless known HIV positive) should be counselled and tested at the 6-week infant immunization visit. The HIV test (if negative) should be repeated every 6 months until complete cessation of breastfeeding. **Note:** key population mothers (FSWs and PWIDs) get retested every 3 months (Table 2.5) ○ Women should be counselled about the schedule for repeat HIV testing in pregnancy and postnatally as part of routine ANC and postnatal education ○ All pregnant and breastfeeding women who are not tested, opt-out or decline HIV, Syphilis or Hepatitis testing during the first contact should be offered counselling and testing in subsequent visits with appropriate linkage and referral for prevention, care and support services. Daily Witnessed Ingestion (DWI) is advised to support Viral suppression for newly initiated clients and those whose regimens are being switched. This is to support viral suppression among women with high viral load. ○ All HIV positive pregnant and breastfeeding women enrolled into care should receive counselling and support (including assisted disclosure), case management linkage and follow-up for comprehensive treatment and prevention (including lifelong ART) ○ All Syphilis and Hepatitis B positive clients should be given appropriate care as defined in Table 7.3 “triple elimination”. ○ All partners of pregnant and breastfeeding women should be offered HIV testing and counselling and all biological children if the mother is HIV positive ● All pregnant and breastfeeding women should receive information on risk reduction, including PrEP where appropriate ● Post-partum contraception: counsel on contraception methods and help patient develop a plan for effective contraception from 6-weeks post-partum to avoid unplanned pregnancies

7.1 Antiretroviral Therapy for HIV-positive Pregnant and Breastfeeding 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. Table 7.2 summarizes recommendations for use of ART for HIV positive pregnant women.

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

Overall recommendations	
When to start	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 after readiness assessment with ongoing enhanced adherence support including community-based case management and support.
What to start with (first-line ART)	TDF/3TC/DTG
Infant prophylaxis	● AZT+NVP for 6 weeks, NVP should be continued until 6 weeks after complete cessation of breastfeeding For more comprehensive information Refer to Table 7.3
Monitoring	**Viral load monitoring during pregnancy and breast-feeding (Figure 6.6)** ● Whenever possible, use same-day point-of-care methods for viral load testing of pregnant and breastfeeding women to expedite the return of results and clinical decision-making. If this is not available, viral load specimens and results for pregnant and breastfeeding women should be given priority across the laboratory referral process (including specimen collection, testing and return of results). ● For pregnant and breastfeeding women newly initiated on ART, obtain VL 3 months after initiation, and then every 6 months until complete cessation of breastfeeding ● For HIV positive women already on ART at the time of confirming pregnancy or breastfeeding, obtain a VL irrespective of when prior VL was done, and then every 6 months until complete cessation of breastfeeding ● For pregnant or breastfeeding women with a VL ≥ 50 copies/ml: assess for and address potential reasons for viremia, including intensifying adherence support, repeat the VL **after 3 months of excellent adherence, including daily witnessed ingestion, where feasible and appropriate** ○ If the repeat VL is 200 - 999 copies/ml consult the Regional or National HIV Clinical TWG ○ If the repeat VL is ≥ 1,000 copies/ml, change to an effective regimen. Refer to Table 6.10 ○ If the repeat VL is < 200 copies/ml (LDL) then continue routine monitoring

Table 7.2 Cont.

Scenario	
Pre-conception planning for women already on ART (not yet pregnant)	Maintain ART Carry out a VL test if not done in the prior six months to confirm viral suppression (Figure 6.6) Refer to Table 4.8 for pre-conception care for women on ART who desire pregnancy, including laboratory screening, TT immunization, folate, etc.
On ART at the time of confirming pregnancy/breastfeeding	Maintain ART. Carry out a VL at first identification of pregnancy, irrespective of when a prior viral load was done, to confirm viral suppression (Figure 6.6) Manage the baby as HEI (Figure 2.1 for EID, and Table 7.3 for infant prophylaxis)
Not on ART at the time of confirming pregnancy	Prepare the patient and start on ART as soon as possible. ART initiation should occur preferably on the same day HIV infection is confirmed. Perform VL 3 months after ART initiation. Pregnant and breastfeeding women with a history of treatment interruption returning to care should have reasons for interruption assessed and preferentially re-started on a DTG-containing regimen unless the reason for interruption was DTG intolerance or failure. Viral load monitoring in this case should be done after 3 months of initiation and 6 months thereafter until cessation of breastfeeding. Additional adherence support should be made available.
Not on ART during labour and delivery	Start on ART during labour. After delivery, continue treatment preparation and adherence support and continue ART Manage the baby as HEI (Figure 2.1 for EID, and Table 7.3 for infant prophylaxis)
Not on ART during post-partum/breastfeeding	Prepare (readiness assessment) and start on ART as soon as possible preferably on the same day HIV infection is confirmed. Manage the baby as HEI (Figure 2.1 for EID, and Table 7.3 for infant prophylaxis). Adherence support for both mother and infant, consider daily witnessed ingestion (DWI) support.
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

Note that certain patient groups e.g., recent HIV infections, pregnant adolescent girls and young women, women with previous children with HIV infection, patients with high viral load at time of pregnancy confirmation, patients with poor social support systems, patients with history of default from care and those with active co-morbidities etc. may require additional adherence and psychosocial support

7.2. Syphilis elimination for Pregnant and Breastfeeding Women and Infant Treatment

The country has adopted triple elimination of HIV, Syphilis and Hepatitis B among pregnant and breastfeeding women. It is recommended that all pregnant women attending ANC and not aware of their HIV status require a dual HIV syphilis test during their first trimester and a second HIV Syphilis test in the 3rd trimester if the initial test was negative.

All women who test positive for syphilis at any point during pregnancy and breastfeeding should be treated with the appropriate regimen. (Table 7.3). All babies born of mothers who test positive for syphilis are suspected to be exposed to syphilis and should also be treated with the correct regimen (Table 7.3). Ensure to perform contact tracing for all the sexual contacts and ensure they are treated for syphilis.

Symptoms of congenital syphilis may not become apparent for several weeks or months after birth.

7.3. Hepatitis B elimination for Pregnant and Breastfeeding Women and Infant Prophylaxis

Requires routine testing of pregnant women to identify women in need of antiviral treatment for their own health and additional interventions to reduce Mother to Child Transmission of viral hepatitis B.

Regular screening should be done by incorporation of viral hepatitis screening as part of the ANC profile. This is recommended for Hepatitis B & C which pose a big risk to both the mother and fetus.

For pregnant and breastfeeding women who are found to be positive for HBsAg, offer appropriate treatment options of ARVs containing TDF/3TC or FTC containing regimens. This treatment also acts as prophylaxis for HBV transmission from mother to child. All pregnant and breastfeeding women without evidence of hepatitis B infection (HBsAg negative) should be vaccinated against hepatitis B. (Chapter 9).

HIV positive infants without evidence of infection should be vaccinated against Hepatitis B. Infants born of mothers who test positive for HBsAG should be treated using Hepatitis B Immunoglobulin (Table 7.3).

Refer to Chapter 9 for management of HIV/HBV coinfection.

Table 7.3: ARV Prophylaxis for HIV-Exposed Infants

Infant Scenario	Infant Prophylaxis	Maternal Scenarios
HIV Exposed Infant	• Infant prophylaxis ○ AZT+NVP for 6 weeks, NVP + cotrimoxazole should be continued until 6 weeks after complete cessation of breastfeeding ○ Infant prophylaxis can be discontinued after a minimum of 12 weeks on NVP if the child is not breastfeeding (death of mother or separation with mother) ○ The infant prophylaxis regimen applies to all infants irrespective of age when identifying HIV exposure (e.g., mother diagnosed HIV-positive in the postpartum period) • DBS or whole blood for PCR at 6 weeks or first contact, following EID algorithm (Figure 2.1) • Birth testing (Figure 2.2) may be conducted in sites where point of care has been implemented and when medically indicated	If mother not on ART, initiate ART as soon as possible (preferably same day) If mother is on ART for ≥ 3 months and the VL is ≥ 50 copies/ml, intensify adherence, repeat the VL If VL <50 copies/ml, continue current regimen Follow Viral load algorithm Figure 6.6
TRIPLE ELIMINATION		
CONDITION in mother	INFANT MANAGEMENT	MATERNAL MANAGEMENT
Syphilis-VDRL or diagnosed with Dual kit	Crystalline Penicillin 50,000 IU/kg BD (if <7 days) or TDS if (>7 days old) for a total of 10 days.	Penicillin G 2.4 MU IM Stat or Ceftriaxone 1gm IM daily for 8-10 days in case of penicillin allergy.
Congenital syphilis		
Hepatitis B – HbsAg test	Hepatitis B immunoglobulin 0.5ml IM within 12 hours after birth. Hepatitis B vaccine 0.5ml three doses at birth, 1 month and 6 months.	Refer to viral hepatitis management guidelines

Note: If child has contraindication or unable to tolerate NVP or AZT then give the tolerated drug up to complete cessation of breastfeeding. If the infant is on AZT prophylaxis, give up to a minimum of 12 weeks or until maternal viral load is suppressed. In situations where neither AZT nor NVP are tolerated 3TC may be used as a third option if available.

HIV exposed infants with TB infection, infant prophylaxis should include AZT plus 3TC fixed dose (60/30 mg). For 12 weeks or until maternal viral load is suppressed (3-5.9 – 1 tab BD, 6-9.9kg 1.5tab BD, 10-13.9 kg 2 tabs BD). For more details, refer to Annex 10 A.

After TB treatment, revert to NVP until 6 weeks post cessation of breastfeeding,

HB monitoring should be done to all HEIs on AZT prophylaxis as per the recommendations (Table 6.7: management of AZT associated bone marrow suppression)

Groups considered higher risk for mother to child transmission who may need additional adherence and psychological support include:

- All new HIV positives irrespective of time identified
- HIV positive adolescent Girls and Young Women (AGYW) <19 yrs. including OVC
- VL >200 copies/ml
- Clients with stigma, declining treatment, poor adherence
- PMTCT client with previous HIV infected infant
- Client with active comorbidities - DM, OIs, malnourished (low MUAC), mental health etc.
- Clients who sero-convert during ANC/PNC follow up
- Poor socio-economic and family support structures
- Those who drop off ART
- Key population – FSW, PWID

Alcohol use and brewers/sellers

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 < 2,000 g	2 mg/kg per dose, OD	4 mg/kg per dose, BD
Birth weight 2,000-2,499 g	10 mg (1 ml), OD	10 mg (1 ml), BD
Birth weight ≥ 2,500 g	15 mg (1.5 ml), OD	15 mg (1.5 ml), BD
> 6 weeks to 12 weeks of age*		
Any weight	20 mg (2 ml), OD	60 mg (6 ml), BD
> 12 weeks (Table 7.5 and 7.6)		

*Dose adjustment required once child reaches 6 weeks of age

If older infant beyond 6 weeks of age is newly identified as HIV exposed infant, should be given AZT+NVP for 6 weeks, NVP + cotrimoxazole should be continued until 6 weeks after complete cessation of breastfeeding

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

Age	Dosing of NVP (10mg/ml) Once Daily
12 weeks – 6 months	25 mg (2.5 ml), OD
7 months – 9 months	30 mg (3 ml), OD
10 months – 12 months	40 mg (4 ml), OD
> 12 months	Consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform)

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

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, BD
6.0-9.9 kg	9 ml, BD
10.0-13.9 kg	12 ml, BD
14.0-19.9 kg	15 ml, BD

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

7.4 Infant and Young Child Nutrition in the Context of HIV

- **Exclusive breastfeeding** involves giving the baby only breast milk with no other liquids (including water) or solids for the first six months of life. Giving of vitamins, mineral supplements or medicines are permitted if prescribed.
- **Mixed feeding** is giving other liquids and/or foods together with breast milk to infants under 6 months of age **and is not recommended.** Mixed feeding during this period is associated with significantly higher risk of mother-to-child HIV transmission, diarrhoeal and respiratory tract illnesses, among other consequences and should be prevented

- All infants irrespective of HIV status should be exclusively breastfed for the first 6 months of life, with timely introduction of appropriate complementary foods after 6 months, and continued breastfeeding up to 24 months or beyond.
- Should mothers be physically separated from their infants (back to work), support them to sustain lactation and to exclusively breastfeed including mentorship on expressing breast milk (refer to current MIYCN Policy)
- All mothers, irrespective of HIV status, should be encouraged and supported to exclusively breastfeed for the first six months and continue breastfeeding with appropriate complementary feeding after 6 months, for a period of 24 months or beyond. Breastfeeding should ONLY stop once a nutritionally adequate and safe diet without breast milk can be sustained.
- HIV positive mothers and HIV positive infants should always be on ART and given extra attention for adherence support, VL monitoring and optimal retention in care
- Breastfeeding mothers who do not know their HIV status or who previously tested HIV negative should be encouraged to be retested for HIV at the 6-week immunization visit, and then every 6 months thereafter until complete cessation of breastfeeding (Table 2.5)
- Access for HIV testing and STI/HIV prevention interventions should be reinforced for partners of pregnant and breastfeeding women
- Mothers who are diagnosed with HIV while breastfeeding should immediately start appropriate ART, giving extra attention to adherence support, VL monitoring, and optimal retention in care. The infant should immediately start ARV prophylaxis and receive PCR testing (Table 7.3).
- Mothers who decide to stop breastfeeding at any time should stop gradually within one month (and only when a nutritionally adequate and safe diet without breast milk can be sustained), and HIV positive mothers and HIV positive infants should continue with ART. Continued breastfeeding is recommended for HIV positive infants for as long as the mother is willing and able to do so.
- In special medical circumstances, determined by clinicians, where an infant cannot breastfeed, refer to current MIYCN Policy and Breast Milk Substitute (BMS) Regulation and Control Act, 2012.
- **Complimentary feeding** means giving other foods to complement breast milk after six months of exclusive breastfeeding. Complimentary feeds provide additional nutritional value to meet the child's increasing nutritional needs for growth (Table 7.7). Furthermore, complementary feeding helps the child to gradually become accustomed to eating family foods while breastfeeding continues to be an important source of nutrients. It is worth noting that breastfeeding continues to have child growth/survival benefits for up to two years or longer. Emphasis should be made on consuming all the seven (7) food groups for children in various meals.
    - Cereal/tubers and roots
    - Beans, pulses and nuts
    - Dairy and dairy products
    - Eggs and Flesh (meat/poultry/insects/organ meat)
    - Vitamin A rich food (orange/yellow fruits) and green vegetables
    - Fats and high sugar foods
- Other fruits and vegetables

Table 7.7: Complementary Foods for Children 6-24 Months Old

Foods to Offer			
Age	**Texture**	**Frequency**	**Amount of food per meal**
6 months	Start with thick porridge or well mashed foods	2 times per day	2 tablespoons each feed, increasing to 3 tablespoons in the 3rd to 4th week
7-8 months	Mashed/pureed family foods By 8 months can begin finger foods	3 meals per day, plus frequent breastfeeds	Increase amount gradually to ½ of a 250 ml cup Use a separate plate/bowl
9-11 months	Finely chopped or mashed foods, and foods that baby can pick up	3 meals and 1 snack, plus frequent breastfeeds	¾ of a 250 ml cup/bowl Use a separate plate/bowl
12-23 months	Cut food into small, soft pieces that child can pick up, chew and swallow comfortably	3 meals and 2 snacks, plus breastfeeds	One 250ml cup/bowl Use a separate plate/bowl
24-59 months	Cut food into small, soft pieces that child can pick up, chew and swallow comfortably	3 meals and 2 snacks, plus breastfeeds if still breastfeeding	1 ½ - 2 cups of 250ml cup/bowl Use a separate plate/bowl

8. TB/HIV Co-infection, Prevention and Management

TB is a leading cause of morbidity and mortality among people living with HIV. 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 in combination with TB Preventive Therapy are effective ways 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 at every clinical visit. Symptom-based TB screening using the ICF tool MUST be performed at every clinic visit to rule out active TB; patients who screen positive (presumptive TB cases) must complete definitive diagnostic pathways (Figure 8.1 and Table 8.1) and patients who screen negative should be evaluated for TB preventive therapy (TPT).

Active Case Finding (ACF) differs from ICF. ICF refers to TB screening among PLHIV, whereas Active TB case finding (ACF) refers to special efforts made by the NTP or other partners that go beyond passive TB case finding at health facilities, in which communities or population groups that are underserved or at higher risk of TB are actively reached for providing access to care, including screening and testing

Intensified Case Finding Screening Questions

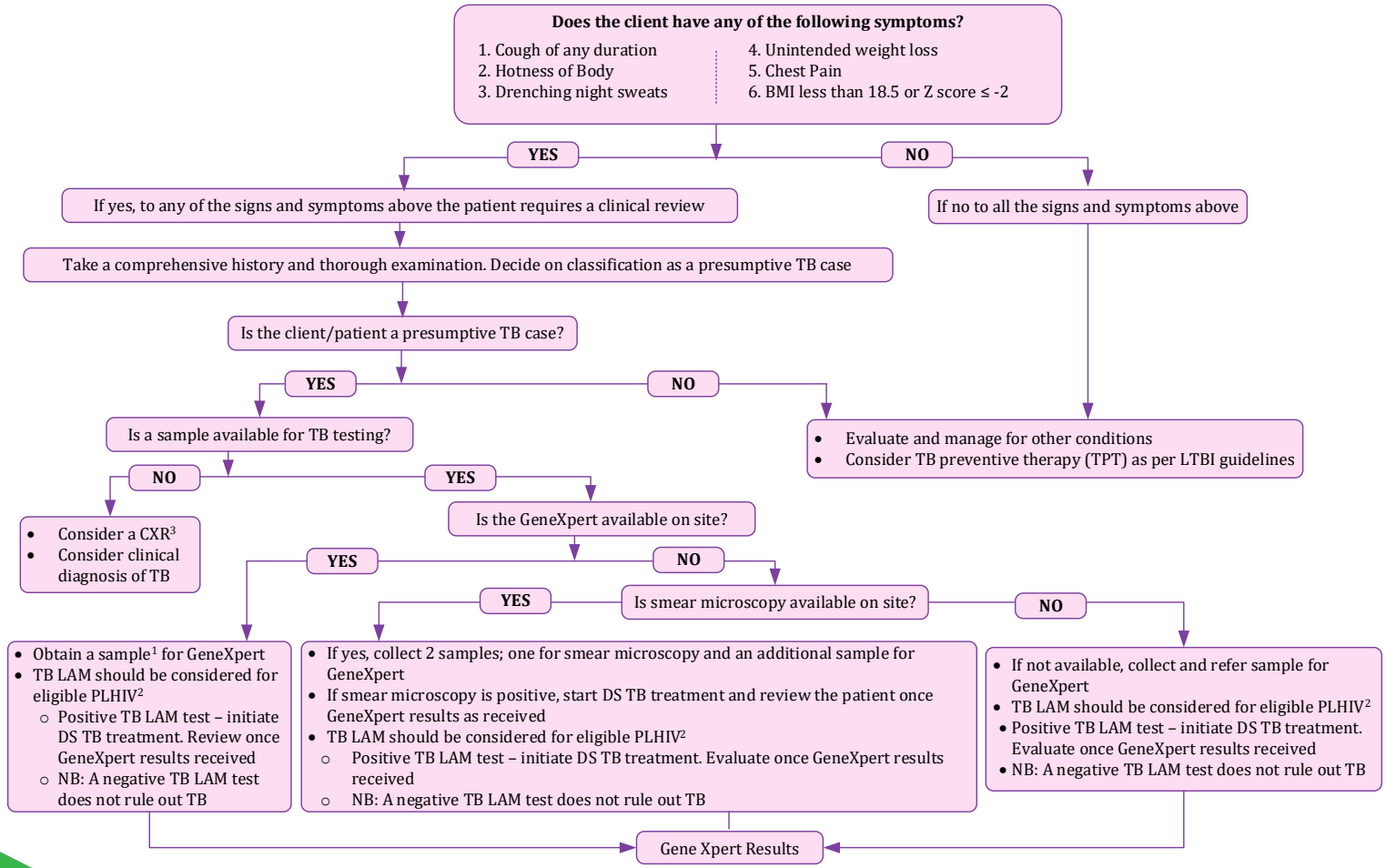
- If "Yes" to any question, take a detailed history, examine the patient and do sputum examination (sputum smear or GeneXpert)
- If "No" to questions 1-5 above, consider TPT eligibility and work up for TB Preventive Therapy and repeat screening on subsequent visits
- Questions 5 and 6 do not apply to adults

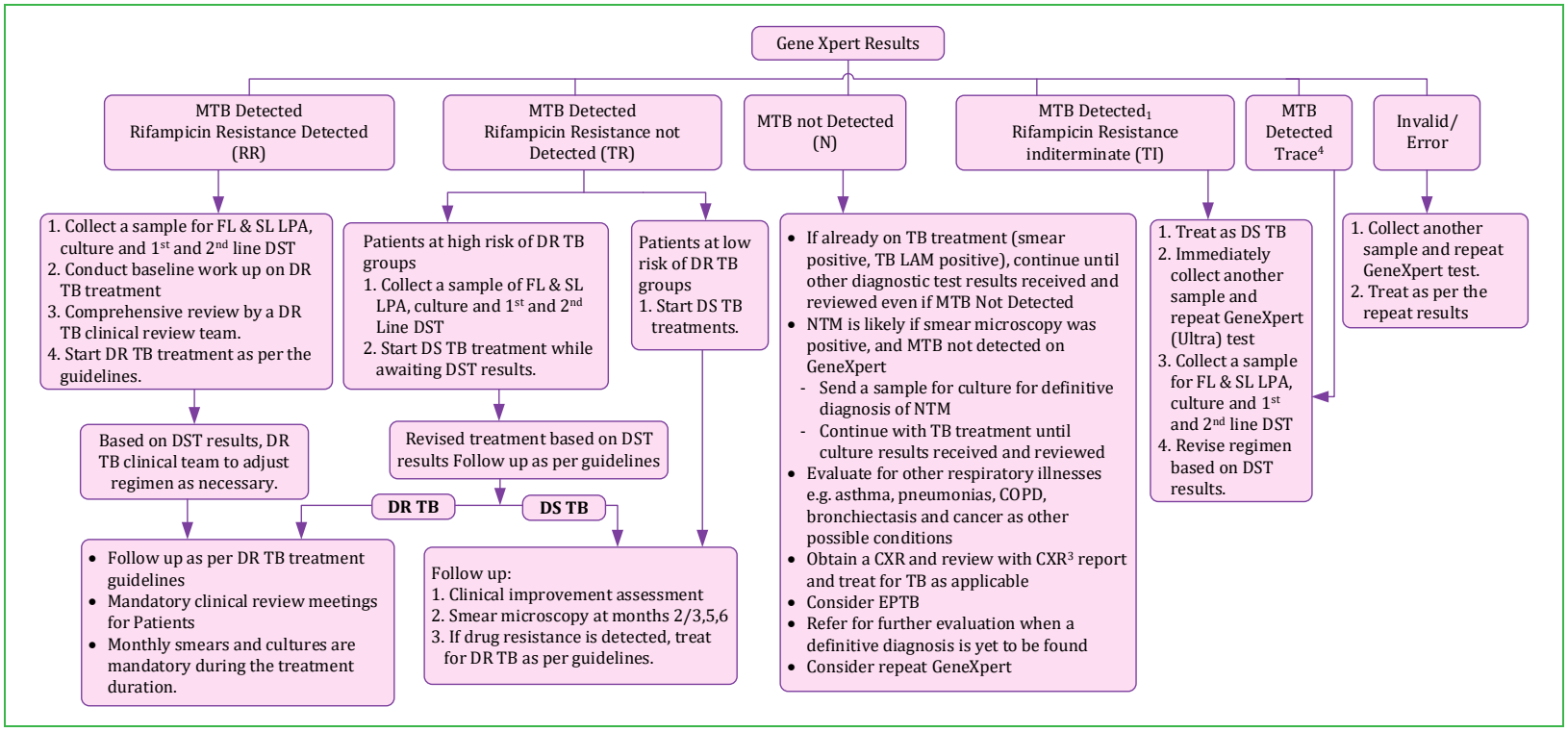
The following are the intensified case finding screening questions:

- Cough of any duration (Y/N)
- Fever (Y/N)
- Noticeable weight loss/ Failure to thrive/ Poor weight gain (Y/N)
- Night sweats (Y/N)
- Reduced playfulness/ Lethargy/ Irritability (Y/N)
- Contact with a TB case (Y/N)

GeneXpert is the recommended initial test for TB diagnosis. However, where a facility has no GeneXpert, smear microscopy SHOULD BE USED as another sample is collected & referred for GeneXpert.

TB LAM should be used where indicated among PLHIV as per guidelines. TB LAM SHOULD nOT be used as an alternative to GeneXpert testing.




Gene Xpert Results
MTB Detected Rifampicin Resistance Detected (RR)
MTB Detected Rifampicin Resistance not Detected (TR)
MTB not Detected (N)
MTB Detected1 Rifampicin Resistance inditerminate (TI)
MTB Detected Trace4
Invalid/ Error
1. Collect a sample for FL & SL LPA, culture and 1st and 2nd line DST
2. Conduct baseline work up on DR TB treatment
3. Comprehensive review by a DR TB clinical review team.
4. Start DR TB treatment as per the guidelines.
Patients at high risk of DR TB groups
1. Collect a sample of FL & SL LPA, culture and 1st and 2nd Line DST
2. Start DS TB treatment while awaiting DST results.
Patients at low risk of DR TB groups
1. Start DS TB treatments.
If already on TB treatment (smear positive, TB LAM positive), continue until other diagnostic test results received and reviewed even if MTB Not Detected
NTM is likely if smear microscopy was positive, and MTB not detected on GeneXpert
- Send a sample for culture for definitive diagnosis of NTM
- Continue with TB treatment until culture results received and reviewed
Evaluate for other respiratory illnesses e.g. asthma, pneumonias, COPD, bronchiectasis and cancer as other possible conditions
Obtain a CXR and review with CXR3 report and treat for TB as applicable
Consider EPTB
Refer for further evaluation when a definitive diagnosis is yet to be found
Consider repeat GeneXpert
1. Treat as DS TB
2. Immediately collect another sample and repeat GeneXpert (Ultra) test
3. Collect a sample for FL & SL LPA, culture and 1st and 2nd line DST
4. Revise regimen based on DST results.
1. Collect another sample and repeat GeneXpert test.
2. Treat as per the repeat results
Based on DST results, DR TB clinical team to adjust regimen as necessary.
Revised treatment based on DST results Follow up as per guidelines
DR TB
DS TB
Follow up as per DR TB treatment guidelines
Mandatory clinical review meetings for Patients
Monthly smears and cultures are mandatory during the treatment duration.
Follow up:
1. Clinical improvement assessment
2. Smear microscopy at months 2/3,5,6
3. If drug resistance is detected, treat for DR TB as per guidelines.

Footnotes

[1] Samples for GeneXpert, sputum, CSF, Pleural aspirate, Periloneal fluid, synovial fluid, Gastric Aspirate, Nasopharyngeal aspirate, FNA, Lymph node biopsy, Pus, stool

[2] Indications for use of TB-LAM, as an adjunct test to GeneXpert:

- PLHIV with advanced disease (WHO stage 3 or 4 or CD4 count ≤200 cells/mm^3 (or≤25% for children ≤5years old) with presumed TB
- PLHIV that have any danger signs of severe illness: respiratory rate >30breaths per minute, temperature >39°C, heart rate>120beats per minute, unable to walk unaided
- Currently admitted to hospital

[3] All CHEST X-rays should be reported and the reports reviewed by the clinician for definitive management. Refer to the CXR algorithm for TB diagnosis

[4] MTB detected Trace – Results from sample with few bacilli (paucibacillary TB). Rifampicin resistance status.

HIV Testing, using the HTS algorithm 1, is recommended during TB screening and diagnosis.
Screening for diabetes is recommended among all adult patients with TB disease

Key

CBR - Chest X-ray	**LPA** Line Probe Assay
DR TB - Drug Resistant TB	**MTB** Mycobacteria Tuberculosis
DS TB- Drug Susceptible TB	**NTM** Non-Tuberculous Mycobacteria
DST - Drug Susceptibility Testing	**TST** Tuberculin Skin test
EPTB - Extra Pulmonary TB	**SL** Second line
FL - First Line	

DR TB risk classification among patients

High risk for DR TB*

1. All previously treated TB patients: treatment failures, relapses, treatment after loss to follow up
2. Contacts of Drug Resistant TB patients
3. TB patients with a positive smear result at month 2 or month 5 of TB treatment
4. Patient who develops TB symptoms while on IPT or has had previous IPT exposure
5. Healthcare workers with 18 symptoms
6. Prisoners with TB symptoms
7. Refugees with TB symptoms

Low risk for DR TB

All presumptive TB cases who are **NOT** in the high risk group

***ALL** the high risk patients **MUST** be prioritized to receive DST, GeneXpert, FL and SL LPA, culture and FL and SL DST.

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DS TB follow up and DR TB surveillance

POSITIVE SMEAR RESULT AT	Action
Month 2/3	• Evaluate for **adherence,** and other causes of **delayed conversion** • Request for **all** the following **drug susceptibility tests** (DST); GeneXpert, FL, LPA and SL, LPA, Culture and FL and SL DST • **Continue with RHZE** for one more month, or longer if DST results not received by then • Adjust treatment regimen based on DST results • Repeat smear microscopy at end of month 3. If smear positive continue with RHZE and review DST results and inform the SCTLC immediately • Do not proceed to the continuation phase (RH) without a DST result confirming susceptibility to RH (rifampicin and isoniazid)
Month 5 or Month 6	• **Declare treatment failure** and stop anti-TB treatment • Review by the sub county and county TB clinical review teams • Evaluate for adherence, other causes of delayed conversion and treatment failure • Request for GeneXpert, FL LPA and SL LPA, culture and FL and SL DST • Review DST results and re-initiate treatment based on DST results and other clinical findings

DS TB follow up and DR TB surveillance

Smear Positive or culture positive at months 3 or later	• Evaluate for **adherence,** and other causes of **delay conversion**
	• Request for the following **drug susceptibility tests** (DSTI) (GeneXpert, Culture and First Line (FL) and SL DST, FL LPA and SL LPA) depending on the initial resistance pattern
	  ○ Review by the sub county and county clinical review teams
	  ▪ Evaluate for adherence, other causes of reversion and treatment failure
	  ▪ Review the DST results
	  ○ Declare failure if at the end of the extended intensive phase (refer to DR TB guidelines)
	  ○ Send a case summary to the national clinical team after review by the county clinical team
	• Do not proceed to the continuation phase (depending on treatment regimen) without a DST result

Smear Positive smears and/or cultures during continuation phase	• Declare treatment failure
	  ○ Review by the sub county and county clinical review teams
	  ▪ Evaluate for adherence, other causes of reversion and treatment failure
	  ▪ Review the DST results
	• Send a case summary to the national clinical team after review by the county clinical team

Figure 8.1: TB diagnosis- GeneXpert Ultra algorithm

Table 8.1: TB Diagnosis in Children <10 Years Old

<table>
<tr><th colspan="3">ALGORITHM FOR PULMONARY TB DIAGNOSIS IN CHILDREN</th></tr>
<tr><td>History of presenting illness</td><td colspan="2">For all children presenting to a health facility ask for the following suggestive symptoms
● Cough
● Fever
● Poor weight gain
● Lethargy or reduced playfulness
Suspect TB if the child has two or more of these suggestive symptoms
Ask for history of contact with adult/adolescent with chronic cough or TB within the last 2 years</td></tr>
<tr><td>Clinical evaluation</td><td colspan="2">Examine the child and check for:
● Temperature > 37.5º (fever)
● Weight (to confirm poor weight gain, weight loss) – check growth monitoring curve)
● Respiratory rate (fast breathing)
● Respiratory system examination – any abnormal findings
Examine other systems for abnormal signs suggestive of extra-pulmonary TB#</td></tr>
<tr><td>Investigations</td><td colspan="2">Obtain specimen’ for Xpert MTB/RIF (and culture when indicated**)
Do a chest Xray (where available)
Do a Mantoux test** (where available)
Do a HIV test
Do other tests to diagnose extra-pulmonary TB where suspected#</td></tr>
<tr><td>Diagnosis</td><td>Bacteriologically Confirmed TB:
Diagnosis if specimen is positive for MTB</td><td>Clinical Diagnosis of PTB:
Child has two or more of the following suggestive symptoms
● Persistent cough, fever, poor weight gain, lethargy
PLUS, two or more of the following:
● Positive contact, abnormal respiratory signs, abnormal, positive Mantoux
Note: If the child has clinical signs suggestive of EPTB, refer to EPTB diagnostic table*</td></tr>
<tr><td>Treatment</td><td colspan="2">Treat for TB as follows:
● All children with bacteriologically confirmed TB
● All children with a clinical diagnosis of TB
NB: In children who do not have an Xpert result, or their Xpert results is negative, but they have clinical signs and symptoms suggestive of TB they should be treated for TB
All forms of TB (Except TB meningitis, bone and joint TB) Treat for 6 months (2 RHZE/ 4 RH)
TB meningitis, bone and joint TB: Treat for 12 months (2 RHZE/ 10 RH)</td></tr>
<tr><td colspan="3">*Specimen may include: Expectorated sputum (child > 5 years), induced sputum, nasopharyngeal aspirate and gastric aspirate. Attempt to obtain specimen in every child
**Do a culture and DST for the following children:
1. Rifampicin resistance detected by the Xpert test
2. Refugees and children in contact with anyone who has Drug Resistant TB
3. Those not responding to TB treatment
4. Those with indeterminate Xpert results
***This may include IGRA in facilities where it is available
#Use IMCI guidelines to classify severity of disease</td></tr>
</table>

Table 8.2: Drug Susceptible TB Treatment Regimen for Children, Adolescents and Adults

TB disease category	Recommended regimen	
	Intensive phase	Continuation phase
All forms of TB except TB meningitis, bone and joint TB (osteoarticular TB)	2 RHZE	4 RH
TB meningitis Osteoarticular TB	2 RHZE	10 RH
Drug resistant TB	**Refer to a DRTB Clinical Team**	

- Follow up smears should be done for all bacteriologically confirmed pulmonary TB cases at end of month 2, 5 and 6 of TB treatment using smear microscopy
- Follow up of RR TB and DR TB should be done as per PMDT guidelines
- Patients taking isoniazid containing regimen should also be given Pyridoxine (Vitamin B6) daily for the duration of treatment to reduce the risk of developing peripheral neuropathy (see Annex 10 for pyridoxine dosing)

Once TB treatment is started it should be completed; unless another definitive diagnosis (like lung cancer) is established and TB is ruled out.

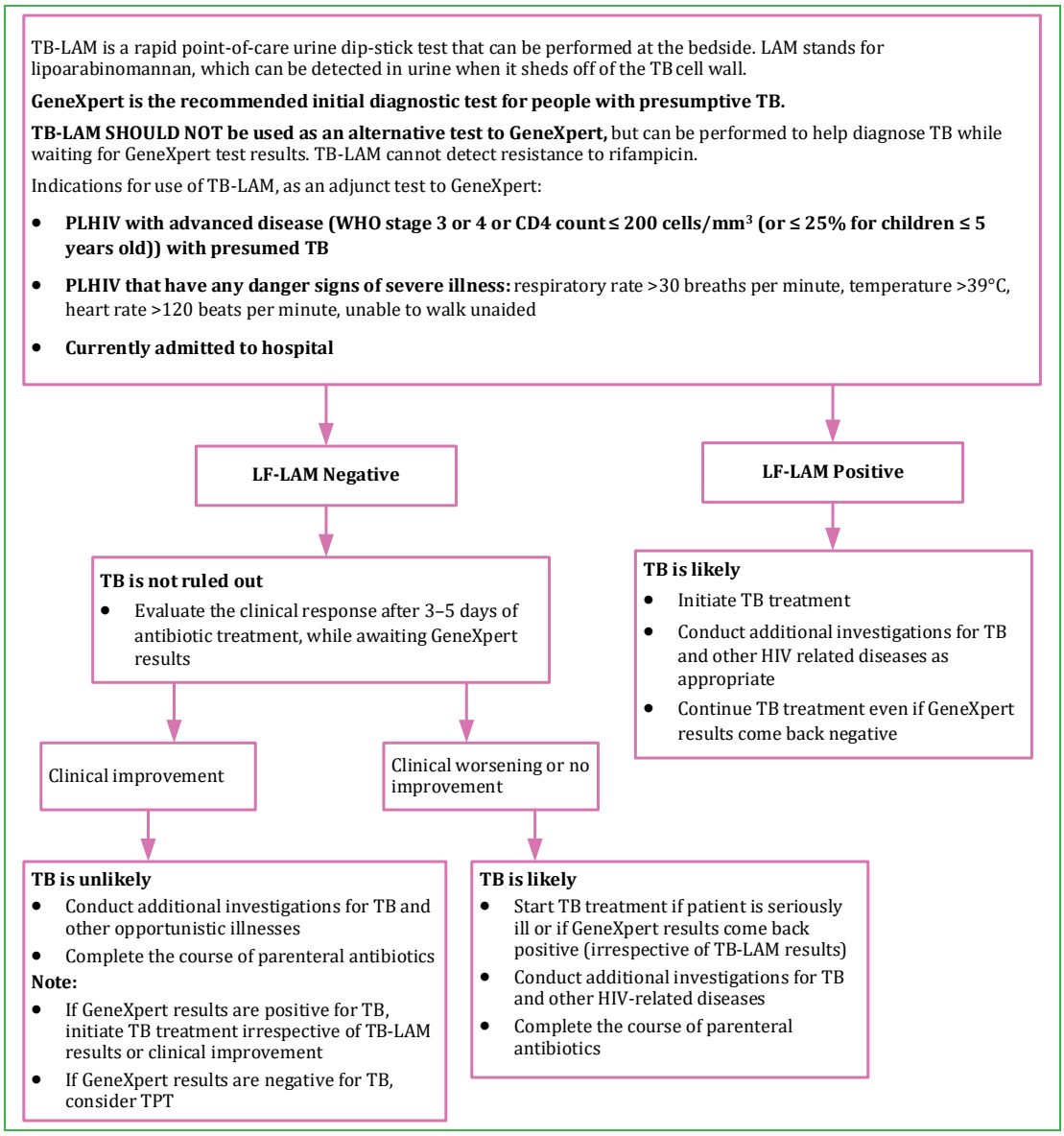


Figure 8.2: Use of TB-LAM for Diagnosis of TB among PLHIV

8.2. TB Preventive Therapy (TPT)

This section summarizes the current national recommendations for treatment of latent TB infections (LTBI) in the PLHIV population. These are in line with the updated World Health Organization guidelines which include the use of shorter, safer LTBI treatment options for an expanded at-risk population. For further guidance, refer to the national guidelines on LTBI management.

8.2.1. Indications for TPT

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

- All PLHIV above 12 months of age (children, adolescents and adults including pregnant and breastfeeding women)
- All household contacts of persons with bacteriologically confirmed pulmonary TB
- Prisoners and staff working in prison setting
- Health care workers and other staff in health care setting
- Other clinical risk groups as defined in LTBI guidelines

*Neonates born to mothers with TB, or exposed to close contacts with TB should be given TPT once TB disease has been ruled out. BCG should be given 2 weeks after completion of TPT or anti-TB treatment

Summary of recommendations for TPT among the PLHIV

- PLHIV are at a much higher risk of getting TB disease compared to the general population
- TB preventive therapy should be given to all PLHIV above 12 months of age who do not have active TB disease. This should be done irrespective of immune status, ART status, previous history of TB and pregnancy status.
- Children aged <12 months living with HIV who are household contacts of a person with bacteriologically confirmed pulmonary TB, and whom active TB has been ruled out should receive TB preventive therapy.
- TPT may be given immediately following successful completion of TB treatment among the PLHIV.
- **Repeat TPT is not recommended among PLHIV except if a PLHIV becomes a household contact of a person with bacteriologically confirmed pulmonary TB**
- PLHIV aged 15 years and above should be provided with 3 months of weekly Rifapentine and Isoniazid (3HP), while those less than 15 years are given 6 months of daily INH (6H)
- In PLHIV on PI/r-based ART, pregnant women and those who do not tolerate 3HP should be given six months of daily INH (6H)
- For eligible patients previously treated for TB, initiate TPT upon completion of their TB treatment.

8.2.2. Contraindications to TPT

Patients with the following should not receive TPT until the underlying issue(s) are addressed

- Active tuberculosis disease
- Active hepatitis (acute or chronic)
- Chronic alcohol abuse
- Symptoms of peripheral neuropathy

8.2.3. Dose and Duration of TPT

Table 8.3: Recommended TPT Regimens for PLHIV

Target populations	TPT Regimen
• Adult PLHIV excluding patients on PI/r-based ARV regimens	Rifapentine and Isoniazid (3HP) Once weekly for three months *(12 doses)*
• Adult PLHIV on PI/r-based ARV regimens • All CALHIV aged below 15 years • Any patient with intolerance or contraindication to 3HP • Pregnant women	Isoniazid (6H) Once daily for 6 months
• The 3RH (rifampicin and isoniazid) regimen is not recommended for PLHIV due to drug- drug interactions • All TPT regimens should be given with Vitamin B6 (pyridoxine), if available, to reduce the risk of developing peripheral neuropathy • Comprehensive health education and adherence counselling should be conducted prior to initiation of TPT • Dosing of TPT is in Annex 10	

- Children should be weighed at each visit and correct weight-based dosing confirmed.
- Clients on 3HP should receive weekly dose of pyridoxine, Those on Rifapentine and Isoniazid regimen should be given pyridoxine once a week
- **The 3RH (rifampicin and isoniazid) regimen is not recommended for PLHIV due to drug-drug interactions.** 3RH is used in HIV negative populations

8.2.4. Follow-up of Patients on TPT

Patients on TPT should be followed up on a monthly basis and their return-to-clinic dates harmonized with any other routine schedules. During each clinic visit, conduct the following;

- Symptom screening for active TB disease and update status
- Assess and reinforce adherence to treatment
- If a patient screens positive for TB while on TPT, stop TPT and manage according to National TB guidelines
- Assess for any adverse drug reactions at each visit and intervene appropriately
- Provide/update TPT appointment card
- Document and update the relevant recording and reporting tools, e.g., ICF/TPT cards, Contact Management/TPT register
- Document outcome of TPT use e.g., completion in the relevant tools and/or EMR

**Baseline liver function tests are not mandatory for patients initiating TPT. These may, however, be considered on an individual basis, especially for patients taking other medications for chronic medical conditions or symptomatic patients suspected to have active hepatitis*

8.3. Identifying and Managing Drug Toxicities from TPT

The management of drug toxicities should be based on severity, with appropriate grading of individual patients. The most common adverse drug reactions associated with TPT are peripheral neuropathy, drug-induced liver injury (DILI), and rash.

8.3.1 Peripheral Neuropathy - *Suspected drug: INH*

Diagnosis of Peripheral Neuropathy

- Symptoms include: burning sensation, numbness, or tingling, usually starting at the feet on both sides
- May have decreased sensation on examination
- May develop weakness in severe cases
- May be potentiated by other neurotoxic drugs, alcoholism, metabolic disease (e.g., diabetes), malnutrition and infections
- Rarely severe enough to require drug withdrawal

Management of INH-induced Peripheral Neuropathy

- Increase the dose of pyridoxine to 100 mg per day
- For children give double the standard weight-based dose
- Assess for other causes of peripheral neuropathy (e.g., diabetes, thyroid disorder, B12 deficiency, syphilis, etc.)
- Relief of symptoms can be achieved with analgesics, tricyclic antidepressants (amitriptyline, nortriptyline), anticonvulsants (carbamazepine, phenytoin)
- If symptoms do not improve, or there is any worsening, then discontinue TPT; symptoms may persist even after discontinuing TPT

8.3.2 Drug-Induced Liver Injury (DILI) -Suspected drugs include Isoniazid (H), Rifapentine (P), Rifampicin (R)

- Elevation of liver enzymes may occur in the first weeks of treatment
- In asymptomatic patients, serum liver enzyme levels do not need to be monitored routinely
- All clients with gastrointestinal symptoms (nausea and vomiting, liver tenderness, hepatomegaly or jaundice) should have their liver function assessed
- Patients should be screened for other causes of liver injury (the hepatitis viruses-A, B, C)
- Table 8.4 shows the grading of liver injury and management of DILI
- Once the drugs are discontinued, no attempt should be made to reintroduce these drugs until liver functions have normalized
- An expert with experience in managing DILI should be involved in the further management of such cases

Diagnosis of DILI

- Jaundice, abdominal pain, nausea, vomiting, anorexia, etc.
- Abnormal liver enzymes

Table 8.4: Grading and Management of DILI

	Grade 1: Mild	Grade 2: Moderate	Grade 3: Severe	Grade 4: Life threatening
ALT (SGPT)	*1.25 – 2.5 x ULN*	*2.6 – 5.0 x ULN*	*5.1 – 10.0 x ULN*	*> 10.0 x ULN*
AST (SGOT)	*1.25 – 2.5 x ULN*	*2.6 – 5.0 x ULN*	*5.1 – 10.0 x ULN*	*> 10.0 x ULN*
ACTION	Continue treatment regimen; patients should have weekly followed up until resolution (return to baseline) or stabilization of AST/ALT elevation	Continue treatment regimen; patients should have weekly followed up until resolution (return to baseline) or stabilization of AST/ALT elevation	Stop all drugs, including TPT drugs; measure LFTs weekly; TPT **should not** be reintroduced after severe DILI[1]	Stop all drugs, including TPT drugs; measure LFTs weekly. TPT **should not** be reintroduced after life threatening DILI[1]

1. PLHIV who develop DILI during treatment of active TB disease, may have anti-TBs reintroduced after toxicity is resolved in consultation with a senior clinician

8.3.3 Management of TPT-associated Rash - Suspected Drugs include Isoniazid (H), Rifapentine (P), Rifampicin (R)

- A rash may occasionally develop, usually within a few days following initiation of TPT. It is often a relatively mild maculopapular rash with or without pruritus.
- Flu-like and other systemic hypersensitivity reactions are rare amongst children. Hypersensitivity reactions in adults are usually mild and self-limiting
- Rarely, rash may develop with severe exfoliation of the skin and Stevens-Johnson syndrome
- Rash severity should be assessed and managed appropriately as shown in table 8.5

Table 8.5: Management of TPT-Associated Skin Rash

Severity	Characteristics	Action
Mild	Dry; erythema +/- fine papules; pruritus; affecting < 50% of body surface area	Continue TPT; close monitoring; symptomatic treatment with antihistamines +/- topical steroids (NOT oral steroids)
Moderate	Dry; erythema +/- fine papules; pruritus; affecting ≥ 50% of body surface area	Stop TPT; 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 TPT; admission to hospital for supportive management (IV fluids, wound care, pain control, infection control, monitoring for super-infection); **patient should NEVER be re-challenged;** document and report adverse event and issue patient alert card

8.4. 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 TB treatment immediately
  - Initiate ART as soon as anti-TB medications are tolerated, preferably within 2 weeks
  - For TB meningitis delay ART for 4 to 8 weeks
  - Monitor closely for IRIS (Annex 16)

- Patients who are already on ART
  - Start TB treatment immediately
  - Continue ART, assessing for treatment failure and making any required adjustments to the ART regimen based on drug-drug interactions (Table 8.7)
  - Monitor closely for IRIS (Annex 16)
- Patient being treated concurrently for TB and HIV require close monitoring for toxicity
- MDR TB and HIV co-infection should be managed in settings where close toxicity monitoring and follow up by experienced clinicians or multi-disciplinary team is possible

Preferred ART regimens for patients with TB/HIV co-infection are summarized in Tables 8.6 - 8.8.

Table 8.6: Preferred ART Regimens for TB/HIV Co-infection for Patients Newly Initiating 1st Line ART [1]

Age	Weight	1st Line ART if TB/HIV Co-infection
Birth to 4 weeks	Any	Start anti-TB treatment immediately; start ART after 4 weeks of age, once tolerating anti-TB drugs (follow the regimen recommendations for children ≥ 4 weeks old)
> 4 weeks to < 15 years	< 30 kg	• ABC + 3TC + DTG • Increase DTG dosing frequency to twice daily for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to once daily dosing
	≥ 30 kg	• Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to TDF/3TC/DTG FDC once daily
≥ 15 years	Any	• Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to TDF/3TC/DTG FDC once daily

1 Refer to Annex 10 for weight-based ARV dosing

Table 8.7: Preferred ART Regimens for Patients who Develop TB while Virally Suppressed on 1st Line ART [1,2]

Current Regimen[3]		Recommended Substitution

PI/r-based[4]	All ages	• Switch from PI/r to DTG and continue this regimen even after completing TB treatment. Follow DTG dosing as below
		• If it is not possible to switch to DTG:
		  ○ Children < 30 kg requiring PI/r-based ART should receive LPV/r with additional ritonavir super-boosting for the duration of rifampicin-based TB therapy, reverting to standard LPV/r dosing 2 weeks after completing TB treatment
		  ○ Patients ≥ 30 kg who cannot switch to DTG should be switched to EFV-based ART and maintained on EFV-based ART after completion of TB treatment

RAL-based	All ages	Switch from RAL to double-dose DTG dosing during TB treatment and maintain on DTG after completion of TB treatment
DTG-based	All ages	Administer the double-dose of DTG (i.e., the standard weight-based dose of DTG given twice daily) while taking rifampicin containing TB treatment. Two weeks after completion of TB treatment revert to the recommended DTG dose once daily.

1 Always assess for HIV treatment failure in patients who develop TB after being on ART for ≥ 6 months. For patients failing 1st line ART refer to Table 8.8 for recommended 2nd line regimens

2 For patients on 2nd line ART, subsequent regimens, or nonstandard drugs who require regimen change because of TB treatment, consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform)

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 to manage the drug interaction between LPV/r and rifampicin (see Annex 10 for dosing recommendations)

Table 8.8: Recommended ART Regimens for Patients who Develop TB while Failing 1st Line ART [1]

Age/ Scenario	First-line ART	Second-line ART
< 30 kg body weight	LPV/r-based 1st line	• Start anti-TB immediately. • Change to DTG-based second-line immediately. Increase DTG dosing frequency to twice daily for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to once daily dosing • Immediately collect a sample for DRT[2] • Assess for and address reasons for treatment failure. • If unable to switch to DTG then use super-boosted LPV/r[3]
	ABC (or AZT) + 3TC + DTG	• Start anti-TB immediately • Increase DTG dosing frequency to twice daily for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to once daily dosing. • Follow the viral load monitoring algorithm (Figure 6.6), including assessing for and addressing reasons for treatment failure, and collecting DRT. Consult the Regional or National TWG to constitute a second-line regimen based on DRT results
≥ 30 kg or ≥ 15 years old	TDF (or ABC or AZT) + 3TC + DTG	• Start anti-TB immediately • Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to TDF/3TC/DTG FDC once daily • Follow the viral load monitoring algorithm (Figure 6.6), including assessing for and addressing reasons for treatment failure, and collecting DRT. Consult the Regional or National TWG to constitute a second-line regimen based on DRT results
	TDF (or ABC or AZT) + 3TC + EFV	• Start anti-TB immediately • Continue current regimen while following the viral load monitoring algorithm (Figure 6.6), including assessing for and addressing reasons for treatment failure. • Once treatment failure is confirmed and patient ready to switch to 2nd line, switch to TDF + 3TC + DTG (maintain the TDF, even if the patient was already on a TDF-containing regimen), increasing the DTG dose to twice daily for the duration of rifampicin-based TB therapy, switching back to standard DTG dose 2 weeks after rifampin is discontinued.
	PI/r-based 1st line	• Start anti-TB immediately • Switch to TDF+3TC+DTG immediately. Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to TDF/3TC/DTG FDC once daily • Immediately collect a sample for DRT2 • Assess for and address reasons for treatment failure.
Pregnant or Breastfeeding	Follow the same recommendations as for ≥ 30 kg or ≥ 15 years old.	
HIV/HBV Co-infection	Always maintain TDF or TAF in second-line instead of switching to a different NRTI and instead of adding an additional NRTI	

Table 8.8 Cont.

1. For patients on 2nd line ART, subsequent regimens, drug intolerance, or nonstandard drugs who require regimen change because of TB treatment, consult the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform)
2. Contact the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000; https://nhcsc.nascop.org/clinicalform) for guidance on urgent collection of DRT samples
3. Use "super-boosted" LPV/r by adding additional ritonavir to manage the drug interaction between LPV/r and rifampicin (see Annex 10 for dosing recommendations). **Two weeks after TB treatment is completed the child should go back to standard LPV/r dosing.**

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

9.1 Hepatitis B/HIV Co-infection

HIV and Hepatitis-B Virus (HBV) share infection 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 drug-related hepatotoxicity, drug-drug interactions and ART-related immune reconstitution hepatitis.

9.1.1 Screening

All adolescents and adults living with HIV (plus children who did not complete routine childhood immunizations) should be screened for HBV infection, using HBsAg, as part of initial evaluation. To promote population-wide prevention, hepatitis B prevention should be integrated into routine HIV prevention and care programs. In this setting, other indications for HBsAg screening could include

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

PLHIV 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 PLHIV 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 (Table 9.1)
- HIV exposed infants (HEI) should also receive hepatitis B vaccination as part of childhood immunization (Table 4.21)
- 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 who test HBsAg negative.

- Babies and young children (through EPI and catch-up immunization for those who missed EPI vaccination)
- Household contacts of HBsAg positive people
- 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
Non-adjuvanted formulation	Double the standard dose	0, 1, 2, and 6 months
Adjuvanted formulation	Standard dose	

*Booster vaccination is not required for persons who have completed the full vaccination schedule

B. General preventive measures: General measures for infection prevention adopted by PLHIV 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, razors, combs and other grooming equipment
- Harm reduction counselling and services for PWID as outlined in Chapter 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 stage or 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 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 adolescents and adults with HIV/HBV co-infection is TDF + 3TC + DTG, including for women and adolescent girls of childbearing potential

Treatment with both TDF (or TAF) and 3TC is recommended as 3TC without TDF or TAF will result in rapid emergence of resistance. In case of renal impairment (as assessed by creatinine clearance), the dose of TDF and 3TC should be adjusted (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 discuss or refer to a consultant for additional evaluation and management
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 other 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 < 50 ml/min. In such patients, avoid FDCs. Instead administer the ART as single drugs to allow for dosage adjustment as shown in Table 9.3
Comorbidities	HCV antibody, random blood sugar, lipid profile, alcoholic and non-alcoholic liver disease, hepatocellular carcinoma (family history)	Consult/Refer the patient for additional investigations where these are suspected

Table 9.3: Dose Adjustment of TDF and 3TC in Patients with Impaired Renal Function [1]

Drug	Creatinine clearance (ml/min)			Haemodialysis
	50 - 80	30-49	10-29	
TDF 33 mg/g granules (=1scoop)	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	Unchanged: 300 mg once daily	300 mg every 48 hrs	300 mg every 72 to 96 hours (twice weekly). For patients getting hemodialysis, administer 300 mg once weekly after completion of dialysis sessions [2]	
3TC 300mg	Unchanged: 300 mg once daily or 150 mg BD	150 mg once daily	150 mg once daily	50 mg first dose, 25 mg once daily

[1] Patients with impaired renal function in whom the benefits of 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

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

C. Follow-up/Monitoring

Follow-up of HIV/HBV co-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 classes of ARVs by 3-5 times, especially when anti-TB and ART are given simultaneously. Also, hepatic flare-up (AST > 5 times normal value) can occur, often in the initial 3 months.

Note: ALT elevations 5-10 times normal can be tolerated in the first 3 months of ART 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).

Patients with persistently elevated ALT levels during follow-up should be referred to a specialist. 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-containing ART should not be stopped 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 in the ART regimen for patients switching from TDF-based-therapy. So, for example, if a patient with HIV/HBV co-infection fails TDF/3TC/EFV in first-line, they should switch to TDF/3TC/DTG in second-line.

HIV/HBV co-infected patients failing second-line ART should be discussed in the MDT and discussed with the Regional or National HIV Clinical TWG (Uliza Hotline 0726 460 000.)

9.2 Hepatitis C/HIV Co-infection

In Kenya, the prevalence of HCV infection is high in PWID (estimated to be 12-16%). The prevalence in the general population and among PLHIV is low (estimated to be < 3%), but likely to be higher in HIV infected PWID due to shared routes of transmission. HIV/ HCV co-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 manage 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.

9.2.1 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 with doubtful infection prevention precautions
- Children born to HCV positive mothers

Up to 30% 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 measures for prevention of blood-borne infections are effective in preventing HCV transmission.

- Recommendations for healthcare settings

  Training of healthcare providers on:

  - 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
- Recommendations for PWID
  - Harm reduction counselling and support (Table 12.1)
- 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 of STIs, frequent testing for HIV and HCV testing)

9.2.3 Treatment of HIV/HCV Co-infection

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, at baseline
HCV genotype	May be important for selecting appropriate DAA regimen. (Current regimens pan-genotypic, so HCV genotype testing not required)	
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, random blood sugar, lipid profile, alcoholic and non-alcoholic liver disease, hepatocellular carcinoma (family history)	Consult/Refer the patient for additional investigations where these are suspected

Table 9.5: Recommended DAA for the Treatment of HCV among PLHIV

Genotype	DAA Regimen*	Duration of treatment
1 and 4	Sofosbuvir + Ledipasvir (Harvoni)	12 weeks
All	Sofosbuvir + Velpatasvir (Epclusa)	12 weeks

* DAA regimen availability continues to evolve; this table just shows the most readily available regimens at time of publication. Always start DAA HCV therapy, and review most recent drug-drug interactions with ARVs.

10. ARVs for Post-exposure Prophylaxis

An ARV regimen, with preferably three-drugs, should be offered as post exposure prophylaxis as soon as possible (preferably within 72 hours) after an exposure.

10.1 What is PEP?

Post-exposure prophylaxis (PEP) is short-term use of antiretroviral treatment to reduce the likelihood of HIV infection after potential exposure.

People can be accidentally exposed to HIV through healthcare work or due to exposures outside healthcare setting, for example, through unprotected sex or sexual assault among adults and children. Healthcare workers are at increased risk of exposure to HIV through contact with contaminated blood and other body fluids containing HIV through needle stick injuries and injuries by other sharp objects or through non-intact skin and mucous membranes.

10.2 Recommended ARVs for PEP

Three-drug regimens are preferred for PEP. However, if the person is unable to tolerate the third drug, (usually the PI/r), two drugs can be used.

Table 10.1: Recommended ARVs for PEP

Age	Weight	Preferred	Alternate
<15 years	< 30kg	ABC + 3TC + DTG	• AZT + 3TC + DTG • AZT+3TC and LPV/r may be used as the third drug
	≥ 30 kg	TDF + 3TC /FTC + DTG	• TDF+3TC/FTC and ATV/r may be used as alternative third drug
≥ 15 years	Any weight	TDF + 3TC/FTC + DTG	• TDF+3TC/FTC and ATV/r may be used as alternative third drug

.

10.3 Eligibility For PEP

PEP should always be offered as soon as possible, preferably within 72 hours, after an exposure. Persons who present after 72 hours should be provided with other appropriate services including counselling and support.

Eligibility assessment for PEP is based on the type of exposure, HIV status of source where possible and timing of seeking care.

The following include the eligibility criteria for PEP.

- Exposed individual is HIV negative at baseline.
- Exposure must have occurred within the past 72 hours.
- Exposure to bodily fluids pose a significant risk (exposure and/or material):
  - **Type of exposure:** mucous membrane (i.e. sexual exposure; splashes to eye, nose, or oral cavity), non-intact skin, percutaneous injury or parenteral exposures
  - **Material**: blood, blood-stained body fluids, breast milk; semen; vaginal secretions; synovial, pleural, pericardial, amniotic fluids; CSF, and HIV cultures in laboratories

Exposures that do not require HIV PEP include:

- When the exposed individual is already HIV positive.
- Exposures to bodily fluids that do not pose a significant risk, i.e., tears, non-blood-stained saliva, urine, and sweat.

10.4 Management and Follow Up

Patients should be counselled and encouraged to complete the full course of PEP once a decision has been made to initiate PEP.

For occupational exposure, immediate care of the exposure site includes washing the site with soap and water and allow the wound to bleed freely for several minutes

NOTE: Do not do anything that will increase tissue damage such as squeezing, scrubbing, or cutting the site further.

Table 10.2: Recommendations for PEP Management and Follow-up

Considerations	Recommendation
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 the exposed individual tests HIV-negative at baseline (if HIV testing not feasible, offer 1-2 days of PEP to cover until HIV test performed) • Provide first aid in case of broken skin or other type of wound
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 if tested HIV negative)
Dose of PEP	Same as indicated for treatment; use weight-based dosing for children
Laboratory investigation at baseline	• Conduct creatine testing (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. • HBsAg testing is recommended. Do not delay administration of PEP while waiting for lab results. If negative provide HBV vaccination • Pregnancy testing for women of childbearing potential in case of sexual assault.
Follow-up	• Follow up client at 7 days, 14 days, 28 days, and 12 weeks after starting PEP • Assess for and manage side effects due to PEP • Follow-up HIV testing should be done at the completion of PEP and if negative, test again at 12 weeks • Link to HIV treatment if positive
Counselling	Counselling at baseline should include: • Adherence counselling • Information on side effects • Risk reduction counselling • Trauma and mental health counselling • Specific support for sexual assault
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**

10.5 Risk reduction counselling

To reduce the risk of further HIV transmission, it is necessary to prevent transmission to sexual partners and the children of breastfeeding mothers. Risk reduction counselling should form part of each consultation with the individual. Measures to reduce transmission to another person may include:

- The use of condoms and safe injecting practices to prevent secondary transmission
- Avoiding blood donation until confirmed HIV negative at 12 weeks post exposure

Table 10.3 Considerations for special circumstances

Circumstance	Recommendation
Breastfeeding women	• Breastfeeding is not a contraindication for PEP • The risks and benefits of continuing breastfeeding while HIV transmission risk is unknown and should be discussed with the mother
Children	• HIV testing approaches for children should be in line with national guidelines and age appropriate • Informed consent from the caregiver is needed
Adolescents	• Requiring parental consent for adolescents can be a barrier to HIV testing, particularly in cases of sexual assault • HIV testing should be performed in accordance with national guidelines and consenting requirements

10.6 Preventing HIV exposure

To avoid or minimize the risk of exposure to HIV the following infection prevention control (IPC) measures are recommended:

- Precautions should be taken when handling contaminated body fluids including the use of appropriate barriers such as gloves, gowns, and goggles.
- Care with sharps including minimizing blind surgical procedures and proper handling and disposal of sharps.
- Safe disposal of contaminated waste
- Safe handling of soiled linen.
- Adequate disinfection procedures
- Universal Hepatitis B vaccination of non-immune at-risk groups including HCWs, police, prison staff and rescue workers.

In cases that do not require PEP, the exposed person should be counselled about limiting future exposure risk.

11. Pre-Exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis (PrEP) is the use of antiretroviral medication to prevent the acquisition of HIV infection by an uninfected person at ongoing risk of acquiring HIV infection.

PrEP is recommended for use as follows:

- Daily Oral PrEP for all individuals, irrespective of gender or sexual orientation who are at risk of HIV infection.
- Event-Driven (ED) PrEP is currently recommended for all people born male who are not taking exogenous estradiol-based gender affirming hormones

11.1 Indications for PrEP and Criteria for Eligibility

11.1.1 Indications for PrEP

PrEP is indicated for;

- HIV uninfected persons at ongoing risk of HIV acquisition
- Some risk situations that place one at ongoing risk include individuals or sexual partner/s who is/are:
    - HIV positive and: not on ART, or on ART < 6 months, on ART with viral non-suppression, or on ART with suspected poor adherence
    - In sero-discordant relationships trying to conceive
    - Of unknown HIV status and at high-risk of HIV infection
    - Engaging in transactional sex or sex work
    - With history of recent or current sexually transmitted infections
    - With recurrent use of Post-Exposure Prophylaxis
    - With a history of sex whilst under the influence of alcohol or recreational drugs
    - Inconsistent or no condom use or unable to negotiate condom use during intercourse with persons of unknown HIV status
    - Using injection drugs where needles and/or syringes are shared

11.1.2 HIV Risk Assessment

Clients accessing health services should be screened for HIV risk and additionally provided with information on HIV prevention options available including the availability of PrEP. This is in addition to the use of HIV testing services (HTS), as clients are assessed for HIV risk before testing.

The risk assessment questions are enquiry of behavioural practices that may expose an individual to HIV (Table 11.2).

A simple Risk Assessment Tool (RAST) is provided to guide the provider in generating a conversation about HIV risk. Screening for HIV risk should be integrated within other service delivery points. HIV negative individuals who answer “yes” to any of the screening questions should be engaged in a discussion about the risks and benefits of PrEP. The client then is evaluated for eligibility to receive PrEP.

Table 11:1 HIV Screening questions

Screening question refer to the past 6 months & include;

- "Have you had sex with more than one person?"
- "Have you had sex without a condom?"
- "Have you had sex with anyone whose HIV status you do not know?"
- "Are any of your partners at risk of HIV?"
- "Have you had sex with a person who has HIV?"
- "Have you received a new diagnosis of a sexually transmitted infection?"
- "Do you desire pregnancy?"
- "Have you used or wanted to use PEP or PrEP for sexual exposure to HIV?"
- "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 received money, housing, food or gifts in exchange for sex?"
- "Have you been forced to have sex against your will?"
- "Have you been physically assaulted, including assault by a sexual partner?"

11.1.3 Criteria for PrEP Eligibility

To be eligible for PrEP, individuals identified to be at risk of HIV infection from Risk Assessment must meet ALL the following criteria prior to initiating PrEP.

- Confirmed HIV negative status through rapid antibody testing following the HTS algorithm.
- Determine if the client is willing to take PrEP as prescribed. (This is done by adherence education and counselling on the PrEP regimen to be given, and assessing the client's readiness to follow the regimen.)
- Does not have a current or recent (within the 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.
- No contraindication to use of any of the ARVs recommended for PrEP e.g., TDF +/- FTC (or 3TC) for those who choose oral PrEP.
- Renal or liver disease
    - Clients with renal and liver disease should receive further clinical and laboratory tests, to determine the renal/liver function and extent of disease.

Other important factors for screening

1. ***Gender based violence (GBV) screening:*** All clients accessing PrEP must be screened for gender-based violence, especially intimate partner violence (IPV), and appropriate intervention offered or client linked to appropriate.
2. ***Mental Status Assessment:*** Psychological issues that may influence adherence should be assessed and addressed. It is important to carry out basic mental health evaluation and offer appropriate referral as necessary.

HIV self-test (HIVST) should not be used as a definitive HIV test for PrEP initiation and follow up monitoring.

11.2 Package of PrEP Service

PrEP should be offered as part of the comprehensive prevention package which includes behavioural, bio medical and structural components. Integration of PrEP services is recommended within different service delivery points, including in the community, ANC and FP clinics.

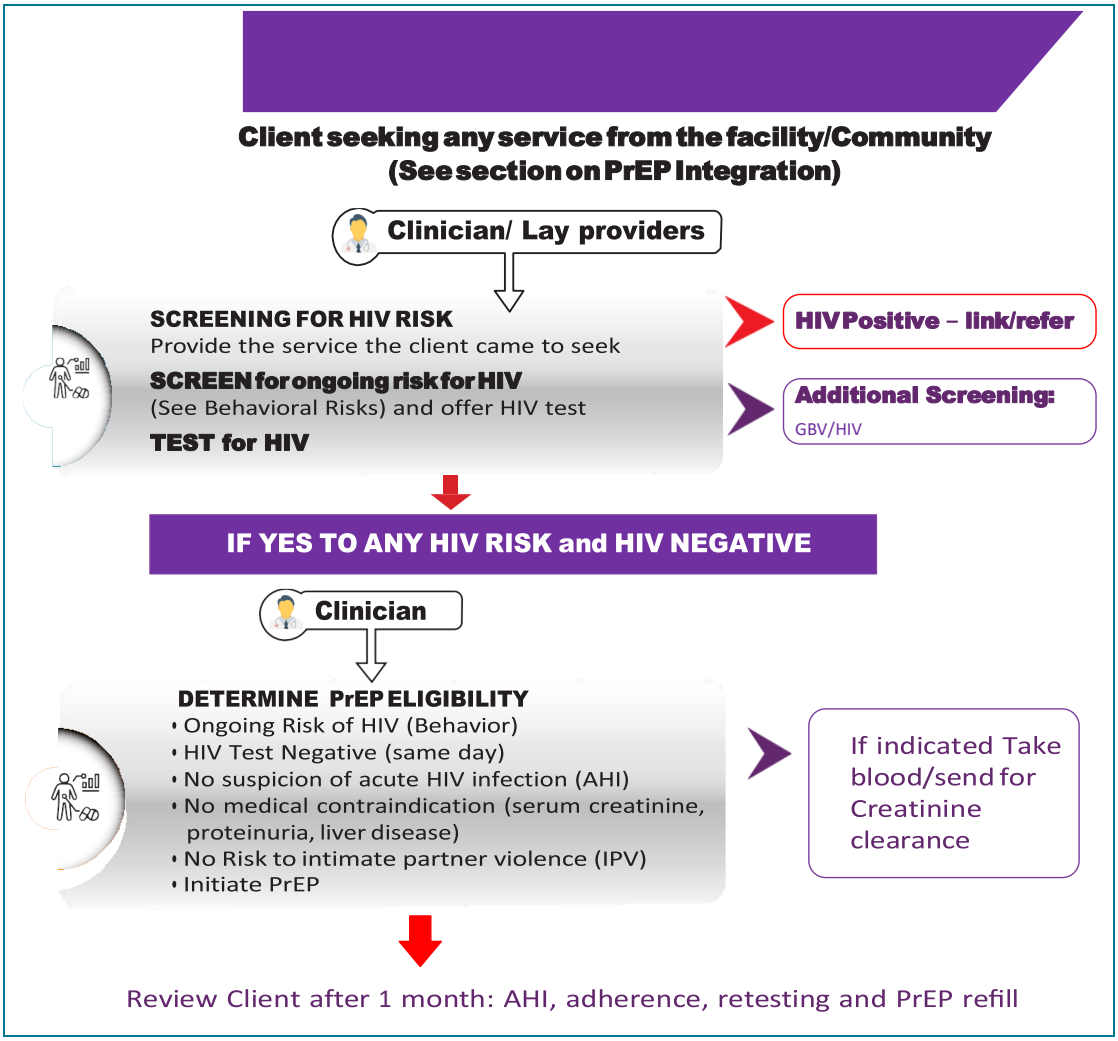


Figure 11.1: Package of Service for PrEP

11.2.1 Pre-Initiation Checklist

This checklist is intended to help the service provider ensure all necessary screening and assessments are done prior to PrEP initiation

Table 11.2: Pre-Initiation Assessment Checklist

ITEM	Y/N
Screening and Support for GBV	
HIV Testing	
Check symptoms of acute viral infection in last 6 weeks	
Behavior risk assessment	
Substance use and mental health screening	
Partner information	
Pre-initiation education and understanding of PrEP	
Client readiness and willingness to adhere to prescribed PrEP and follow-up schedule	
STI screening and treatment	
For women ✓ Pregnancy test, pregnancy intention and / or breastfeeding ✓ Screen for contraception use using appropriate contraceptive screening tool ✓ Highlight the need for condom use	
Discussed plans for continually accessing PrEP	
Additional laboratory tests (Availability of these test should not delay initiation of PrEP) ✓ Serum creatinine and creatinine clearance ✓ HBsAg ✓ HCV serology *NB: absence of these tests should not hinder initiation*	
Medication history and potential drug interactions	

11.2.2 Pre-initiation client education

The following components should be discussed prior to PrEP initiation:

Table 11.3: Client Education Checklist

Topic		Check
✓	Explain how PrEP works as part of combination HIV prevention	✓
✓	Explain the need for baseline and follow-up tests including regular HIV testing	✓
✓	Explain PrEP use: include the following: (refer to the different types of PrEP available for details) o The medications used (show the client the pills or other PrEP options o How the medications are used (frequency of dosing for the various options) o Number of doses required to achieve efficacy (7 doses for daily oral PrEP, loading dose for event driven oral PrEP) o What to do when doses are missed (continue for daily doses) o Discontinuation of PrEP, how and when it can be discontinued. o Side effects and what to do in case these are experienced (including when to consult the clinician)	✓
✓	Discuss what to do in case client experiences symptoms of seroconversion (acute HIV infection)	
✓	Discuss the Limitations of PrEP o PrEP reduces but does not eliminate the risk of acquiring HIV. o PrEP does not prevent pregnancies and STIs.	✓
✓	Risk reduction counselling and support education o Managing mental health needs o Couple counselling o Access to, and consistent use of condoms and lubricants o Access to and need for frequent HIV testing. o Early access to ART o VMMC o STI screening and treatment o Harm reduction for PWID	✓

11.3 Recommended ARVs for PrEP

The preferred ARV regimen is Tenofovir 300mg/ Emtricitabine 200mg (TDF/FTC) given as one fixed dose combination (FDC) tablet orally daily.

Table 11.4: Antiretrovirals for Use in PrEP

PrEP Dosing Strategies	Preferred	Alternative
Daily Oral PrEP	TDF/FTC (300 mg/200 mg) as FDC once daily	TDF/3TC (300 mg/300 mg) as FDC once daily
Event Driven Oral PrEP	TDF/FTC (300 mg/200 mg) as FDC – two pills taken between 2 and 24 hours in advance of anticipated sex; then, a third pill 24 hours after the first two pills and a fourth pill 48 hours after the first two pills; 2-1-1	TDF/3TC (300 mg/300 mg) as FDC – two pills taken between 2 and 24 hours in advance of anticipated sex; then, a third pill 24 hours after the first two pills and a fourth pill 48 hours after the first two pills; 2-1-1
*Recommended Long-acting Products: These products are at different stages of approval and availability in Kenya. The Ministry of Health will issue specific implementation guidelines when they become available.		
*Long Acting Cabotegravir Injection	Initiation injections: 600 mg Intramuscular (IM) x 2 doses given 1 month apart (the second initiation injection can be given up to 7 days before or after the date scheduled to receive injection) THEN Continuation injections: 600 mg IM every 2months	
*Dapivirine vaginal ring	Dapivirine vaginal ring, 25mg, inserted vaginally every 28 days.	

The drugs can be taken with or without food, and can be stored at room temperature.

Prescription intervals for daily oral PrEP

The first prescription should be for 30 days to allow for the first follow-up visit during which a repeat HIV test should be conducted, and adherence, tolerability and adverse effects assessed.

During the one-month visit, if no major concerns are noted, PrEP should be prescribed for 2 months and thereafter 3-monthly. Clients with sub-optimal adherence and or other major concerns should be given monthly follow up visit.

Remind individuals using daily oral PrEP that it takes 7 doses (equivalent to 7 days) of continuous PrEP use to achieve adequate levels of the ARVs in tissues for it to be effective. During these days, safer sex practices should be encouraged (including abstinence and condom use). This only applies for individuals born female. Those born male can have protective levels as soon as 2 hours before sex but ideally 24 hours. This is true even for people intending to take daily oral PrEP for ongoing exposure.

11.3.1 Schema for follow up for daily oral PrEP

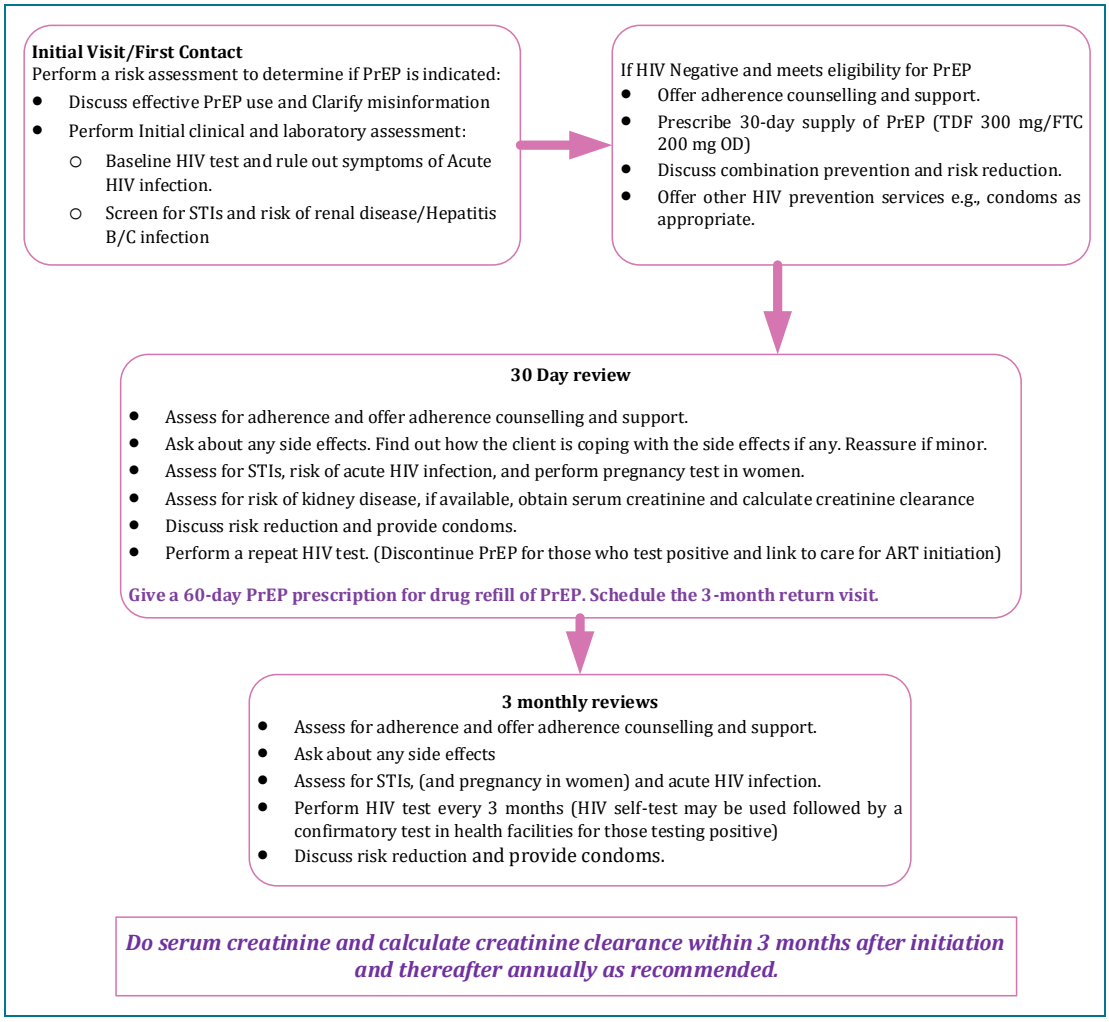


Figure 11.2: Schema for Follow-up for Daily Oral PrEP

11.3.2 EVENT DRIVEN PrEP (ON DEMAND PrEP or 2+1+1 PrEP)

What is event driven?

An "Event" refers to a sexual act. Event driven PrEP is where oral PrEP is to be used when an isolated sexual act is anticipated.

Event-Driven PrEP is recommended for all people assigned male at birth not taking exogenous estradiol-based gender affirming hormones

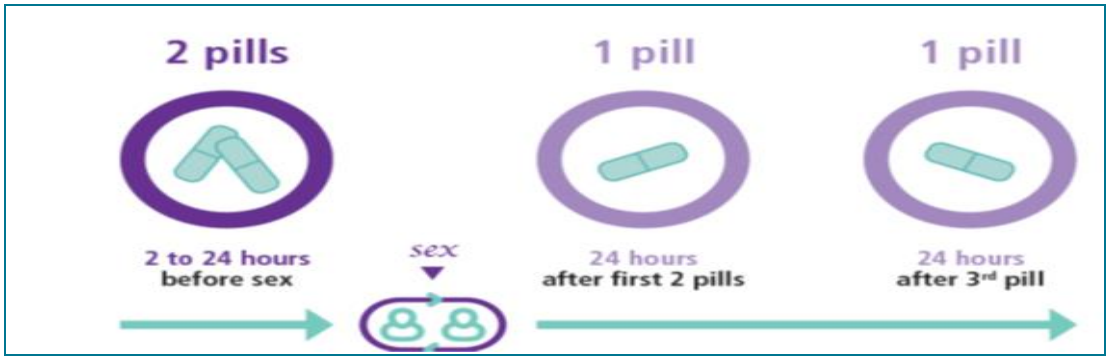


Figure 11.3 Schema for Event-Driven PrEP

When is ED -PrEP considered most appropriate?

Event driven PrEP is most appropriate for men who:

- Have infrequent sex (for example, sex less than 2 times per week on average).
- Can plan for sex at least 2 hours in advance or who can delay sex for at least 2 hours.
- Would find ED-PrEP more convenient

Clients on Event driven PrEP require follow up. Figure 11.4 shows the schema for follow up of event driven PrEP.

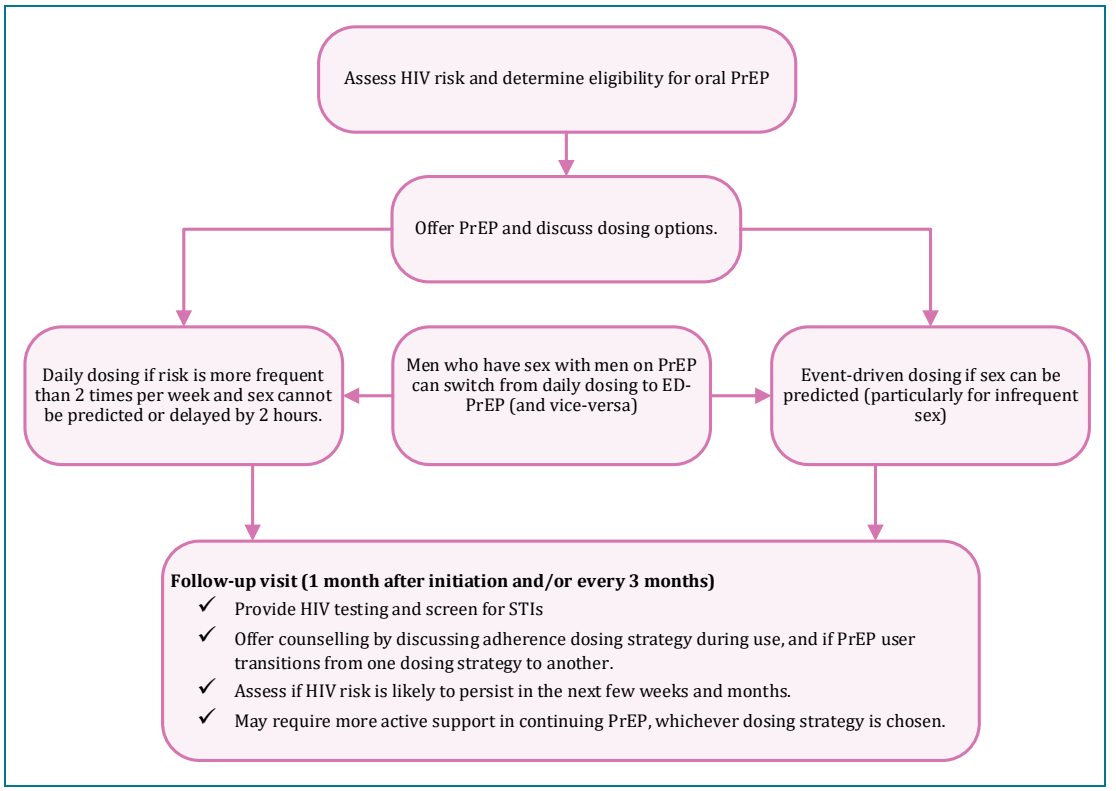


Figure 11.4 Schema for Initiation and Follow-up for Event-driven PrEP

Changing between ED PrEP and daily oral PrEP

Men can be offered the two dosing options: daily oral PrEP or Event driven PrEP.

- Daily dosing is appropriate for those whose occurrence of sex cannot be predicted and for those whose potential exposures to HIV are more frequent than 2 times per week, such that ED-PrEP would be taken so frequently that it would effectively resemble daily PrEP.
- If sex continues beyond one day, a user of ED-PrEP can stay protected by taking another pill each day as long as sex continues and stopping 2 days after the last sex act.
- On the other hand, if an individual starts daily oral PrEP, but then sex becomes infrequent and predictable, ED-PrEP can be used instead.

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

Table 11.5 Initial & follow up laboratory test

Laboratory Test	Guidelines for clients initiating PrEP	Guidelines for clients on follow up
HIV Rapid Test	Before initiating PrEP as per the National HTS algorithm	At Month 1, Month 3, thereafter every 3months
Creatinine Test	Test within 1-3 months of PrEP Initiation	If client >50years – Screen every 6-12months
	Clients of any age with renal comorbidity: recommended before initiating PrEP	Screen every 6-12months
Hepatitis B Surface Antigen (HBsAg)	Test once within 3 months of initiating PrEP. If negative, offer/refer for immunization	
Hepatitis C Virus Serology	Test once within 3months of PrEP initiation	Every 12 months for persons at high risk of Hepatitis C infection

Table 11.6: 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. Take DBS or plasma sample for drug resistance testing.
Positive STI Screen	Thorough genitourinary and anorectal examination, urine dipstick for urethritis, serological testing for syphilis, full STI evaluation if 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 oral PrEP. However, will require monitoring of liver function and referral for management of liver disease. **NB: TDF-based daily or event-driven oral PrEP can be safely offered to persons with HBV infection.**
Hepatitis C - Negative	Continue PrEP and follow Hepatitis C testing algorithm.
Hepatitis C - Positive	Continue PrEP, refer for Hepatitis C confirmatory testing and management with directly acting antivirals (DAAs).
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 – individuals may experience 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 PrEP 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. PrEP should not be prescribed for individuals using nephrotoxic drugs like acyclovir, aminoglycosides, retinoids etc. instead, offer alternative HIV prevention services.
Pregnancy or Breastfeeding	Pregnancy and breastfeeding are not contraindications to provision of PrEP. Pregnant or breastfeeding women whose sexual 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 women in sero-different 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.

Table 11.7: Summary of PrEP Initial and Follow-up Assessment

Visit	Action
First (Screening Visit) Clinician Visit	• HIV testing and counselling. • Evaluate for eligibility, willingness and readiness to take PrEP. • Educate about the risks, benefits, and limitations of different PrEP options • Educate client about recognizing symptoms of Acute HIV Infection (AHI) and what to do if such symptoms occur (i.e., urgently return for HIV testing) • Conduct behavior risk assessment • STI screening and treatment • Pregnancy, contraceptive use and counselling (for women); if pregnancy suspected, obtain a pregnancy test. However, pregnancy is not a contraindication to PrEP. • Adherence counselling • Discuss combination prevention. • Laboratory test; serum creatinine test and calculate Creatinine Clearance (CrCl), HBsAg, pregnancy test, Hepatitis C (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 • Assess for side effects and adverse effects • Safety monitoring clinical assessment/ Review lab results • Conduct a HIV test as per the national algorithm • Behavioral risk assessment. • Review for PrEP continuation or discontinuation • Adherence and risk reduction counselling • Give a prescription for PrEP for 2 months. • Offer HBV vaccination if available and HBsAg negative (follow HBV vaccination schedule complete series
Follow up visits - Months 3, 6, 9, 12, 15….. Clinician/Counsellor-led visits	• HIV testing and counselling • HIV risk assessment • Review for PrEP continuation or discontinuation • Assess for side effects and adverse effects • Safety monitoring clinical assessment/ Review lab results • Adherence and risk reduction counselling • Give a prescription for PrEP for 3 months • Refill PrEP prescription • Serum creatinine and creatinine clearance

Table 11.7 Cont: Summary of PrEP Initial and Follow-up Assessment

During every visit

- Assess adherence
- Reassess risk of HIV infection and offer risk reduction counselling
- HIV testing should be repeated at month 1 and thereafter, every 3 months (this applies for both daily and Event driven PrEP)
- Assess for adverse effects

11.5 Contra-indications to Oral PrEP (daily or ED 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.

11.6 Criteria for Discontinuing Oral PrEP

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

- Positive HIV test during follow up.
- Change in risk status (no ongoing risk)
- Renal dysfunction with creatinine clearance below 50 ml/min
- Client request to stop.
- Sustained non-adherence.

Discontinuing daily oral PrEP: Users discontinuing PrEP due to no ongoing risk or requesting to stop should continue PrEP for at least 7 days after the last potential exposure to HIV. Reasons for discontinuation should be documented in the client's record.

Discontinuing event–driven PrEP: Event-driven PrEP can be stopped after two daily doses following the last sexual exposure.

11.7 Restarting PrEP

Any client restarting PrEP regardless of the preferred method should be assessed for HIV status and a rapid HIV test conducted:

- ***Daily Oral PrEP***: Clients who stop PrEP for more than 7 days and wishes to restart should be assessed for resumption of PrEP similar to the assessment done for an initial (first) visit. Importantly, conduct a HIV test before re-starting PrEP. If a high-risk exposure occurred in the previous 7 days (i.e., acute HIV infection is suspected), defer PrEP and obtain repeat HIV test after 4 weeks; if negative, PrEP can be prescribed if the other criteria are fulfilled. The use of condoms should be recommended during the waiting period.
- ***Event driven Oral PrEP***: Clients who have stopped PrEP for more than a week and who are restarting ED-PrEP should commence with a double dose (two pills) of PrEP as new initiators. Risk assessment should be conducted. If a high-risk exposure occurred in the previous 7 days (i.e., acute HIV infection is suspected), defer PrEP and obtain repeat HIV test after 4 weeks; if negative, PrEP can be prescribed if the other criteria are fulfilled. The use of condoms should be recommended during the waiting period.

11.8 Improving adherence to PrEP

Approaches to improve adherence include:

- Encourage ring users to keep ring in place continuously through the 28-day period from initial insertion
- Disclosure of PrEP use to a partner or trusted person
- Use of reminder devices like a cell phone alarm.
- SMS reminders where available and feasible
- Exploring and mitigation of other barriers to adherence
- Peer support

11.9 Monitoring Sero-conversion among PrEP users

PrEP substantially reduce the risk of HIV acquisition. The efficacy of PrEP is correlated with adherence. Sero-conversion during use of PrEP should be monitored critically as it is increasing the risk of developing drug resistance if clients continue the use of PrEP while HIV infected.

Factors that lead to HIV seroconversion among PrEP sero-converters include:

- Inconsistency in use of PrEP (non-adherence).
- Social-behavioral factors e.g., poverty, HIV stigma and relationship status that may affect the ability to use PrEP as prescribed.
- Possible infections with drug resistant strains

What should be done upon identification of a PrEP sero-converter?

HIV testing among PrEP should be conducted consistently as per the algorithm. Identification of new HIV positive diagnosis among PrEP users should be followed with:

- Immediate discontinuation of PrEP
- Counselling of client on positive results
- Linkage to care and ART (immediate ART initiation).
- Assessment of barriers to adherence that may affect use of ART.
- Document sero-conversion in client file, PrEP registers, and monthly reporting as required.

12. People Who Inject Drugs (PWID) and HIV

12.1 Introduction

The use of ART for HIV treatment in key populations should follow the same general principles and recommendations as for all adults. Individuals within key populations groups may experience discrimination and marginalization that can impede their access to health care, including treatment for HIV, and frequently present late for treatment. It is important to ensure that people from key populations have equitable access to HIV treatment and care. Programs should ensure that missed opportunities are minimized and every single encounter with key populations is optimally used. ART service delivery includes decentralization of HIV care and treatment and integration of ART services into other clinical services such as Medically Assisted Therapy and drop-in centers where appropriate capacity exists.

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 their HIV status. Despite this, PWID have limited access to HIV treatment and prevention services.

Every effort should be made to implement 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).

Package of care for PWID

PWID have complex needs related to 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, drug-drug interactions and non-adherence. These patients are best comprehensively managed by providers who have received specific training in the management of injection drug users. 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 likely to be diagnosed late and therefore have poorer treatment outcomes following ART initiation. ● PWID should be offered HIV testing and counselling and be linked to comprehensive HIV treatment and prevention services including harm reduction counselling and support. ● Retest for HIV every 3 months if there is ongoing risk. ● HIV self-testing should be integrated into drop-in centers (DICEs) through both assisted and non-assisted approaches after initial testing by a provider. ● HTS should also be offered to sexual partners of PWID.
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 behavior. PWID should be informed of where and what harm-reduction services are available, and linked to appropriate services. 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 unintended pregnancy and sexual transmission of HIV and other 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 genital ulcer diseases increase the risk of HIV infection and transmission and are often a sign of unsafe sexual behavior 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.
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 workers. ● Once active TB is ruled out, TPT should be provided to PWID living with HIV as per National guidelines for TPT. ● PWID with active TB should receive standard TB treatment as per the National guidelines and be supported to complete treatment. ● Anticipate and manage complications due to viral hepatitis or renal impairment.

Table 12.1 Cont.

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 behavioral interventions are also effective in reducing risk of infection/transmission of HBV and HCV.
	● Peer interventions should be offered to people who inject drugs to reduce the incidence of viral hepatitis
	● PWID should be screened for HBV (by HBsAg) and HCV (by HCV 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 (day 0, 7, 21, and a booster at 12 months). If the rapid regimen is not available, the standard regimen should be offered. For PWID who are HIV positive, they should follow the dosing schedule in Table. 9.1
	  ○ HBV/HIV co-infected PWID should be started on TDF- or TAF-containing ART (the current recommended first line is TDF/3TC/DTG) 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 should be provided in consultation with expertise in the management of HCV infection (refer to national guidelines on management of viral hepatitis)

Needle and syringe programmes (NSPs)	NSPs help decrease drug-related risk behaviors, reduce quantity of contaminated needles in circulation, reduce risk of new HIV infections and improve referrals and linkage to HTS and HIV treatment and prevention services. NSPs are effective means for introducing combination prevention to PWID including HTS, STI screening and treatment, condoms provision, OST, and HIV treatment and prevention. **All PWID should be linked to NSPs to access sterile injecting equipment**
Opioid substitution therapy (OST)	OST using methadone or another suitable alternative is effective in the treatment of opioid dependency, reducing risk behaviors related to drug use and therefore reducing HIV transmission and improving PWIDs' adherence to ART **Identify and link all PWID who have opioid dependence for opioid substitution therapy**

Table 12.1 Cont.

Antiretroviral therapy (refer to Table 12.2 for details)	• ART is effective in managing HIV infection in PWID. However, poor adherence may interfere with ART success. Intensive support is required including OST, enhanced counselling techniques and daily witnessed ingestion (DWI) when available. • Close monitoring of ART is necessary because of risk of drug-drug interactions, renal and liver toxicity. • HIV-positive PWID should be offered comprehensive HIV treatment and prevention services including ART. When ART is provided with additional targeted support, PWID can achieve and maintain viral suppression. • Oral PrEP 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 treatment and prevention services. Peer-led, community-based approaches are particularly useful in improving adherence and retention.

12.3 ART in HIV positive PWID

Antiretroviral therapy is part of the comprehensive care package for PWID living with HIV. ART service provision should follow the same general principles and recommendations as for all adults.

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 (first-line ART)	Irrespective of OST, PWID with HIV infection should be initiated on a first-line regimen of **TDF + 3TC + DTG** including women of childbearing potential. TDF + 3TC + ATV/r may be offered as an alternative where DTG cannot be used. (Table 6.3)
TB Co-infection	ART should be started as soon as possible within two weeks of initiating TB treatment, regardless of CD4 cell count. For PWID with TB/HIV co-infection on DTG, give TDF/3TC/DTG FDC given in the am + DTG 50mg given in the pm for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment is completed, then revert to TDF/3TC/DTG FDC once daily.
Second-line ART	Patients failing DTG-based first line ART (including PWID) should be managed as per the viral load monitoring algorithm (Figure 6.6), including performing a DRT for selection of a second-line regimen (Table 6.10)
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 benefit from additional preparation and support to increase their chances of successful treatment including: ● Harm reduction interventions ● Thorough baseline assessment for important comorbid conditions like Advanced HIV Disease (AHD) including TB, hepatitis, renal impairment and depression or other psychiatric disorders ● Negotiation for, and access to daily witnessed ingestion (DWI). ● Community outreach and support

Table 12.1 Cont.

Preventing and managing drug-drug interactions	Selection of drugs should take into consideration possible drug to drug interactions and their effects on opioids, OST and ART. Any interaction that reduces the levels of methadone may induce withdrawal symptoms and require an increased dose of methadone.
	● **ARV interactions with methadone and opioids**
	  ○ NRTIs
	  ▪ TDF, TAF, 3TC, FTC: no significant interactions
	  ▪ AZT levels are increased, with higher risk of AZT toxicity.
	  ▪ ABC levels are decreased, and methadone levels are decreased.
	  ○ NNRTIs
	  ▪ EFV: methadone levels are decreased and may induce withdrawal symptoms.
	  ○ PI/r: all boosted PIs decrease methadone levels.
	  ▪ LPV/r and methadone increase risk for prolonged QT syndrome and sudden cardiac death.
	  ○ INSTIs: no significant interactions
	● **ARV interactions with buprenorphine**
	  ○ ATV/r and DRV/r increase concentrations of buprenorphine or its active metabolites and may increase risk of toxicity.
	  ○ EFV decreases buprenorphine levels substantially.
	  ○ No known significant interactions with other ARVs
	● Rifampicin and Rifapentine decrease levels of methadone and buprenorphine and may induce withdrawal symptoms.
	● INH can be used safely with methadone or buprenorphine
	● **Management of Drug-Drug Interactions (Annex 13)**

Monitoring ART	● PWID on ART require more frequent monitoring and support to ensure adherence to treatment and harm reduction interventions, assessment for and management of adverse drug reactions or drug-drug interactions ● Ongoing monitoring should also include screening for other illicit substance/drug use.

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, otorrhea, 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 (<1,000/mm^3), or thrombocytopenia (<30,000/mm^3) 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 leukoencephalopathy PML) • HIV encephalopathy

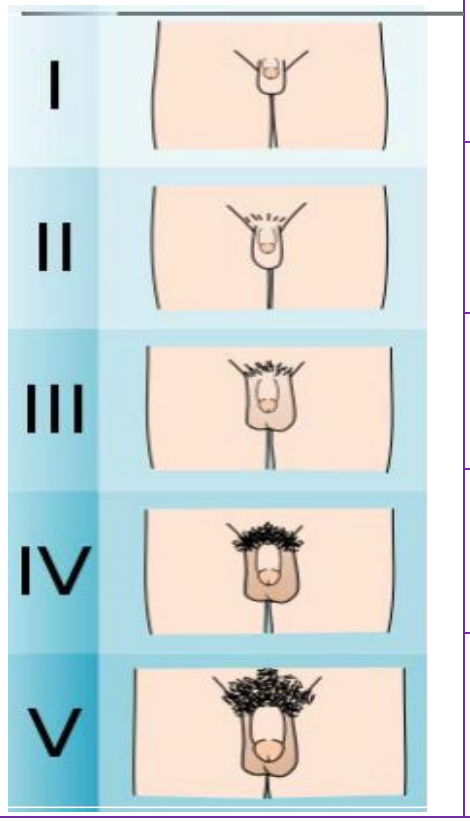
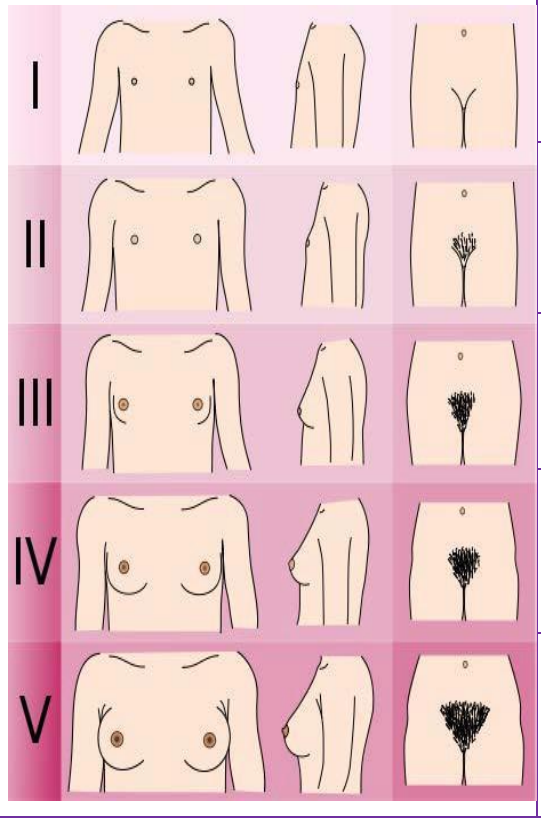
NOTE: WHO Clinical Staging should be carried out only on children confirmed (by serology or DNA PCR) to be HIV infected

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

Stage 1	**Stage 2**
• Asymptomatic • Persistent Generalized Lymphadenopathy (PGL)	• Moderate unexplained weight loss (< 10% of presumed or measured body weight) • Minor mucocutaneous manifestations (seborrheic dermatitis, papular pruritic eruptions, fungal nail infections, recurrent oral ulcerations, angular cheilitis) • Herpes zoster • Recurrent upper respiratory tract infections (sinusitis, tonsillitis, bronchitis, otitis media, pharyngitis)
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)	**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 leukoencephalopathy (PML) • Any disseminated mycosis (e.g., histoplasmosis, coccidiomycosis) • Candidiasis of the esophagus 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

Annex 3: Normal Developmental Milestones in Children

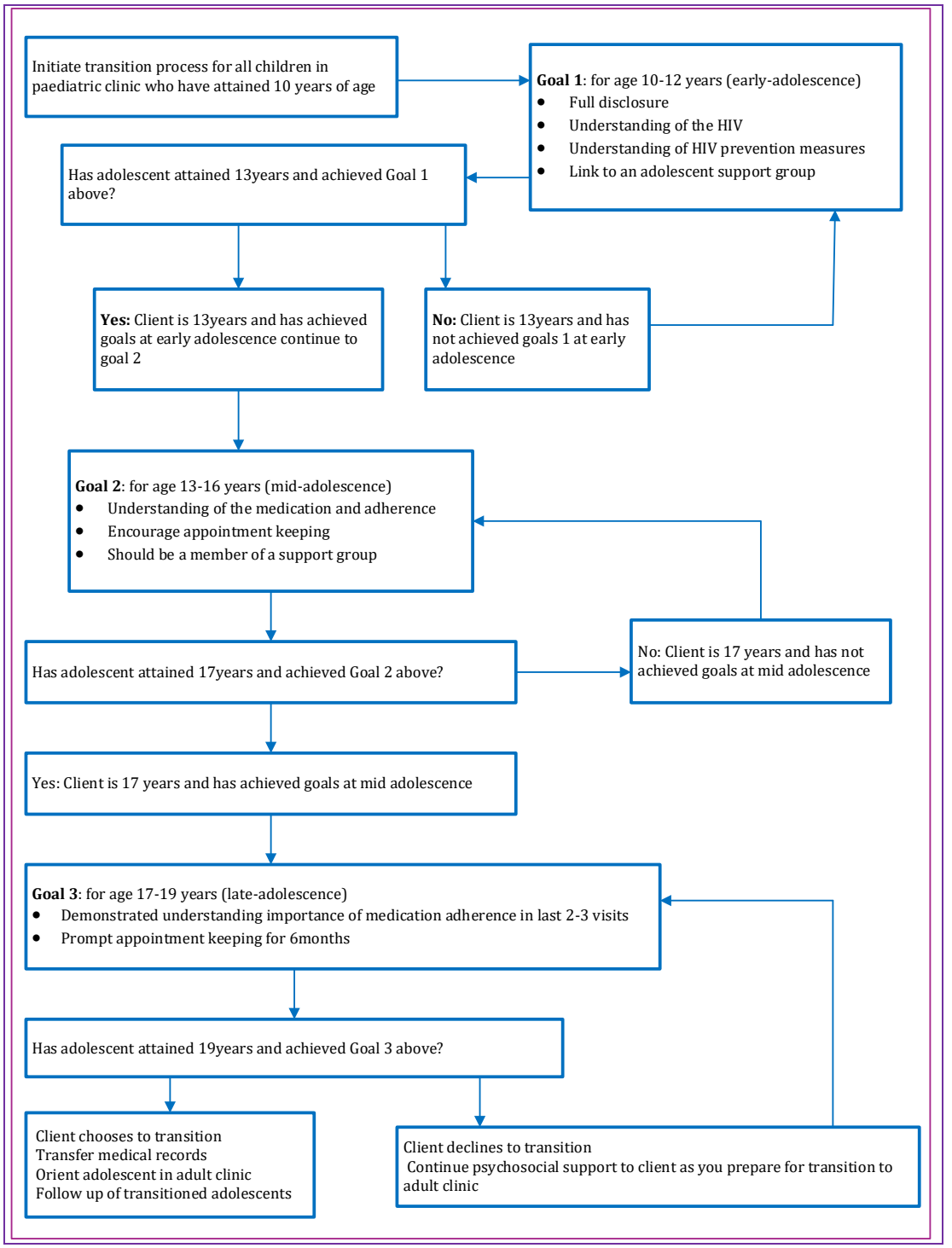
AGE	GROSS MOTOR	FINE MOTOR	WARNING SIGNS
 3 Months	**Supine:** • Pull to sit: • 45 ◦ head lag still present **Sitting: Propped up** • Flexed/C-Position • Hold head steady **Prone:** • Bears weight on flexed arms • Lifts head 45 ◦ turn head to side	**Eyes:** • Follow through 90 ◦ in lying **Hands:** • Open for longer • Shake a rattle when it is placed in the hand (not intentional) • Mouthing begins	• No visual fixation or following asymmetry of tone or movement. • Floppy/stiff • Consistent fisting • Unstable to turn or lift head • Failure to smile • Poor sucking & swallowing
 6 Months	**Supine:** • Pull to sit, no more head lag • Plays with feet • Rolls from back to tummy **Sitting:** • Unaided supported by arms **Standing:** • Bears weight on legs, equal both sides **Prone:** • Props self on straight arms, legs extended, toes turned outwards	**Eyes:** • Follow through 180 ◦ in lying • Focus on small objects **Hands:** • Hands on midline • Banging blocks against the table reaches and attains objects at will Holds and actively plays with rattle	• Floppiness • No head control • Failure to use both hands • Asymmetrical movement squint • Failure to turn to sound • Poor response to people
 9 Months	**Sitting:** • Sits without support lean forward • And sit up again without losing balance **Standing:** • Remain standing for a few seconds by holding onto an object, falls down again **Prone:** • Baby starts to crawl	**Eyes:** • Extremely accurate vision **Hands:** • Can pick up and button • Holds a block in each hand • Points	• Unable to sit • Failure to use both hands • Fisting • Squint • Persistence of primitive reflexes
 12 Months	**Sitting:** • Turns around to reach nearby toys • Sits down unaided from standing **Standing: (Walking)** • Walks forward if held by one hand • Walks around furniture sideways-cruising **Prone: (crawling)** • Crawls • Pulls up to standing by holding onto object	**Eyes:** • Looks for toys when out of sight **Hands:** • Able to pick up a button with thumb and index finger (pincer grasp) • Release on request • Hold with 1 hand and play with the other • Throws things into a container and take it out again	• Unable to bear weight on legs • Not yet crawling and pulling to stand • Abnormal grasp • Failure to respond to sound • Unable to start with solids independently
 15 Months	**Sitting:** • Stand up from sitting • Will climb on a chair and sit down **Standing: (Walking)** • Bend over to pick up an object • Squat and stand up again • Walks alone, broad base with arms in the airs **Prone: (crawling)** • Able to crawl fast and manage obstacles e.g., stairs	**Eyes:** • Hold crayon in a fist when scribbling • Turn pages of a book roughly • Hold 2 small toys in 1 hand • Put lid back on container	• Unable to bear weight on legs • Not yet walking • Abnormal grasp • Abnormal posture: floppy/spastic • Failure to respond to sound • Not yet talking
 18 Months	• Walking with more confidence • Walk, squat and pick up something, stand up and walk again • Starts running, often falls • Take few steps backwards • Runs and change direction easily • Jump off step with 2 feet together • Stand and kick a ball • Able to throw a ball	• Build a 3-cube tower • Scribbles • Holds the crayon in a fist • Turn pages of a book • Page through a book page by page • Obvious hand preference • Uses lines: I, _,0 • Completes 3-piece puzzle • Remove a sweet wrapper with little help	• Failure to walk • Unable to pick up small objects e.g., buttons • Abnormal posture • Not yet talking • Unable to understand simple commands • Poor co-ordination
 36 Months	• Walk forward and backward • Walks on tip toes • Walks on straight line • Jump 2 feet together • Able to climb on chair • Catch a big ball (hugging against chest) • Holds ball above head and throws • Runs and kicks ball	• Copies the following shapes: _, I, O, T • Start coloring in, go over the lines • Pencil grip: • Holding crayon to draw (still developing) • Builds a 9-block tower • Thread big beads on a shoelace • Draw a man: at least 4 parts	• Using only single words • Ataxia

Annex 4 B: Tanner Staging of Sexual Maturity in Boys		Annex 4 A: Tanner Staging of Sexual Maturity in Girls	
Tanner Staging in	**Age Range (Year)**	**Tanner Staging in**	**Age Range (Year)**
	0-15		0-15
	10-15		8-15
	10-16		10-15
	Variable (12-17)		10-17
	13-18		12-18

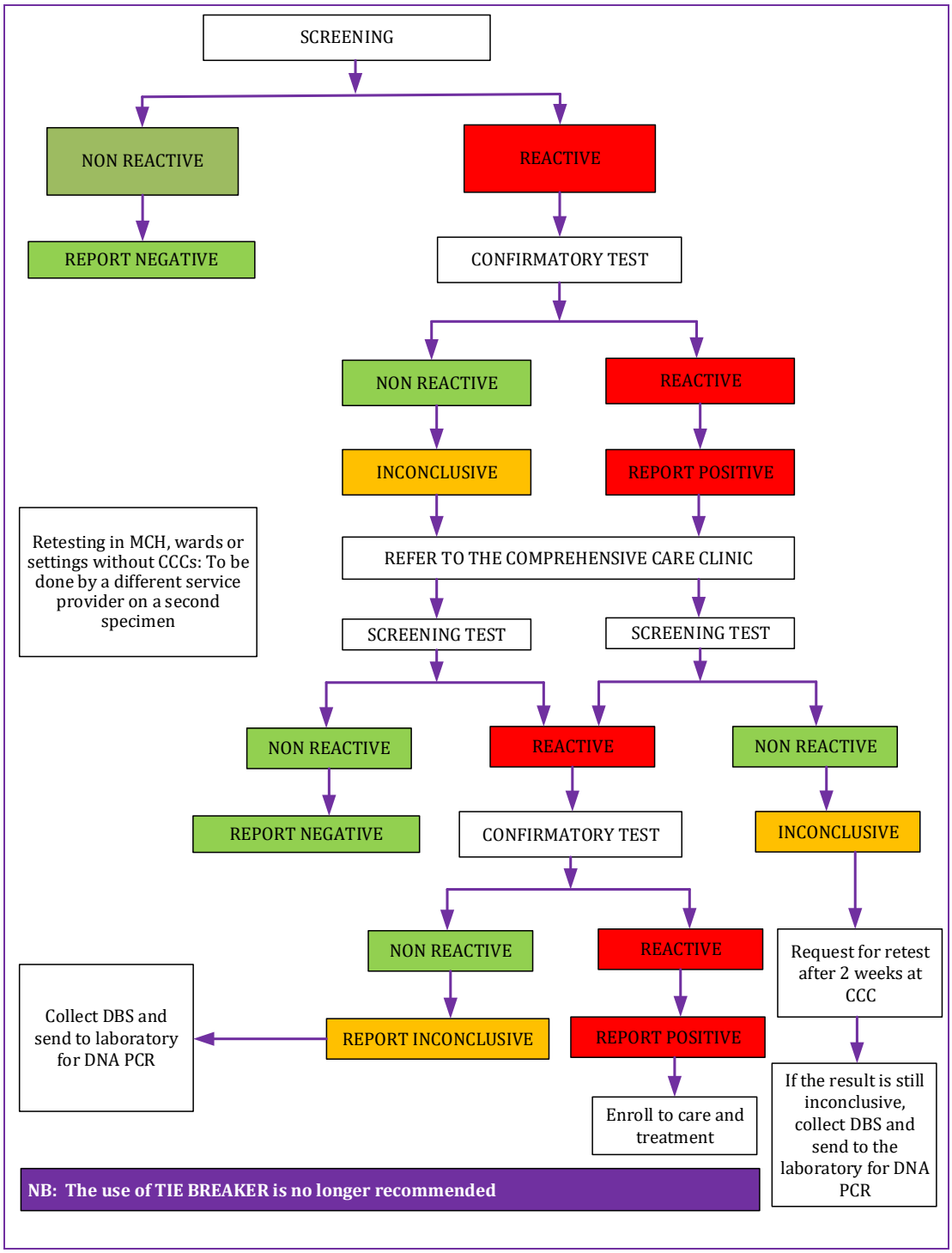
Annex 5: Age-Appropriate Disclosure for Children and Adolescents

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 keeps 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's social support system to ensure availability of sufficient support once disclosure is completed **Stage 2** Assess the child's prior knowledge about HIV 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 reactions 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, e.g., 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: Transitioning from Adolescent to Adult HIV Services



Annex 7: 2018 HIV Testing Services Algorithm



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

Annex 8: Cont.

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 a lot 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 3 months
  - After 3 months of treatment, we expect the amount of virus in your body to be undetectable; if your VL is detectable then we have to discuss the reasons
  - Having an "undetectable" VL means the test cannot measure the virus in your blood because your ART is working, but it does not mean you are no longer infected with HIV
  - 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 again every 6 months (for children/adolescents and pregnant/breastfeeding) or annually
  - For HEI with positive PCR, we also measure viral load at the start of treatment

- **What do viral load measurements mean**
  - After being on treatment for 3 or more months, your viral load should be undetectable
  - If your viral load is undetectable, 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 detectable, 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 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 attack 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 frequently, but we will use the VL test to monitor your response to anti-retroviral treatment

Annex 8: Cont.

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 allowing the body to protect itself against opportunistic infections
  - 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 healthy 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 undetectable
  - You should practice safer sex to reduce the risk for other infections as well, 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 and the drugs stop working against the virus

Annex 8: Cont.

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 virus begins to increase to high levels again
- **What happens if the viral load increases:**
  - When the virus is allowed to increase again, it will also affect your immunity and reduce your CD4 count putting you at risk of opportunistic infections
  - 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
  - The risk of resistance increases 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:**
  - The ART no longer works because the virus has become resistant to it
  - If treatment fails, 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:**
  - Sometimes 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
- **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. If this occurs then contact the clinic immediately
  - The clinician will help you manage the side effects, and occasionally the ART may need to be changed

Annex 8: Cont.

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 not be effective and will result in resistance and treatment failure. Never share your ART with someone else
  - For children, the dosage keeps changing as they grow and gain weight
  - 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 breakfast every day.
    - 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., 8.00 am and 8.00 pm 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 6.00 am and 8.00 pm every day)
  - If you miss a dose of ART then take your dose as soon as you remember, as long as it is not within a couple of hours of your next dose, and then return to your regular schedule. Do not take a double-dose of ART to make up for a missed dose
  - 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 sometimes 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

Annex 8: Cont.

- 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 taken ART correctly, every day, for the rest of your life?"*
- Discuss strategies to manage any expected barriers 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 enroll 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, if we have your permission
    - 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

Annex 8: Cont.

Section 9: Other medications

- What other medications will you take, in addition to ART:
  - CPT: all PLHIV should take cotrimoxazole preventive therapy once per day, in order to reduce the chance of getting other infections such as pneumonia, malaria, and diarrhoea
  - TPT: all PLHIV should receive 6 months of isoniazid preventive therapy (or another approved TPT regimen), 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 look healthy
- What can you do to improve your nutrition?
  - Eat a balanced diet from a variety of foods.
  - 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
  - Physical activity and exercise is encouraged.

Section 11: Follow-up

- How often will you need to come to the 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 be 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 3 months) is undetectable then you can be seen every 1-6 months depending on other factors that will be discussed with the clinician
  - 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 the 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 5.4) 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

Annex 8: Cont.

Section 13: Management plan

• Which investigations will you have today
  - See Table 3.2 and Table 3.5 for recommended baseline and follow-up investigations respectively
• Which medications will you start today
  - May include: ART; CPT; TPT; 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 A: 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

- 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. There are several possible reasons for this such as problems with adherence, dosing of your medications, interactions with other drugs or foods, or possible drug resistance. It is very important for us to work with you determine which may apply to you."
- 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 multiply. 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?"

Annex 9A: Cont.

Behavioural Barriers

- Review how the patient takes drugs

"Please explain how 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 a couple of hours before the next scheduled dose). 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 from 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 ARVs
- Due to 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 work on that problem?"

Annex 9A: Cont.

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:
  - 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)
  - 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 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 to the clinic on 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

Annex 9A: Cont.

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 can own them
- Some examples of addressing adherence challenges:
  - 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
  - Refer to clinician in case of side effects
  - Socio-economical barriers: move on to disclosure process; identify a treatment buddy; join a support group; refer to CBO/NGO to learn about income generating activities
  - 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

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 if 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

Annex 9A: Cont.

Session 3 (usually 2 weeks after Session 2, 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

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 if 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

Repeat Viral Load

- If the adherence is good: plan for the next VL testing after 3 months and explain possible ways forward, emphasizing the roles of the patient, the support systems and the health facility. You can continue follow-up adherence counselling sessions during the 3-month period if you and the patient think there would be a benefit to them

"If your results come back and your VL is undetectable then you will be able to continue with same ART. If your viral load is still greater than 1,000 copies/ml then you will need to switch to a new regimen, probably after doing some additional testing to see which regimen may work best for you. If your viral load is detectable but less than 1,000 copies/ml we will discuss options, including changing regimens or continuing to monitor." (Adapt to individual patient/context)

- If adherence challenges persist: plan further Enhanced Adherence Counselling Sessions before repeating the VL

Annex 9A: Cont.

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 < 50 copies/ml) CONGRATULATE the patient!!!
  - Explain the way forward: will continue with same ART regimen and repeat the VL again in 6 months
- If viral load is ≥ 1,000 copies/ml
  - Explain the way forward: will probably need to switch to a new ART regimen after discussing as an MDT, and additional testing to see which regimen may work for the patient
  - 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
- If viral load is 50 - 999 copies/ml
  - Explain the way forward: will reassess barriers to adherence, support systems, and other reasons for viremia; once reason/s for viremia have been addressed then will repeat the viral load after another 3 months of excellent adherence

Annex 9 B: Case Summary Form

MINISTRY OF HEALTH
NATIONAL AIDS AND STI CONTROL PROGRAMME
CLINICAL SUMMARY FORM

Name of Facility		**MFL Code**	
Patient CCC no. (*Do not write name*)		**Date**	
Patient Details	Date of Birth: Enrollment Date: Gender: Current Weight (Kg): Height (cm):		
Clinician's Name			
Facility Contacts	Tel:	Email:	
What is the primary reason for this consultation:			
Clinical Evaluation: history, physical, diagnostics, working diagnosis (*excluding the information in the table below*			
Complete the table below chronologically, including all ART regimens and laboratory results (and any previous history available for transfer-in patients)			

Date	CD4	HB	CrCl/ eGFR	Viral Load	Weight (z-score/BMI for children)	ARV Regimen	Reason for Switch	New OI or other clinical event

Annex 9 B: Cont.

Adherence and Treatment Failure Evaluation	
Parameters of Evaluation	**Findings**

• Number and findings of adherence counseling/assessment sessions done in the last 3-6 months including the following:
  ○ Findings from MMAS-8
  ○ Adherence barriers identified
  ○ Recommendations	

Number of home visits conducted in last 3-6 months, and findings	
Describe support structures (e.g., treatment buddy, support group attendance, caregivers) in place for this patient	
Evidence of adherence concerns (e.g., missed appointments, pill counts)	
Describe daily witnessed ingestion done in last 3-6 months (Who performed it, which tool was used, how long was session done etc.)	
Describe likely root cause/s of poor adherence for this patient (e.g., stigma, disclosure, side effects, alcohol or other drugs, mental health issues, caregiver changes, religious beliefs, inadequate preparation, etc.)	
Evaluation for other causes of treatment failure, e.g.: • Inadequate dosing/dose adjustments (particularly for children) • Drug-drug interactions • Drug-food interactions • Impaired absorption (e.g., chronic severe diarrhea)	
Other Relevant ART History	
Comment on treatment interruptions, if any	
Has Drug Resistance Testing been done for this patient? If yes, state date done and attach the detailed results	
Has facility multidisciplinary team discussed the patient's case? If yes, comment on date, deliberations and recommendations (indicate how treatment failure was established and confirmed, proposed regimen and dosage, current source of drugs if patient already on 3rd line)	
MDT members who participated in the case discussion (names and titles)	

Annex 9 C: Enhanced Adherence Counselling Form

ENHANCED ADHERENCE COUNSELLING FORM							
(To be completed by the counsellor) • *Start each session by reviewing the adherence barriers and action plan from the previous session* • *For each session assess major barriers to adherence (cognitive, behavioral, emotional, socio-economic)*							
Session #:		Date:		Adherence % (from pill count):		MMAS-8 Score:	
Treatment motivation:							
Barriers to adherence:							
Your impression about patient's current adherence:		☐ Excellent		☐ Unsure		☐ Inadequate	
Adherence plan:							
Next appointment date:							

Annex 9 D: Home Visit Checklist

HOME VISIT CHECKLIST		
Patient Name	Tel No:	Sex: M F
Family Member	Tel No:	Sex: M F
Physical Landmark:		File No.

This checklist is not all-inclusive but highlights critical areas that can affect adherence.

	Areas to Assess and Discuss	Comments
I	Is the patient independent in the activities of daily living (e.g., feeding, grooming, toileting) [1]	
2	Are the patient's basic needs being met (e.g., clothing, shelter, food) [1]	
3	Has the patient disclosed their HIV status to other household members	
4	How are the patient's ARVs stored and taken?	
5	Does the patient receive social support from household members	
6	Does the patient receive social support in the community e.g., linked to OVC, income generating activities, community-based support group, CBO, cash transfer program?	
7	Is the patient linked to non-clinical services (e.g., spiritual, legal or nutritional)	
8	Does the patient have mental health issues that need to be addressed (use PHQ9 to screen for depression), or use drugs or alcohol?	
9	Is the patient suffering from a stressful situation or significant loss/grief?	
10	Is the patient having any side-effects from the medications?	

Annex 9 E: Management Protocol for Patients Switching to 3rd Line ART

Management Protocol for patients switching to 3rd line ART

Pre – Initiation MDT Meeting

- Confirm what 3rd line ARV regimen is prescribed, its availability and the management plan
- Assign a case manager to patient

Initiation of 3rd Line ART

- **Triage**
  - Record vital signs and take actions as needed

- **Adherence support**
  - Conduct patient education on the new ART regimen: Treatment goals, dosing, drug interactions and potential side effects and adverse events
  - Conduct adherence assessment and counselling
  - Link patient to adherence support systems

- **Clinical assessment**
  - Take history and conduct physical examination
  - Complete clinical encounter form and MOH 257 (Green Card)
  - Manage any co-infection and co-morbidities
  - Review for potential drug interactions and contraindications
  - Conduct adherence assessment and review adherence support systems including daily witnessed ingestion plan
  - Reinforce patient education messages on new regimen
    - Currently limited future treatment options
    - Need for perfect adherence (>95%)
    - Dosing schedule and timing
    - Potential side effects and what the patient should do
  - Prescribe new regimen for 2 weeks
  - Confirm dosing as per the weight (for ≤15)
  - Continue other medication e.g., CPT, OI treatment etc.

- **Dispensing**
  - Confirm ARV dosing as per the weight (for ≤15)
  - Conduct medication use counselling
  - Dispense 3rd Line ARVs for 2 weeks
  - Check for possible drug interaction

- **Community follow up**
  - Link all patients to support group, CHV/CHA
  - Plan for home visits as required

Annex 9 E: cont.

Patient Follow Up after Treatment Initiation

- **Frequency**
  - First follow-up should be within 2 weeks of initiation of 3rd line ART
  - Subsequent visits should be monthly (or more frequent) until confirmed viral suppression at 6 months
  - Thereafter, follow-up can be 1-3 monthly

- **Triage**
  - Record vital signs and take action as needed

- Adherence Support (adherence should be reinforced during every clinic visit, in addition to enhanced adherence counselling sessions)
  - Review and address knowledge deficits on new regimen
  - Confirm understanding of adherence, conduct adherence assessment, and reinforce key adherence messages
  - Document reasons for missed doses and manage obstacles to perfect adherence. Review and reinforce adherence support systems

- **Clinical Assessment**
  - Take history and conduct physical examination
  - Complete Clinical Encounter Form and MOH 257 (blue card)
  - Manage any co-infections and co-morbidities
  - Evaluate for potential drug interactions
  - Evaluate for and manage any drug side effects and adverse events
  - Conduct adherence assessment and review adherence support systems
  - Reinforce patient education messages on new regimen
    - Review and address knowledge gaps on ART regimen
    - Need for perfect adherence (>95%)
    - Dosing schedule and timing
    - Potential side effects and what the patient should do
  - Prescribe 3rd line ARVs

- **Viral load should be conducted 3 months after change of regimen**

- **Dispensing**
  - Confirm ARV dosing as per the weight
  - Conduct medication use counselling
  - Dispense 3rd line ARVs

- **Community Follow up**
  - Review linkage to community adherence support systems
  - Conduct home visits as required
  - Continue DOTS

- **NOTE: 3rd line annual report with viral load, adherence, and outcomes to be sent to NASCOP**

Annex 10 A: Dosing of Solid and Liquid Formulations for Twice-Daily Dosing in Infants and Children 4 Weeks of Age and Older [1]

Drug	Strength of tablets	Number of tablets by weight band morning and evening										Strength of adult tablet	Number of tablets by weight band	
		3–5.9 kg		6–9.9 kg		10–13.9 kg		14–19.9 kg		20–24.9 kg			25–34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
AZT/3TC	Tablet (dispersible) 60/30 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 /150 mg	1	1
AZT/3TC/NVP[2]	Tablet (dispersible) 60/30 mg/50 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 /150 /200 mg	1	1
ABC/3TC	Tablet (dispersible) 120/60 mg	0.5	0.5	0.5	1	1	1	1	1.5	1.5	1.5	600 /300 mg	0.5	0.5
ABC/3TC/LPV/r	30/15/40/10 mg	2	2	3	3	4	4	5	5	6	6			
SOLID SINGLE FORMULATIONS														
AZT	Tablet (dispersible) 60 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 mg	1	1
ABC	Tablet (dispersible) 60 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 mg	1	1
NVP[2]	Tablet (dispersible) 50 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	200 mg	1	1
	Tablet 200 mg	–	–	–	–	0.5	0.5	1	0.5	1	0.5	200 mg	1	1
LPV/r[3]	Tablet 100/25 mg	–	–	–	–	2	1	2	2	2	2	100/25 mg	3	3
	Tablet 200/50 mg	–	–	–	–	–	–	1	1	1	1	200/50 mg	2	1
	Granules[4] 40/10 mg per sachet	2	2	3	3	4	4	5	5	6	6			
DRV[5]	Tablet 75 mg	–	–	–	–	3	3	5	5	5	5			
RAL[6]	Chewable tablets 25 mg	–	–	–	–	3	3	4	4	6	6	400 mg	1	1
	Chewable tablets 100 mg	–	–	–	–	–	–	1	1	1.5	1.5	400 mg	1	1
	Granules (100 mg/sachet)	0.25	0.25	0.5	0.5	–	–	–	–	–	–		–	–
LIQUID SINGLE FORMULATIONS														
AZT	10 mg/ml	6 ml	6 ml	9 ml	9 ml	12 ml	12 ml	–	–	–	–	–	–	–
ABC	20 mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	–	–	–	–	–	–	–
3TC	10 mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	–	–	–	–	–	–	–
NVP[2]	10 mg/ml	5 ml	5 ml	8 ml	8 ml	10 ml	10 ml	–	–	–	–	–	–	–
DRV[5]	100 mg/ml	–	–	–	–	2.5 ml	2.5 ml	3.5 ml	3.5 ml	–	–			

Notes

[1] For infants younger than 4 weeks of age refer to Table 10C for more accurate dosing information

[2] NVP dose escalation with half dose for 2 weeks when initiating ART is still recommended for infants > 2 weeks of age and not already on NVP prophylaxis to avoid toxicity from high initial NVP levels. HEI already on NVP prophylaxis who are confirmed positive can initiate full dose (twice daily) NVP without dose escalation

[3] The LPV/r heat-stable tablet formulation must be swallowed whole and should not be split, chewed, dissolved or crushed. The adult 200/50 mg tablet may be used for patients 14-24.9kg (1 tab am and 1 tab pm) and for patients 25-34.9kg (2 tabs am and 1 tab pm) who are able to swallow them whole. The 100/25 mg tablet is smaller than the adult formulation and may be used by children of lower weight bands able to swallow tablets whole.

[4] LPV/r granule formulation can be used in infants over 2 weeks of age. Transition to tablets as soon as a child is able to swallow tablets whole. The 4-in-1 ABC/3TC/LPV/r may be used after 1 month of age if the combination is appropriate and once it becomes available.

[5] DRV must be administered with 0.5 ml of RTV 80 mg/mL oral suspension if less than 15 kg and with RTV 50 mg solid formulation in children 15 to 30 kg

[6]RAL granules are approved for use in newborn children, however the administration procedure is complex and the formulation has very limited availability. If this RAL must be used, consult the regional/national clinical support center

Annex 10 B: Simplified Dosing of Child-Friendly Solid and Oral Liquid Formulations for Once-Daily Dosing in Infants and Children 4 Weeks of Age and Older[1]

Drug	Strength of tablet	Number of tablets or capsules by weight band once daily					Strength of adult tablet	Number of tablets or capsules by weight band once daily
		3–5.9 kg	6–9.9 kg	10–13.9 kg	14–19.9 kg	20–24.9 kg		25–34.9 kg
EFV[2]	Tablet (scored) 200 mg	–	–	1	1.5	1.5	200 mg	2
ABC/3TC	Tablet (dispersible) 120/60 mg	1	1.5	2	2.5	3	600 mg/300 mg	1
DTG	Tablet (dispersible) 10 mg	0.5	1.5	2	2.5	3[3]		
DTG	Tablet 50 mg	-	-	-	-	1	50 mg	1
DTG/TDF/ 3TC		-	-	-	-	-	50/300/300	1
ATV[4]	Capsules 100 mg	–	–	1	2	2	300 mg	2 (100 mg) or 1 (300 mg)
TDF[5]	Oral powder 40 mg/scoop	–	–	3	–	–	300 mg	1 (200 mg)[d] or 1 (300 mg)
	Tablets 150 mg or 200 mg	–	–	–	1 (150 mg)	1 (200 mg)		

Notes

[1]For infants younger than 4 weeks of age refer to Table 10C for more accurate dosing information

[2]EFV is not recommended for children younger than 3 years and weighing less than 10 kg. Where there are no suitable alternatives, EFV may be used in children less than 3 years weighing more than 3.5 kg (3.5-5 kg two 50 mg capsules; 5-7.5 kg three 50 mg capsules; 7.5-15 kg one 200 mg capsule).

[3]DTG dispersible tablets have higher bioavailability than film tablets and doses are not interchangeable. Children can transition to the 50 mg film tablet once they reach 20 kg. If unable to swallow the tablets whole, the dispersible tablets may be given at a dose of 30 mg daily.

[4]ATV is only approved for use in children 3 months and older. ATV single strength capsules should be administered with RTV 100 mg for all weight bands. ATV powder formulation enables administration of ATV to infants and children as young as 3 months. Infants and children 5-10 kg should be given 200 mg of ATV powder (4 packets, 50 mg/ packet) with 80 mg of RTV oral solution (1 ml)

[5]TDF is can be used in children 2 years and older. Target dose: 8 mg/kg or 200 mg/m[2] (maximum 300 m

Annex 10 C: Drug Dosing of Liquid Formulations for Twice-Daily Dosing in Infants Less than 4 Weeks of Age

Drug	Strength of oral liquid	2-3 kg	3-4 kg	4-5 kg
AZT	10 mg/mL	1 mL	1.5 mL	2 mL
NVP[1]	10 mg/mL	1.5 mL	2 mL	3 mL
3TC	10 mg/mL	0.5 mL	0.8 mL	1 mL

Notes [1] NVP for treatment can be initiated with twice daily dosing for infants < 2 weeks of age (they do not require once-daily lead-in dosing)

Annex 10 D: Simplified Dosing of INH and CTX Prophylaxis for Infants and Children Who Are at Least 4 Weeks of Age

Drug	Strength of tablet or oral liquid	Number of tablets or ml by weight band once daily					Strength of adult tablet	Number of tablets by weight band
		3–5.9 kg	**6–9.9 kg**	**10–13.9 kg**	**14–19.9 kg**	**20–24.9 kg**		**25–34.9 kg**
INH	100 mg	0.5	1	1.5	2	2.5	300 mg	1
CTX	Suspension 200/40 per 5 ml	2.5 ml	5 ml	5 ml	10 ml	10 ml	–	–
	Tablets (dispersible) 100/20 mg	1	2	2	4	4	–	–
	Tablets (scored) 400/80 mg	–	0.5	0.5	1	1	400 mg/80 mg	2
	Tablets (scored) 800/160 mg	–	–	–	0.5	0.5	800 mg/160 mg	1

Annex 10 E: TB Preventive Therapy dosing

A. Daily INH for 6 months (6H)			
Weight (Kg)	Dose (mg)	Number of 100mg INH tablets	Number of 300mg (Adult) tablet
<5	50	½ tablet	-
5.1-9.9	100	1 tablet	-
10-13.9	150	1½ tablet	½ tablet
14-19.9	200	2 tablets	-
20-24.9	250	2 ½ tablets	-
≥25	300	3 tablets	1 tablet
Adult	300	3 tablets	1 tablet

Annex 10 E: Cont.

B1. Daily INH for 6 months (6H)		
Weight (Kg)	Number of tablets (RH 75/50mg	How to reconstitute the medicine
Less than 2	¼	Dissolve one (1) tablet of RH in 20 ml of safe drinking water. Once fully dissolved. Give 5ml (¼) of this solution measured with a syringe.
2-2.9	½	Dissolve one (1) tablet of RH is 20 ml of safe drinking water. Once fully dissolved, give 10ml (½) of this solution measured with a syringe.
3-3.9	¾	Dissolve one (1) tablet of RH in 20 ml of safe drinking water. Once fully dissolved, give 15 ml (¾) of this solution measured with a syringe.
After giving the child their dose for that day, discard the rest of the solution. Prepare a fresh solution. Prepare a fresh solution every day.		
4-7.9	1	Dissolve the tablet(s) of RH in 20mls of safe drinking water. Once fully dissolved, give ALL this solution to the child
8-11.9	2	
12-15.9	3	
16-24.9	4	

B2. Daily RH for 3 months (3RH) for children ≥25kgs (To use adult formulation)	
Weight (Kg)	Number of tablets (RH 150/75mg)
25-39.9	2
40-54.9	3
55kg and above	4

C. Weekly 3HP (3HP) (For adults and adolescents ≥15 years)	
3HP products	No of Tablets
Rifapentine 150mg tabs	6
Isoniazid 300mg tabs	3
Rifapentine 300mg+Isoniazid 200mg (FDC)	3

Annex 10 E: Cont.

D. Dosage of Pyrldoxine (Vitamin B6)			
Weight (Kgs)	Dosage In mg	Number of 25mg tablets	Number of 50mg tablets
<5	6.25mg	½ Tablet 3 times a week, alternate days	-
5.0-79	12.5mg	Half a tablet	-
8.0-14.9	25mg	One tablet	Half of 50mg tablet
15kg and above	50mg	Two tablets	One 50mg tablet
Adults	50mg	Two tablets	One 50mg tablet

Annex 10 F: Ritonavir Dosing for Super-Boosting LPV/r in Children Taking Rifampicin

Dosing for RTV super-boosting of LPV/r for children receiving rifampicin-containing TB treatment*

Drug	Strength of paediatric tablets or oral liquid	Number of tablets or MLS by weight-band morning (AM) and evening (PM)										Strength of adult tablet	Number of tablets by weight band	
		3–5.9 kg		6–9.9 kg		10–13.9 kg		14–19.9 kg		20–24.9 kg			25–34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
For children able to swallow tablets														
LPV/r[b]	Tablet 100/25 mg	–	–	–	–	2	1	2	2	2	2	100/25 mg	3	3
RTV	Tablet 100 mg	–	–	–	–	1	1	1	2	1	2	100 mg	2	2
	Tablet 50 mg	–	–	–	–	2	2	3	3	3	3			
	Tablet 25 mg	–	–	–	–	4	4	6	6	6	6			
For children unable to swallow tablets														
LPV/r	Oral solution 80/20 mg/ml	1 ml	1 ml	1.5 ml	1.5 ml	2 ml	2 ml	2.5 ml	2.5 ml	3 ml	3 ml	-	-	-
	Pellets 40 mg/10 mg	2	2	3	3	4	4	5	5	6	6	-	-	-
	Granules 40 mg/10 mg sachet	2	2	3	3	4	4	5	5	6	6	-	-	-
RTV[e]	Oral solution 80 mg/ml	0.8 ml	0.8 ml	1.2 ml	1.2 ml	1.5 ml	1.5 ml	2 ml	2 ml	2.3 ml	2.3 ml	-	-	-
	Powder 100 mg/packet	-	-	1	1	1	1	1	2	1	2	-	-	-

[a] Suggested RT V dose for super-boosting to achieve the same dose as LPV in mg, in a ratio equal or approaching to 1:1. This dosing approach is supported by a study which explored this approach in young children receiving LPV/r[12].

[b] the LPV/r heat-stable tablet formulation must be swallowed whole and should not be split, chewed, dissolved or crushed. Adult 200 / 50 tablet could be used for patients 14-24.9kg (1 tab am and 1 tab pm) and for patients 25-34.9kg (2 tab am and 1 tab pm).

[c] LPV/r liquid requires a cold chain during transport and storage.

[d] LPV/r pellets formulation should not be used in infants younger than 3 months. More details on the administration of LPV/r pellets can be found at https://www.who.int/hiv/pub/toolkits/iattfactsheet-lopinavir-ritonavir/en/. The dosing schedule provided applies to equivalent solid dosage forms that may become available such as LPV/r granules, which are approved by US FDA for use from 2 weeks of life.

[e] RT V oral solution dosing is based on the dosing tested in the trial that supports the use of super boosting

Annex 11: Overlapping toxicities between ARVs

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	No food restrictions	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 OR 300 mg/dose OD	No food restrictions	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 or 600mg OD	No food restrictions. 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.

Table 12 A: Cont.

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
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) Various co-formulations available or being developed	As TAF 25 mg alone or as part of co-formulated FDC	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: Use of Non-Nucleoside Reverse Transcriptase Inhibitors for Adults

Drug name	Dose (in adults)	Dietary restrictions	Major side effects	Comments
Efavirenz (EFV) Available in 200mg & 600mg tablets and as FDC with TDF/3TC	600mg OD Best taken at bedtime	Preferably taken on an empty stomach. Can be given with food, but avoid high fat meals which increase absorption.	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 (ETR) Available in tablets of 200 mg	200 mg BD	Take 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) 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	ATV 300mg / RTV 100mg OD	Take with food. Take 2 hours before or 1 hour after antacids and buffered medications such as buffered ddI (reduced ATV concentrations if administered together)	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 25ºC) for 30 days	Recommended 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 as DTG 50mg, 10mg dispersible tablet Or FDCs: ABC/3TC/DTG (600/300/50mg) and TDF/3TC/DTG (300/300/50mg)	50 mg once daily If co-administering with EFV, carbamazepine, or rifampicin, use DTG 50 mg BD If suspected or confirmed INSTI resistance use DTG 50 mg BD	No food restrictions	Rare - Hypersensitivity; Hepatotoxicity especially in those with HBV and HCV infection, fatigue Insomnia, headache, diarrhea, nausea is common but usually minor and resolve with continued use	Interacts with carbamazepine, phenobarbital and phenytoin, use alternative anticonvulsants. Administer DTG at least 2 hours before or 6 hours after taking supplements or antacids containing Mg, Al, Fe, Ca and Zn. For Ca or Fe, if DTG is taken with a meal then dose separation is not required
Raltegravir (RAL)	ADULT and CHILD over 16 years, 400 mg BD	No food restrictions	Nausea, vomiting, diarrhoea, flatulence, constipation Severe skin (SJS and TEN) and hypersensitivity reactions have been reported	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)
ANTIRETROVIRALS		
Dolutegravir	Co-administration not recommended because NVP decreases levels of DTG	Co-administration not recommended because EFV decreases levels of DTG. If must be used together then increase DTG to 50 mg BD when co-administered with EFV
Raltegravir	No interaction or not studied	Efavirenz decreases RAL plasma levels but it is unlikely to be clinically significant
Atazanavir/ritonavir	Co-administration not recommended because ATV/r may increase the serum concentration of NVP leading to increased risk of toxicity, and NVP decreases the serum concentration of ATV/r which may lead to resistance and treatment failure	Co-administration not recommended because EFV decreases the serum concentration of ATV/r which may lead to resistance and treatment failure
Lopinavir/ritonavir	Co-administration not recommended because NVP decreases levels of LPV/r	AVOID: this combination increased risk of prolonged-QT syndrome and sudden cardiac death
Darunavir/ ritonavir	No significant interaction when NVP is combined with ritonavir-boosted darunavir	Co-administration not recommended because DRV/r may increase the serum concentration of EFV leading to increased risk of toxicity, and EFV decreases the serum concentration of DRV/r which may lead to resistance and treatment failure

Annex 13 A: Cont.

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
Bedaquiline (BDQ)	No dose adjustment required	Do not co-administer
Delamanid (DLM)	No interaction expected	No interaction
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

Annex 13 A: Cont.

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
ANTI-HYPERTENSIVES		
Angiotensin-converting enzyme inhibitors (ACEIs): E.g. - Enalapril, Lisinopril	No known interactions	No known interactions
Angiotensin II receptor blockers (ARBs): e.g., Losartan, Telmisartan	Telmisartan, Candesartan: None Losartan: Potential interactions with all NNRTIs, net effect of interaction difficult to predict, use with caution	Telmisartan, Candesartan: None Losartan: Potential interactions with all NNRTIs, net effect of interaction difficult to predict, use with caution
Beta blockers: e.g., Atenolol, Carvedilol and Propranolol	No known interactions	No known interactions
Calcium channel blockers (CCBs): e.g., Nifedipine, Amlodipine and Felodipine	Potential interaction with all NNRTIs: Metabolism of CCBs is induced by EFV or NVP, blunting antihypertensive effect: higher starting dose of CCB may be required	Potential interaction with all NNRTIs: Metabolism of CCBs is induced by EFV or NVP, blunting antihypertensive effect: higher starting dose of CCB may be required
Diuretics: E.g., HCTZ, Indapamide. Furosemide and Spironolactone	No known interactions	No known interactions
Others: Alpha blockers: Methyldopa, Hydralazine	No known interactions	No known interactions

Annex 13 A: Cont.

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 (ATV)	Ritonavir (RTV)	Darunavir (DRV)	Lopinavir (LPV)
ANTIRETROVIRALS				
EFV	Co-administration not recommended because EFV decreases the serum concentration of ATV/r which may lead to resistance and treatment failure	See interaction with specific ritonavir-boosted PI	Co-administration not recommended because DRV/r may increase the serum concentration of EFV leading to increased risk of toxicity, and EFV decreases the serum concentration of DRV/r which may lead to resistance and treatment failure	AVOID: this combination increased risk of prolonged-QT syndrome and sudden cardiac death
ETR	No significant interaction	See interaction with specific ritonavir-boosted PI	No significant interaction	No significant interaction
DTG	No significant interaction	See interaction with specific ritonavir-boosted PI	No significant interaction	No significant interaction
RAL	ATV/r may increase RAL levels but interaction in not clinically significant	See interaction with specific ritonavir-boosted PI	No significant interaction	No significant interaction

Annex 13 B: Cont.

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
Rifapentine	Do NOT co-administer	Do NOT co-administer	Do NOT co-administer	Do NOT co-administer

Annex 13 B: Cont.

Clarithromycin	Clarithromycin 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
Bedaquiline (BDQ)	Increases BDQ exposure and increases risk of prolonged QT syndrome, monitor for increased toxic effects by frequent ECG and transaminases assessment	Increases BDQ exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Increases BDQ exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Do NOT co-administer because of increased risk of prolonged QT syndrome Increases BDQ exposure, monitor for increased toxic effects
Delamanid (DLM)	Increases DLM exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Increases DLM exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Increases DLM exposure, monitor for increased toxic effects by frequent ECG and transaminases assessment	Do NOT co-administer because of increased risk of prolonged QT syndrome Increases DLM exposure, monitor for increased toxic effects
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

Annex 13 B: Cont.

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
ANTI-HYPERTENSIVES				
Angiotensin-converting enzyme inhibitors (ACEIs): E.g. - Enalapril, Lisinopril	No known interactions	No known interactions	No known interactions	No known interactions

Annex 13 B: Cont.

Angiotensin II receptor blockers (ARBs): e.g., Losartan, Telmisartan	*Telmisartan, Candesartan:* None Losartan: Potential interactions with all PIs, net effect of interaction difficult to predict, use with caution	*Telmisartan, Candesartan:* None Losartan: Potential interactions with all PIs, net effect of interaction difficult to predict, use with caution	*Telmisartan, Candesartan:* None Losartan: Potential interactions with all PIs, net effect of interaction difficult to predict, use with caution	*Telmisartan, Candesartan:* None Losartan: Potential interactions with all PIs, net effect of interaction difficult to predict, use with caution
Beta blockers: e.g., Atenolol, Carvedilol and Propranolol	Potential increase in B-blocker effect, careful dose adjustment and ECG where indicated	Potential increase in B-blocker effect, careful dose adjustment and ECG where indicated	Potential increase in B-blocker effect, careful dose adjustment and ECG where indicated	Potential increase in B-blocker effect, careful dose adjustment and ECG where indicated
Calcium channel blockers (CCBs): e.g., Nifedipine, Amlodipine and Felodipine	Potential interaction with all PIs: Metabolism of CCBs inhibited, increasing antihypertensive effect: lower starting dose of CCB may be required, monitor for excessive reduction in BP	Potential interaction with all PIs: Metabolism of CCBs inhibited, increasing antihypertensive effect: lower starting dose of CCB may be required, monitor for excessive reduction in BP	Potential interaction with all PIs: Metabolism of CCBs inhibited, increasing antihypertensive effect: lower starting dose of CCB may be required, monitor for excessive reduction in BP	Potential interaction with all PIs: Metabolism of CCBs inhibited, increasing antihypertensive effect: lower starting dose of CCB may be required, monitor for excessive reduction in BP
Diuretics: E.g., HCTZ, Indapamide. Furosemide and Spironolactone	No known interactions	No known interactions	No known interactions	No known interactions
Others: Alpha blockers: Methyldopa, Hydralazine	No known interactions	No known interactions	No known interactions	No known interactions

Annex 13 B: Cont.

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
OTHER DRUG				
Methadone	No interaction with unboosted 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

Annex 13 B: Cont.

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 13 C: Drug-Drug Interactions – INSTIs

Drugs Affected	Dolutegravir (DTG)	Raltegravir (RAL)
Efavirenz	Co-administration not recommended because EFV decreases levels of DTG. If must be used together then increase DTG to 50 mg BD when co-administered with EFV.	Efavirenz decreases RAL plasma levels but it is unlikely to be clinically significant
Etravirine	Co-administration not recommended because ETR decreases levels of DTG, unless used in combination with a PI/r (which counteracts the interaction between DTG and ETR) If must be used together without a PI/r then increase DTG to 50 mg BD when co-administered with ETR. If used together with a PI/r then standard dose DTG is sufficient	Etravirine decreases RAL plasma levels so co-administration when using once-daily RAL is not recommended. Co-administration when using standard BD RAL dosing is acceptable
Rifampicin	Increase DTG to 50 mg BD when co-administered with rifampicin (for children, use double the standard weight-based DTG dose by administering twice daily). There is no known drug interaction between DTG and rifabutin.	Increase RAL to 800 mg BD when co-administered with rifampicin (for children, use double the standard weight-based RAL dose). Rifabutin may alter RAL plasma levels but it is unlikely to be clinical significant.
Rifapentine	Potential decreased DTG levels when co-administered with once-weekly rifapentine – no dose adjustment required unless viral load becomes detectable, in which case increase DTG to twice daily until two weeks after completion of rifapentine-based TPT	Potential increased RAL levels when co-administered with once-weekly rifapentine – no dose adjustment required but monitor for RAL toxicity
Bedaquiline (BDQ)	No interactions expected	No interactions expected
Delamanid (DLM)	No interactions expected	No interactions expected
Metformin	DTG may increase metformin plasma levels so metformin dose may need to be decreased. Limit daily metformin dose to 1,000mg. DTG does NOT require a dose adjustment is when used with metformin.	No interaction

Annex 13 C: Cont.

Drugs Affected	Dolutegravir (DTG)	Raltegravir (RAL)
Anticonvulsants -Carbamazepine -Phenobarbital -Phenytoin	Avoid use of DTG with carbamazepine, phenobarbital, or phenytoin because they decrease DTG plasma levels. If the DTG must be used in combination with any of these anticonvulsants than increase DTG dose to 50mg BD and monitor viral load.	No interaction
Mineral supplements and antacids containing cations (e.g., calcium, iron, zinc, magnesium, aluminum), including prenatal vitamins	Administer DTG at least 2 hours before or 6 hours after taking any of these supplements (note: if taking DTG with a meal then it is safe to take at the same time as prenatal vitamins, calcium, or iron) There are no drug-drug interactions between DTG and proton pump inhibitors or H2 blockers used for gastritis.	Do not use calcium, magnesium and aluminum containing antacids with RAL.
Methadone	No interaction	No interaction

Annex 14: Health Facility Assessment to Provide Community ART Distribution

Health Facility Assessment to Provide Community ART Distribution*			
Facility name:	**MFL code:**	**Date of assessment:**	
Health system domains for community ART distribution			Yes/No
Leadership: Has the facility identified a focal person to oversee community-based ART distribution?			
Finance: Does the facility have resources to implement and monitor community-based ART distribution?			
Human Resources for Health: Has the facility identified appropriate personnel to distribute ART (peer educators, lay counselors and /or Community Health Volunteers)?			
Does the facility have capacity to train ART distributors?			
Service Delivery: Has the facility achieved a routine viral load monitoring uptake of ≥ 90%?			
Has the facility established a facility-based system for fast-track ART distribution?			
Commodity Management: Does the facility have ≥ three months of ART available on site?			
Has the facility identified a focal person to pre-pack and label ART for community distribution?			
Health Information Systems: Does the facility have an established system to monitor patient level outcomes, specifically retention, loss to follow-up, mortalities and viral load suppression?			
Is the facility able to establish recording and reporting systems for community ART?			
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:	

*None of these criteria are absolute requirements for implementation of community-based ART distribution; implementation can be considered even if some criteria are not met, as long as a plan is in place to address and monitor gaps

Annex 15: Creatinine Clearance

Formula for calculating creatinine clearance for adults:

$$GFR_{Cockcroft} = \frac{(140 - age) \times mass\ (kg)\ [\times 1.23 \text{ if male}]\ [\times 1.04 \text{ if female}]}{mol/l)}$$

Formula for calculating creatinine clearance for children and adolescents (up to 19 years old):

eGFR = *k* x height (cm)/ serum creatinine (mg/dL)

k = 0.45 for infants < 1 year old

k = 0.55 for children (1 – 10 years)

k = 0.55 for female adolescents (11-19 years)

k = 0.70 for male adolescents (11-19 years)

Annex 16: Immune Reconstitution Inflammatory Syndrome

Immune Reconstitution Inflammatory Syndrome (IRIS)

Definition:

IRIS is a paradoxical inflammatory reaction against a foreign antigen (alive or dead) in patients who have started ART with reconstitution (improved functioning) of their immune system. The immune system, once it regains some function, is now able to respond against the foreign antigen.

Classification:

- **Unmasked IRIS:** appearance of a previously undiagnosed opportunistic infection (OI) following ART initiation (or switch of ART to a suppressive regimen)
- **Paradoxical IRIS:** worsening of a previously diagnosed disease after ART initiation (or switch of ART to a suppressive regimen)

Risk Factors for IRIS:

- 10-20% of patients who start ART with advanced immunosuppression (refer to Chapter 3) experience clinical deterioration during the first few months due to IRIS
- High risk patients include:
  - Advanced immunosuppression (WHO Stage 3 or 4, or CD4 count ≤ 200 cell/mm3 (or CD4% ≤ 25% for children ≤ 5 years old))
  - Patients with a diagnosed opportunistic infection like TB, MAC, CMV, and PCP
  - Low baseline CD4 (CD4 count ≤ 50 cell/mm^3 or CD4% ≤ 10%)
  - High baseline viral load
  - Substantial increase in CD4 count and drop in viral load after starting ART

Patient evaluation:

In addition to the clinical evaluation for PLHIV outlined in Table 3.1, emphasis should be placed on the following areas during the patient evaluation:

History:

Symptoms and current ARV history:

- Specific systemic symptomatology
- Date of ARV initiation
- Regimen
- Reason for substitution / switch from previous ART if not first line
- Adherence to ART and other ongoing treatment
- HIV viral load
- CD4 count

Prior History:	**History of treatment of opportunistic infections:**
• ARV toxicity • Drug-drug interaction • CD4 count • HIV viral load	• Date of initiation of treatment • Duration of therapy • Clinical response to treatment • Adherence to the OI treatment • Any default to treatment • Resistance to treatment

Annex 16: Cont.

Physical Examination:

Vital signs assessment: Temperature, Heart Rate, Blood Pressure, Respiratory rate

Conduct a detailed systemic examination:

- Emphasis should be placed on the system(s) which are primarily affected (Table 3.1)

Investigations

- All patients with advanced HIV disease should be screened for common OIs including TB, cryptococcal meningitis and other common OIs depending of their presenting signs and symptoms

.

Diagnosis of IRIS

- IRIS should be suspected any time a patient has clinical deterioration weeks to months after starting ART (or switching to a suppressive ART regimen)
- Clinical deterioration usually occurs within 4-8 weeks of initiation or change of ART (but can be months afterwards)
- IRIS has varied clinical presentations due to multiple possible pathogens that the immune system may be reacting to, and various immune system reactions; there are generally clinical manifestations consistent with an inflammatory condition
- A high level of suspicion is required when making a diagnosis of IRIS, which is generally one of exclusion
- Rule out the possibility of drug reaction, patient non-adherence to OI treatment, persistently active infection and/or drug resistance to OI treatment
- There could be localized tissue inflammation with or without systemic inflammatory response

Major and Minor Presentations of IRIS

Major presentation	Minor presentation
Tuberculosis (TB) Mycobacterium avium complex (MAC) Cryptococcal meningitis Cytomegalovirus (CMV) retinitis Hepatitis B or C virus Progressive multifocal leukoencephalopathy (PML) Kaposi's sarcoma Cerebral toxoplasmosis Autoimmune diseases	Herpes simplex virus (HSV) and varicella zoster virus (VZV) Nonspecific dermatologic complications such as folliculitis, oral and genital warts

Annex 16: Cont.

Management of IRIS

IRIS management is dependent on severity of symptoms and the following general guidance is recommended:

Severity of IRIS	Definition	Management
Mild	• Resolves over time in most patients • Symptomatic treatment is often sufficient	• Treat the OI and manage the associated symptoms • Treat IRIS-associated inflammation: o NSAIDS for discomfort associated with mild inflammation / fevers o Inhaled steroids for bronchospasm or cough associated with mild pulmonary inflammation • Surgical intervention: o Drainage of abscesses o Excision of inflamed and painful lymph nodes
Severe	• Threatens a patient's functional state • Cause permanent disability • Potentially lead to death Examples: • Decline in pulmonary capacity from TB or MAC infection • Neurologic complications from cryptococcal infection • Loss of vision from CMV retinitis infection	• Treat the OI and manage the associated symptoms • Manage the IRIS-associated inflammation: o If NOT KS: give 1 to 2 mg/kg prednisone for 1 to 2 weeks. Follow with a period of individualized tapering of the dose o **Do not use corticosteroids for the management of KS-related IRIS** • Closely monitor patients on corticosteroid therapy for: o Hyperglycemia o Hypertension o Mental status changes o Avascular necrosis o Worsening of an existing infection o Predisposition to a new infection (e.g., TB and CMV)

Annex 17: HTS Adult Screening Tool Enhancement

	County: …….. Sub-County Name: …….. Facility Name:…….. Facility MFL Code: ……..
1	Today's Date …….. Gender M F AGE ☐
2	Have you ever tested for HIV Before? If yes, what was the HIV result? Positive ☐ Negative ☐ If positive, Date of ART initiation. …….. (Not eligible for testing) If Negative, when is the most recent HIV test? Months ☐ Years ☐
3	If negative or status unknown, determine behavioural risk of HIV acquisition by asking the following questions: • Unprotected sex within the last 3 months • Unknown status of the sexual partners • New sexual partner within the last 3 months • Multiple sexual partners • intergenerational relationships • Symptoms of sexually transmitted infection (refer to MoH syndromic chart) or history of STI • Pregnancy for females • Assessing history of recurrent illnesses without resolution of symptoms, acute or chronic febrile illness (symptoms ≥ 14 days) and any other conditions suggestive of HIV
4	Possible Risk exposures: • Defilement • Traditional /non-medical procedures e.g., scarification, plastic tooth extraction, Circumcision, uvulectomy etc.
5	If Risk noted or clinical assessment suggest HIV, eligible for testing
6.	If No risk noted and assessment does not suggest, not eligible
Name	Institutions

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AMPATH Plus	MOH Division of NCCP
ARC Kenya	MOH NASCOP
Center for Disease Control	MOH NHRL
CIHEB Kenya	MOH NLTP
Clinton Health Access Initiative	Moi University
Council of Governors	Nairobi Metropolis Services
Department of Defence	NEPHAK
DnDI	UCSF
EGPAF	UNICEF
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Kenyatta National Hospital	USAID
Mater Hospital	World Health Organization

Kenya HIV Prevention and Treatment Guidelines, 2022

2022 Edition

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