THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

NATIONAL AIDS CONTROL PROGRAMME

NATIONAL INTEGRATED HIV, VIRAL HEPATITIS AND STI MANAGEMENT GUIDELINES

September 2023.

FOREWORD

In our unwavering commitment to combat the HIV epidemic, Tanzania is diligently applying a comprehensive strategy that encompasses prevention, care, treatment, and support, while adhering to global benchmarks. Recent data from UNAIDS underscores our notable progress: 95% of individuals living with HIV (PLHIV) are cognizant of their status, with 94% of informed adults actively participating in antiretroviral therapy (ART), achieving a commendable 92% in attaining suppressed viral loads.

These achievements underline the collaborative efforts with diverse partners in provision and supporting HIV care provision in Tanzania.

Considering these accomplishments and the insights gained from collective experiences, the revision of the National guidelines for HIV/AIDS management has been deemed a necessary measure to sustain current progress and to meet both global and national objectives.

The 2023 National Integrated Guideline for Management of HIV and AIDS, Hepatitis and STI is a sixteen-chapter consolidated document that provides general and specific guidance on the diagnosis of HIV infection, Hepatitis and STI; the use of antiretroviral (ARV) drugs for preventing and treating HIV infection, and Hepatitis, and the care of people living with HIV using a broad range of current technological innovations, interventions, and evidence-based practices. This guideline is structured along the continuum of HIV testing, prevention, treatment, and care in specific groups.

These guidelines collectively provide a comprehensive guide for healthcare providers and professionals involved in HIV and AIDS care and treatment in Tanzania, ensuring high-quality services for PLHIV across various stages of their condition.

Prof Mary Nagu

Chief Medical Officer

ACKNOWLEDGEMENTS

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We would like to recognize all who participated in the revision of the Guidelines, we extend our profound appreciation to Dr. Boniface Silvan, Prof. Samwel Kalluvya, and the secretariat for their outstanding coordination and support. Special recognition is also extended to Dr. Siraji Shabani who spearheaded the development of this guideline. Your commitment and dedication were indispensable in ensuring the timely completion of this critical task.

The Ministry commends the collaboration of organizations under the WHO, US Government partners and other UN family, and all participants listed in Annexes XV, who worked tirelessly alongside the National AIDS Control Program during the revision of the Guidelines.

Furthermore, we extend our commendation to all other institutions and organizations whose partnership with the National AIDS Control Programme greatly contributed to the production of this document.

Dr Catherine
Head of Programs

EXECUTIVE SUMMARY

The 2023 National Integrated Guideline addresses HIV, Hepatitis, and STI in sixteen chapters. It provides guidance on diagnosis, ARV drug use, and care for those living with HIV. This guideline covers the entire spectrum of HIV care, from testing to treatment, with a focus on specific groups.

Chapter I: Overview of HIV and AIDS Service Provision in Tanzania: This chapter introduces the basic facts about HIV, its transmission, and the pathophysiology of HIV infection. It outlines the HIV epidemic in Tanzania and delves into establishing care and treatment services at health facilities, including staffing, scheduled and unscheduled visits, and procedures for care recipients returning after treatment interruptions.

Chapter II: Prevention and Testing of HIV: This chapter covers prevention strategies, including combination prevention interventions and biomedical prevention methods. It details HIV testing services, successful referral and linkage services, and differentiated HIV testing services to cater to different populations.

Chapter III: Antiretroviral Therapy for Adolescents and Adults: This chapter discusses initiating ART for adults and adolescents, including first-line and second-line ART regimens. It also addresses changing antiretroviral therapy, monitoring PLHIV on ART, and clinical management of HIV and AIDS among elderly individuals.

Chapter IV: Paediatric HIV and AIDS-Related Conditions: This chapter focuses on diagnosing HIV infection in children, initiating ART in pediatric patients, monitoring children on ART, and various models for improving the quality of care for children living with HIV.

Chapter V: Prevention of Vertical Transmission of HIV, Syphilis, and Hepatitis B: This chapter covers a comprehensive approach to preventing vertical transmission, including testing and counseling for pregnant and breastfeeding women, care during labor and delivery, post-delivery care, and management of exposed infants.

Chapter VI: Adherence Preparation, Monitoring, Retention, and Support: This chapter discusses factors influencing adherence, barriers to adherence, and various counseling approaches to enhance adherence. It also introduces community-led adherence support programs.

Chapter VII: Community Based HIV Services (CBHS): This chapter introduces community-based HIV services, focusing on the roles, training, and contributions of community-based healthcare providers in the HIV response.

Chapter VIII: TB/HIV Co-Infection: This chapter emphasizes collaborative activities for TB/HIV co-infection, recommended tests for TB diagnosis, TB preventive measures, infection control, and drug-resistant TB.

Chapter IX: Management of Advanced HIV Disease and Opportunistic Infections: This chapter addresses the screening, diagnosis, and management of common opportunistic infections in PLHIV with advanced HIV disease.

Chapter X: Hepatitis B and C Co-Infections: This chapter covers hepatitis B and C co-infections, including screening, clinical evaluation, treatment, and monitoring.

Chapter XI: Screening and Management of Sexually Transmitted and Reproductive Tract Infections Other Than HIV: This chapter discusses approaches to screening and managing STIs/RTIs.

Chapter XII: Integrated Management of Non-Communicable Diseases (NCDs) in HIV: This chapter provides insights into screening, diagnosis, and management of non-communicable diseases among PLHIV.

Chapter XIII: Mental Health Conditions in HIV and AIDS: This chapter addresses mental health complications associated with HIV, including primary mental health disorders and alcohol/drug use.

Chapter XIV: Pharmaceutical and Laboratory Services: This chapter covers rational use of HIV and AIDS commodities, supply chain management, pharmacovigilance, and HIV/AIDS laboratory services.

Chapter XV: Nutrition in HIV and AIDS: This chapter emphasizes the importance of nutrition for PLHIV, discussing nutrient requirements, healthy eating, and nutritional assessment.

Chapter XVI: Monitoring and Evaluation: This chapter outlines the key components of HIV/AIDS monitoring and evaluation, including data recording and reporting.

These chapters collectively provide a comprehensive guide for healthcare providers and professionals involved in HIV and AIDS care and treatment in Tanzania, ensuring high-quality services for PLHIV across various stages of their condition.

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LIST OF ABBREVIATIONS

3TC	Lamivudine
AA	Adherence Assistant
AFB	Acid-Fast Bacilli
AIDS	Acquired Immune Deficiency Syndrome
ALAT	Alanine Aminotransferase
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
ATV	Atazanavir
AZT	Zidovudine
BBP	Blood Borne Pathogen
BCG	Bacille Calmette-Guerin
BMI	Body Mass Index
BP	Blood Pressure
CART	Combination Antiretroviral Therapy
CBHS	Community Based HIV and AIDS Services
CBO	Community Based Organization
CHMT	Council Health Management Team
CHTC	Couples HIV Testing and Counselling
CHW	Community Health Worker
CMV	Cytomegalovirus
CNS	Central Nervous System
CoC	Continuum of Care
CPT	Cotrimoxazole Preventive Therapy
CrAg LFA	Cryptococcal Antigen Lateral Flow Assay
CrAg	Cryptococcal Antigen
CSF	Cerebrospinal Fluid
CTC	Care and Treatment Clinic
CTU	Care and Treatment Unit
CTX	Cotrimoxazole
DACC	District AIDS Control Coordinator
DBS	Dried Blood Spots
DMO	District Medical Officer
DOTS	Directly Observed Therapy, Short course
DRV	Darunavir
DTG	Dolutegravir
ECG	Electrocardiogram
EFV	Efavirenz
EIA	Enzyme Immunoassays
EID	Early Infant Diagnosis
EPI	Expanded Programme of Immunization
EPTB	Extra-pulmonary Tuberculosis

ESR	Erythrocytes Sedimentation Rate
ETR	Etravirine
FBO	Faith Based Organization
FBP	Full Blood Picture
FDC	Fixed Dose Combination
FEFO	First to Expire, First Out
FP	Family Planning
GART	Genotypic Antiretroviral Resistance Testing
GoT	Government of Tanzania
HBA	Home Birth Attendant
HBC	Home Based Care
HBCT	Home Based HIV Counselling and Testing
HCP	Health Care Provider
HF	Health Facility
HIV RNA	Human Immunodeficiency Virus Ribonucleic Acid
HIV	Human Immunodeficiency Virus
HIVST	Human Immunodeficiency Virus Self Testing
HLD	High-Level Disinfectants
HSV	Herpes Simplex Virus
HTC	HIV Testing and Counselling
HVL	HIV Viral Load
IEC	Information Education and Communication
ILS	Integrated Logistic System
IMCI	Integrated Management of Childhood Illnesses
INH	Isoniazid
INSTI	Integrase Strand Transfer Inhibitors
IPD	In-Patient Department
IPT	Isoniazid Preventive Therapy
IRIS	Immune Reconstitution Inflammatory Syndrome
KS	Kaposi Sarcoma
KVP	Key and Vulnerable Population
LAM	Lipoarabinomannan
LFT	Liver Function Test
LIP	Lymphocytic Interstitial Pneumonitis
LPV	Lopinavir
LRTI	Lower Respiratory Tract Infection
M&E	Monitoring and Evaluation
MAC	Mycobacterium Avium Complex
MAT	Medically assisted Therapy
MCH	Maternal and Child Health
MDR	Multi-Drug Resistant
MoH	Ministry of Health
MTCT	Mother to Child Transmission
MUAC	Mid-Upper Arm Circumference

NACP	National AIDS Control Programme
NGO	Non-Governmental Organization
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NRTI	Nucleoside/Nucleotide Reverse Transcriptase Inhibitors
NSAID	Non-Steroidal Anti Inflammatory Drug
NTLP	National TB and Leprosy Programme
NVP	Nevirapine
OI	Opportunistic Infection
OPD	Out-Patient Department
ORS	Oral Rehydration Salts
OST	Opioid Substitution Therapy
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PHDP	Positive Health, Dignity and Prevention
PI	Protease Inhibitors
PITC	Provider Initiated Testing and Counselling
PJP	Pneumocystis Jiroveci Pneumonia
PLHIV	People Living with HIV
PMS	Patient Monitoring System
PMTCT	Prevention of Mother to Child Transmission
PPE	Pruritic Papular Eruption/Personal Protective Equipment
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
QI	Quality Improvement
RAL	Raltegravir
RAMs	Resistance Associated Mutations
RCH	Reproductive and Child Health
RFT	Renal Function Test
RHMT	Regional Health Management Team
RoC	Recipient of Care
RTV	Ritonavir
RUTF	Ready to Use Therapeutic Food
SDM	Service Delivery Models
SOPs	Standard Operating Procedures
SP	Sulfadoxine Pyrimethamine
STGs	Standard Treatment Guidelines
STI	Sexually Transmitted Infection
TAF	Tenofovir Alafenamide
TB	Tuberculosis
TDF	Tenofovir Disoproxil Fumarate
TFDA	Tanzania Food and Drug Authority
THP	Traditional Health Practitioners
TLC	Total Lymphocyte Count
VCT	Voluntary Counselling and Testing

VIA	Visual Inspection with Acetic Acid
VL	Viral Load
VMMC	Voluntary Medical Male Circumcision
VZV	Varicella Zoster Virus
WBC	White Blood Cells
WHO	World Health Organization

CHAPTER I: THE OVERVIEW OF HIV AND AIDS SERVICE PROVISION IN TANZANIA

1.1. Basic Facts about HIV

1.1.1. Aetiology of HIV and Transmission

In Tanzania HIV infection is mainly caused by HIV-1, dominated by sub-types, A, C, D, and their recombinants. Unprotected sexual intercourse with an infected person is the main route of transmission. Other transmission routes include exposure to infected blood and blood products, or transmission from an infected mother to the unborn child in the uterus, during delivery or from breast milk. Apart from blood and genital secretions, transmission through body fluids such as cerebrospinal fluid, pleural fluid and amniotic fluids is also possible but rarely occurs. Unless blood is visibly present in saliva, sputum, sweat, tears, faeces, nasal secretions, urine, and vomits, they carry a very low risk of transmission of HIV. HIV can be transmitted through sharing of unsterilized sharps, needles and shaving tools. There is no evidence of HIV transmission through insect bites such as mosquitoes and bed bugs.

1.1.2. Pathophysiology of HIV Infection

HIV is an RNA retrovirus which enters and multiplies in the host cells in a multistep process as shown in figure 1.1 below. The virus, attaches (*Binding*) to the CD4 receptor and co-receptors (CCR5 or CXCR4) on the surface of T lymphocytes and macrophages to gain entry to the host cells. The HIV viral envelope fuses with the CD4 cell membrane (*fusion*) releasing the HIV capsid into the host cell. Inside the host cell, the virus uses reverse transcriptase to convert its genetic material (HIV RNA) to DNA genetic material (*Reverse Transcription*) which becomes integrated (with the help of integrase enzyme) into the host cell's DNA (Integration). Once integrated into the CD4+ T lymphocyte the virus uses the CD4 cells infrastructure to manufacture HIV proteins (*Replication*). The new HIV RNA and HIV proteins made by the host CD4 move towards the surface and out of the surface (*budding*) leading to death of the infected CD4 cell. Infected CD4 T Lymphocytes thus have a shorter half-life (2 days) leading to their rapid depletion and decline.

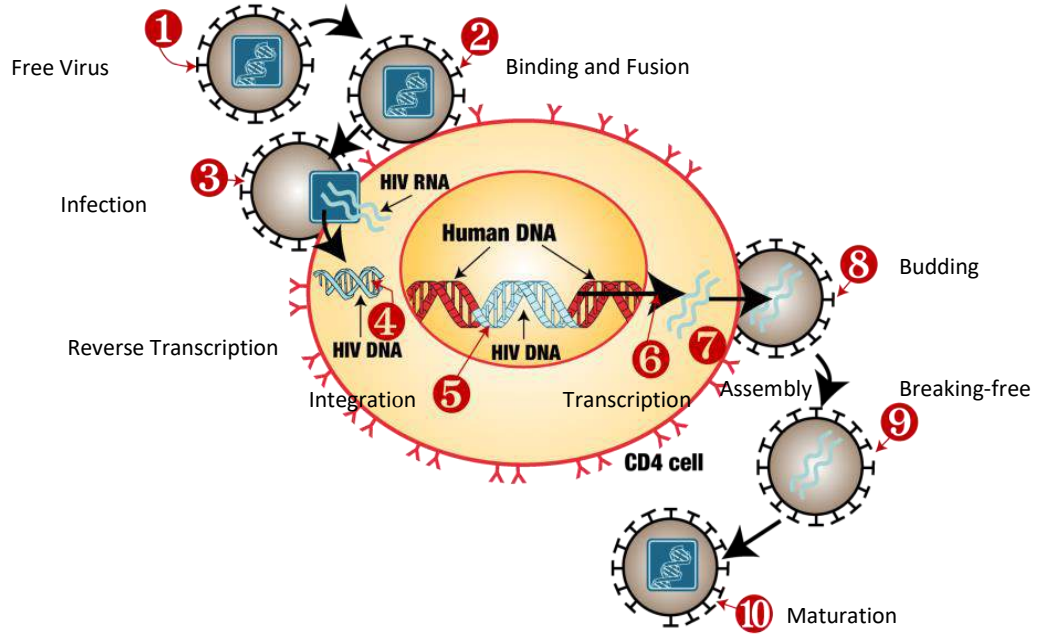
For ART-naive adults, a viral set point occurs earlier compared to children and the median time to AIDS is 10 years. Children have higher viral set points and faster disease progression compared to adults (Barbra et al, 2003), and time to AIDS can be as short as less than 2 years (REF).

Antiretroviral Therapy is directed at one or several of the following stages essential for viral replication: (1) attachment of the HIV virus to the host cell; (2) reverse transcription of viral RNA to DNA; (3) integration of the pro-viral DNA into the host cells' DNA; or (4) expression of the viral gene after it has been integrated into host cell DNA, including the transcription of more viral RNA and the translation of viral proteins[1] (*See Fig. 1.1*). It is recommended to combine antiretrovirals that target more than one part of the virus life cycle to minimize development of resistance. ARVs function by inhibiting HIV replication which results in reduction of viral load and a consequent increase in CD4+T lymphocytes recovery. In the absence of ART, disease progression goes through several stages as described by the WHO

[1] Chan DC, Kim PS (1998). "HIV entry and its inhibition". *Cell*. **93** (5): 681–4.

Clinical Staging Criteria in Annexes 1.

Figure 1.1: HIV attachment, entry, replication, and release from the host cell



1.2. HIV Epidemic in Tanzania

Table 1.1: National Summary of HIV Epidemic 2022

HIV Prevalence	
Adult General Population	5%
Adult Male (15 - 64 yrs)	3.5%
Adult Female (15 - 49 yrs)	6.5%
Number of People Living with HIV	
Total	1,715,886
Children (<15 yrs.)	73,610
New HIV Infections (2022)	
Total	35.203
Children (0-14 yrs)	4,621
AIDS-related Deaths	
Total	21,697
Children (<15 yrs.)	2,921
Mother to Child Transmission of HIV	
MTCT Rate at 6 wks	2.6%
Final MTCT Rate (Total)	6.5%

Table 1.2: National summary of HIV in Key and Vulnerable populations

KVP Group	Population Estimate	Estimated HIV prevalence
Female Sex Workers (FSW)	155,450	26.0%
Men At Risk	49,700	25.0%
People who inject drugs (PWID)	30,000	36.0%

Table 1.3: National Progress towards achieving UNAIDS 95, 95 95 Targets

	All Ages	0-14 yrs	10-19 yrs	Men (15+)	Women (15+)
1st 95	94.3%	68.2%	71.3%	83.3%	99.0%
2nd 95	98.8%	98.2%	98.4%	99.8%	98.3%
3rd 95	96.6%	90.3%	90.3%	96.5%	96.5%

1.3. Establishing Care and Treatment Services at a Health Facility

A dedicated outpatient department (OPD), support services and health care providers with well-defined roles and responsibilities should be available for provision of HIV services.

Dedicated Space for the CTC	Support Services
● Well-ventilated waiting area ● Registration area/desk ● Community-Based Health and AIDS Services (CBHS) space/desk ● Data management room ● Phlebotomy room ● Records/file designated room/space ● Medicine dispensing room ● Consultation rooms ● Counselling rooms ● Exit space/desk	● Laboratory ● Pharmacy ● +/- Radiology

Note*: *Consultation and counselling rooms should be partitioned to maintain audio and visual privacy.

Council Health Management Teams (CHMTs) in collaboration with the Regional Health Management Teams (RHMTs) should conduct a comprehensive assessment to determine the adequacy of space, availability of support services, and minimum required staff for the health facility to establish and maintain a CTC and eMTCT services using the National HIV Programme HF assessment tool (Refer Annex 2).

If a HF meets the minimum criteria for establishment of a CTC, the District Medical Officer (DMO) should inform the Regional Medical Officer (RMO) who shall request an approval and provision of a CTC code number from NACP.

If the HF does not meet the minimum criteria for establishment of a CTC, the CHMT shall identify the areas for strengthening and address them. Reassessment of the HF shall be conducted to ensure the improvement plan has been implemented. Stand-alone PMTCT sites

must follow the same procedures and use the same PMTCT code numbers for running CTC services if approved. HF which does not meet the minimum criteria can be considered as either Outreach sites or ART refill sites temporarily.

1.3.1. Staffing at CTC

The execution of CTC services requires multiple cadres. The required staff to run a CTC is composed of: Clinicians, Nurses, Laboratory Technologists, Pharmaceutical staff, Radiographers where available, and other support staff. Where shortages exist, task Sharing practises and the nurse-initiated management of antiretroviral therapy (NIMART) approach should be deployed to increase access to healthcare services.

Clinic visits for recipients of care on ART

1.3.2. Scheduled visits

a) The first six months of ART

Recipients of care should attend the Care and Treatment Clinic/PMTCT clinic monthly for the first six months for clinical, laboratory evaluation and drug refills.

b) After Six months on ART

Multi-month ARV refill appointments should be offered to RoC who have been on ART for more than six months and are established on ART. 1.6). For pregnant women who are already established on ART and are on MMD, they will continue with their MMD as standard of care for DSDM. (See table 1.6).

1.3.3. Unscheduled visits

In addition to their regularly planned checkups, it's crucial for RoCs to show up at the clinic for a clinical assessment if they develop new signs and symptoms of opportunistic infections or adverse drug reactions. The proper management needed and re-categorization of clinical stability of the RoC will be determined after clinical evaluation.

1.3.4. Interruption in Treatment

Proactive follow-up is needed by clinic team members in collaboration with home based care providers to follow up recipients of care who do not turn up for their scheduled visits. It is important to put in place and look for triggers of treatment interruption interventions throughout follow-up. Use of reminders list, promised to come diaries, appointment blocks and recipients of care healthcare provider ties which have been shown to improve adherence are encouraged.

Appointment and tracking registers should also be used effectively to identify and track recipients of care who have interrupted treatment. A good referral mechanism with a community service directory should therefore be established linking the clinic and other levels of healthcare delivery and other support services.

1.3.5. Procedures for recipient of care returning to care after Interruption in Treatment (IIT)

Interruption in Treatment (IIT) is defined as failure to attend to a Care and Treatment Clinic for ARV pick-up or clinical assessment, or a documented community visit with a community health worker, or peer from an ART refill group for greater than 28 days since the last scheduled visit.

If <6 months of Interruption in Treatment

- Perform thorough clinical review and WHO staging.
- Re-initiate ARV regimen last used by the RoC

If ≥ 6 months of Interruption in Treatment.

- Perform thorough clinical review and WHO staging
- Conduct CD4 test
- If CD4 count <350 cells/mm^3 initiate CPT
- Screen for TB and initiate TPT if eligible
- If the CD4 is < 200 cells/mm^3 offer AHD package of care (refer to Chapter IX)
- Re-initiate ARV regimen last used by the RoC
- After six months of ART, HVL should be conducted together with recategorization of the RoC as either established or not established on ART.

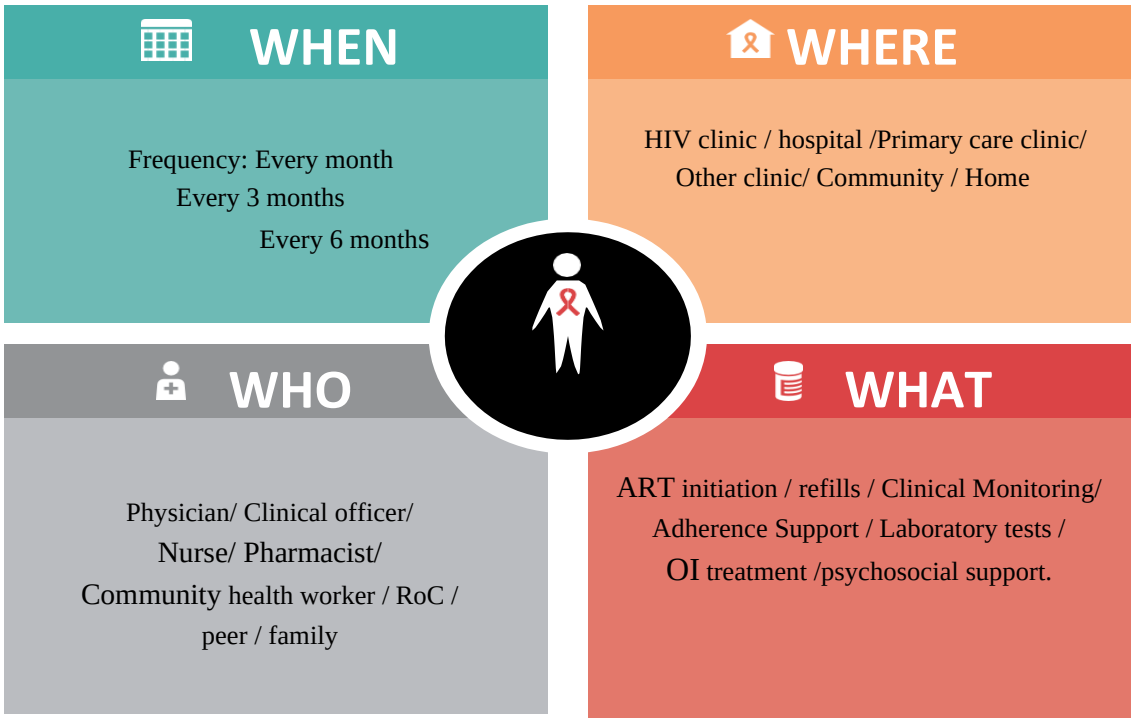
1.4. Differentiated Service Delivery Models (DSDMs)

Differentiated HIV Care is a person-centred approach[2] that simplifies and adapts HIV services across the cascade in ways that both serve the needs of people living with and vulnerable to HIV and reduces unnecessary burdens on the health system. The aim is to reflect the preferences and expectations of various groups of People Living with HIV (PLHIV). The principles of differentiated service delivery can be applied across the HIV continuum of care, including HIV prevention services, HTS, linkage to care, ART initiation, follow-up, integration of HIV care, coinfections and comorbidities.

Differentiated Service Delivery Models are designed using the building blocks approach with four delivery components: (i) the types of services delivered; (ii) the location of service delivery; (iii) the provider of services; and (iv) the frequency of services as in figure below.

[2] "Person-centred health services are an approach to care that consciously adopts the perspectives of individuals, families and communities and sees them as participants and beneficiaries of trusted health systems that respond to their needs and preferences in humane and holistic ways."

Figure 1.2: Building Blocks



a) Differentiated HIV Prevention and Testing Services

Table 1.4: Differentiated HIV Testing Services

General Population	
When	• HTS should be available for 24 hours daily for facilities providing maternity and in-patient care. • For other facilities HTS should be available in all facilities beyond official working hours depending on local needs.
Where	• Targeted testing (PITC/CITC) should be offered in all entry points of the health facilities. These include general OPD, IPD CTC, TB, STI, RCH/PMTCT, and in specialized clinics. • Facility and community-based index client testing should be offered from all facilities. • Targeted testing should also be offered as community-based outreach testing from all facilities.
Who	• Trained Peers should mobilise communities to access HTS. Trained and certified HCP to perform HTS. • Capacitated non healthcare worker's cadres (CHW, CDOs, SWOs, VHWs and CBHS providers) to conduct education and testing (including HIV self-testing) • Every facility to ensure that there is always a HCP on duty who has been trained to perform HTS.

What	• Index testing CITC • HIV self-testing PITC • Integrated approaches should be implemented in community testing strategies. This may include HIV testing, TB and STI screening, blood pressure measurement, blood glucose checks, and nutrition assessments.
Special Considerations for Children and Adolescents	
When	• Extended hours, weekends and public holidays
Where	• Targeted outreach testing to schools, colleges, street children and orphanages should be included in the outreach planning. • PITC should be offered in all entry points of the health facilities including; RMNCH, VMMC clinics adolescent-friendly settings, malnutrition, and paediatric wards.
Who	• Trained peer adolescent should mobilise adolescents for testing. • All cadres of existing health care providers should be trained to prepare DBS samples for EID testing. • All facilities should ensure there is always a HCP on duty who has been certified to provide HTS and trained to prepare DBS samples for EID testing. Trained health care providers should perform HTS and EID DBS during mobile outreach activities.
What	• Index testing CITC • HIV self-testing • Optimized PITC • Social Network Services • Integrated approaches should be implemented in community testing strategies. • This may include HIV testing, TB and STI screening, blood pressure measurement, blood glucose checks, and nutrition assessments.
Linkage to Care	
All HIV-positive RoC identified at a facility should be guided (with their consent) to the CTC for enrolment into ART care. This should ideally be done by the HCP who has performed the test or a community health worker. **Status Neutrality:** All HIV-positive RoC identified should be linked, with their consent, with a community health worker, CBHS providers or other peer networks. A duplicate referral form should be completed for anyone testing positive in the community. A copy of the referral will remain with the community-based HIV services providers for follow up of effective referral. The community-based providers should encourage the client to attend the facility of their choice. All eligible HIV negative individuals should be linked to appropriate HIV preventive services according to preventive services guidelines. Any RoC tested positive and has not been linked to care after one month should be traced. Tracing should initially be by phone followed by a home visit.	

b) Differentiated service delivery for HIV Treatment

Differentiated service delivery refill models reduce the burden on the healthcare system by optimizing scarce resources, improving treatment adherence, and increasing recipient of care satisfaction and quality of life resulting in improved outcomes, reduced costs, and increased retention in care. Its adoption should be prioritized to ensure that all RoCs receive optimal care.

Recipients of care should be assessed and categorized at initiation of ART and six months after initiation based on clinical characteristics, population group and context as shown below.

i. The clinical characteristics of the recipients of care:

At ART initiation, RoC should be assessed on their clinical characteristics, and categorised as early presenters or late presenters (with or without advanced HIV disease) as table 1.5.

Table 1.5: Recipient of care Categories during ART initiation

Category	Characteristic
1. Early presenter – Require additional adherence support to commit to lifelong ART	
	WHO stage 1 or 2 and/or CD4 ≥350 cells/mm^3
2. Late presenter	
a) Without Advanced HIV Disease	WHO stage 3 or 4 and/or CD4 ≥ 200 to <350 cells/mm^3
b) With Advanced HIV Disease	WHO stage 3 or 4 and/or CD4 < 200 cells/mm^3 All children below 5 years

At six months of ART, RoC should be assessed based on viral load and clinical characteristics and categorised as Established on ART (Stable), or not established on ART (Unstable).

Multi-month ARV prescription and dispensing should be offered to RoCs who are established on ART/Stable (including pregnant and breastfeeding women, and those on TPT) (Table 1.6.)

Table 1.6: Client's category after six months of ART initiation

Recipient of care category	Characteristics
Established on ART (Stable)	▪ Age ≥ 2 years. ▪ Have no adverse drug reactions that require regular monitoring. ▪ No current illnesses (OIs and uncontrolled co-morbidities) ▪ Have a good understanding of lifelong adherence of 95% and kept clinic visit appointments for the past six months. ▪ On First, Second-line or Third line ART with viral load of less than 50 copies/ml.
Not established on ART (Unstable)	▪ Age below 2 years ▪ Presence of an active OI (including TB) or uncontrolled co-morbidity/ies in the past six months ▪ Poor or suboptimal adherence to scheduled clinic visits in the past six months. ▪ Recent detectable HVL above 50 copies/ml, ▪ People Who Inject Drugs (PWID)

ii. **The sub-population:** ART delivery should also be differentiated based on the challenges of different sub-populations such as adults, children, adolescents, pregnant and breastfeeding women, men, key and vulnerable populations.

iii. **The context:** In order to maintain quality cART delivery, specific modifications are required when dealing with challenging settings such as conflict, urban/rural, high migration and low prevalence areas.

Table 1.7: Recommended Refill Models in Tanzania

	Individual models	Group models
At facility	● One monthly ART refill tied with clinical review, adherence counselling and lab tests according to algorithm. ● Monthly ART refill ● 3MMD ART refill fast-tracked. ● 6MMD ART refill to be done at health facilities and it's tied with clinical reviews, adherence counselling and annual viral load test ● Expanded hours (evening and weekend) ● Synchronized VL sample collection with ARV refills and VLs collected. ● Case management using an early warning dashboard (e.g. early or late missed appointments) ● Welcome back to care after interruption in care	● Family-centred models with alignment of children and caregiver appointments ● Adolescent clinics ● Operational triple zero clinics (Peer-based)
At Community	● Facility-based mobile outreaches to some individual RoC who have special needs such as those who are bedridden. ● Community ART Distribution Points, Private pharmacies, MSD community pharmacies, Private hospitals.	● Facility-based outreaches to smaller health facilities ● Facility-based groups ART refill at selected places such as WEO, VEO, churches ● Group ART delivery by expert patients or CBHSPs to stable patients

1.5 Quality of Care and Treatment Services

Healthcare services at the CTC should be associated with excellence, superiority, value, performance according to standards and compliance with requirements or specifications. Quality of care and treatment services is based on global principles such as effectiveness, safety, people-centred, timely, equity, integration and efficiency.

(a) Quality Assurance

Quality Assurance (QA): Quality assurance involves planned, step-by-step activities that let one know that health service is being carried out correctly, results are accurate, and errors are found and corrected to avoid adverse outcomes. QA can be done either internally or externally.

Internal Quality Assurance: The facility administration and CTC in charge are responsible for planning regular check-ups to ensure quality of care. This includes establishing and facilitating the work improvement teams (WITs).

External Quality Assurance: National, regional and district QA teams should visit CTC to conduct quality assurance supervision visits. During such visits, areas that might need to be strengthened will be identified and the supervising team will work with CTC staff to develop an action plan. This plan will be documented for future reference.

Quality Assurance for CTC Services: This is implemented by the WIT at the CTC. The health facility management has an obligation on ensuring that the CTC remains functional throughout.

The WIT should conduct assessment of the health facility performance on all indicators that are monitored as per the M& E framework and guidelines. The WIT should document the assessed indicators' performance using the Standard Evaluation System (SES) forms and fulfil all the criteria of data management as described in the national guidelines on management of quality HIV and AIDS data.

(b) Quality Improvement

Quality Improvement (QI) is a systematic process of assessing performance of a health system and its services, identifying gaps and causes, and introducing measures to improve procedures so as to obtain the desired outcome.

For the HIV and AIDS QI, the PDSA cycle model (i.e. a Plan, Do, Study and Act) has been selected as a reference QI model. However, other QI models such as the 5S (Sort, Set, Shine, Standardise, and sustain) and Improvement Collaborative approaches can be used for improving the quality of the HIV and AIDS services.

At regional, district and Health Facility levels, QI Teams (QIT) and Work Improvement Team (WIT) should be formed to carry out their roles and responsibilities as stipulated in the QI guidelines. The National Quality Improvement Framework (NQIF) also describes roles and responsibilities of QIT and WIT and should be referred to for these roles and responsibilities.

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CHAPTER II: PREVENTION AND TESTING OF HIV

2.1. Prevention of HIV Transmission

2.1.1 Combination Prevention Intervention

The general community (including PLHIV) should be provided with combined prevention approaches addressing social, behavioural, biomedical, and structural factors that contribute to HIV transmission. These strategies can be grouped into three main categories: (i) social and behavioural change, (ii) biomedical, and (iii) structural prevention.

Social and Behaviour Change Communications (SBCC)

Communication enables interactive engagement between SBCC practitioners and communities. The exchange of information, ideas or feelings promotes understanding and skills empowering communities to positively change their behaviours.

To change people's behaviour, SBCC providers should combine interventions that promote advocacy, communication, and social mobilization.

Advocacy aims to influence leaders to create laws that promote change, while communication can help change behaviour through various channels. Social mobilization encourages communities to support change and addresses barriers that contribute to the spread of diseases like HIV/AIDS. Drivers of social environments and behaviour can either promote health or contribute to the spread of illnesses.

Essential Behavioural Intervention; *Peer education, targeted IEC materials, demand creation, condom programming, harm reduction and risk assessment, risk reduction and skills building.*

Table 2.1: Structural and Behavioural Drivers

Structural drivers	Behavioural drivers
● Migration and mobility ● Disempowerment through poverty ● Unemployment and economic inequality ● Gender inequality ● Social and cultural norms ● Weak policies, laws and law enforcement ● Barriers to accessing prevention and other services ● An absence of services	● Stigma, discrimination, and lack of open communication around HIV and sex ● Multiple concurrent sexual partnerships ● Improper and inconsistent condom use ● Intergenerational and transactional sex ● Gender based violence ● Alcohol and drug abuse

Source: Adapted from Situation and Response Analysis Report on SBCC for HIV and AIDS, TB and STIs in SADC Member States, Coxswain Social Investment Plus.

SBCC agents, including Health care providers should be able to use SBCC as a tool to persuade and influence health behaviours in the continuum of care.

Integrate Positive Health, Dignity and Prevention (PHDP) into Care and Treatment of HIV RoC

''Positive Health, Dignity and Prevention'' promotes shared responsibility for prevention of HIV transmission, meaningful involvement of people living with HIV (PLHIV) and AIDS in

response to the epidemic and facilitation of resiliency in PLHIV to live a fulfilled and healthy life despite being HIV-positive. The PHDP package must include a synergistic combination of interventions which are integrated into routine care. The following prevention services will be available to PLHIV.

- Condom promotion and distribution
- Messaging and counselling support for social and behavioural change including: sexual risk reduction, continuity to treatment, adherence to medications, and social and sexual partner HIV testing and counselling
- HIV testing and counselling
- ART as prevention
- Voluntary Medical Male Circumcision (VMMC)
- Screening and treatment of STIs and RTIs
- Prevention of Mother to Child Transmission (PMTCT)
- Safer pregnancy counselling and family planning services integration
- Identification of social needs, referral and linkage for community-based services
- Pre-Exposure Prophylaxis

Health care providers will use the appropriate CTC2 Code to select discussion topics on regular basis.

Condom promotion and distribution

Both male and female condoms are highly efficacious and cost effective in preventing sexual transmission of HIV and other STIs, for both high-risk groups and the general population.

Condoms should be made acceptable and accessible. Condom distribution should follow the principles outlined in the Tanzania Condom Distribution Guide. Healthcare providers and other trained experts should provide education and demonstrations promoting consistent and proper condom use, including available options to both males and females. Mass media marketing and promotion of condoms should also be used to increase availability, accessibility, and utilization. Technologies such as digital vending machines should be used as has shown to be effective in reaching key and vulnerable populations as a mode for differentiated prevention of HIV.

HIV Testing for prevention

Healthcare providers should encourage RoC visiting their service delivery testing to test for HIV and know their status. Both provider initiated and client initiated can be used as described in the HIV Testing guideline. Use of HIV self-testing should also be promoted in all testing points. PLHIV should be encouraged to bring in their social and sexual partners for HIV testing and counselling.

People who test Positive for HIV and are initiated on ART remain healthy and will not transmit if they attain and maintain undetectable status. People who test negative for HIV can make decisions about health behaviours and avoid HIV risk behaviours. If eligible, HIV negative RoC should be enrolled into prevention services including pre-exposure prophylaxis (PrEP), STI services, VMMC, and condom use.

Screening for Sexually Transmitted and Reproductive Tract Infections (STIs/RTIs)
STIs/RTIs facilitate sexual acquisition and transmission of HIV infection as well as impacting the socio-economic status of families. The general community and PLHIV should be regularly screened for STI/RTI and those identified as positive, initiated on effective treatment. Syndromic management of STIs (based on defined symptoms and easily recognizable clinical signs) should be applied where appropriate. (Refer Chapter XI)

Family Planning and Safer Pregnancy Counselling Services
Healthcare providers should support people living with HIV to safely plan for pregnancies and avoiding unwanted pregnancies, respecting their right to express their sexual desires. Providers need to assess fertility desires of both male and female RoC. HIV care facilities should promote male partners involvement to ensure shared decision-making about pregnancy and contraception.

CTCs should offer integrated family planning services, including dual protection and safer pregnancy counselling, to support informed reproductive decision-making for HIV positive and discordant couples.

2.1.2 Biomedical Prevention of HIV

Infection Prevention and Control (IPC)
HIV and other Blood Borne Pathogens (BBPs) such as Hepatitis B and Hepatitis C may be transmitted in healthcare settings from patient to patient, and patient to healthcare worker, or vice versa. The following IPC measures should be implemented at the facility setting to avoid accidental transmission of HIV and other Blood Borne Infections:

- Adherence to standard precautions such as hand hygiene;
- Use of Personal Protective Equipment (PPE) such as gloves;
- Proper healthcare waste management
- Decontamination of instruments
- Cleaning and sterilization using High-Level Disinfectants (HLDs)
- Observing safe work practices

Post Exposure Prophylaxis (PEP)
PEP should be provided as soon as possible but within 72 hours after a high-risk event for HIV transmission. High-risk events include exposure to body fluids or blood, rape, unprotected sex including condom failure during sex. PEP use within the recommended timeframe can significantly reduce the risk of HIV transmission. Effective post-exposure management entails the following elements:

- Management of the exposure site,
- Exposure reporting,
- Assessment of infection Risk,
- Prompt provision of PEP starter pack (preferably within half an hour)
- Initiation of appropriate PEP regimen and/or treatment, or linkage to care
- Follow-up and counselling

When an exposure occurs, the circumstances and post exposure management procedure applied should be recorded in the exposed person's confidential form for easy follow up and care.

Recommended PEP Regimen:

For adult and adolescents: TDF+3TC+DTG once a day for four weeks and for children ABC + 3TC + DTG (based on body weight) for four weeks.

Note:

- *HIV antibody tests should be performed (preferably before) and at least after 4-6 weeks' post-exposure (i.e. at 6 & 12 weeks). Initiate on ART if the test is positive.*
- *Monitor for drug toxicity at baseline and 2 weeks after starting PEP (full blood picture (FBP), renal function test (RFT-Serum creatinine and urinalysis) and hepatic function tests (LFT- ALT*).

Pre –Exposure Prophylaxis (PrEP)

People who are at a substantial risk for HIV acquisition can use Pre-Exposure Prophylaxis (PrEP), to lower their chances of getting infected.

Targeted Populations for PrEP

Targeted population for PrEP include Sex workers', men at high risk, people who inject drugs, vulnerable adolescent girls (15-19), young women (20-24), high risk pregnant and breastfeeding women, and HIV negative partner of a sero-discordant couple when the HIV infected partner has not attained viral suppression of less than 50 copies/ml.

Table 2.2: Eligible Criteria for PrEP

Eligible recipient of care for PrEP
● Aged 15 years and older. ● HIV sero negative ● At substantial risk* of HIV infection ● No suspicion of acute HIV infection ● Creatinine clearance >60ml/min** ● Willingness and consent for PrEP use as prescribed ● HIV negative sero discordant pregnant women

***Substantial risk of HIV infection means:** *Vaginal or anal sex without a condom with more than one partner or, history of a new sexually transmitted infection or, use of post exposure prophylaxis for sexual exposure or, has a known HIV positive sexual partner(s) who is not on ART/ on ART less than six months or has not attained viral suppression less than 50 copies/ml. or refuses to report a risk category but still requests PrEP.*

Table 2.3: Recommended PrEP regimens in Tanzania

Oral PrEP	Emtricitabine (FTC) 200mg/Tenofovir Disoproxil Fumarate (TDF) 300mg (Truvada) PO Daily. Once daily until for seven days to achieve protective concentrations and continue 28 days after the last exposure
Others	Long acting Injectable Cabotegravir
	Dapivirine Vaginal Ring (DVR)

Note:
PrEP should be provided for at least 28 days after the last possible exposure to HIV. The client should return after completing the final prescription for an HIV test to confirm status. Refer the client to other relevant prevention services. RoC should continue using PrEP until there is no ongoing risk of HIV acquisition. (Refer to PreP framework for more guidance).

Voluntary Male Medical Circumcision (VMMC)
Medical male circumcision offers significant protection against heterosexual HIV transmission from females to males, with studies showing a risk reduction of about 60%. Therefore, healthcare providers should strongly consider recommending medical male circumcision to all uncircumcised males as part of HIV prevention efforts to reduce the risk of HIV transmission. It is important to ensure that the procedure is conducted safely and with informed consent from RoC.

Early Infant Male Circumcision (EIMC) should be performed in infancy (within 60 days after birth) where there are lower rates of adverse events.

Table 2.4: Minimum Package for VMMC and EIMC) Services

Minimum Package for VMMC Services	● Educate recipient of care on the link between VMMC and HIV prevention ● Offer HIV testing and counselling so that RoC know their HIV status and refer those who test positive to a care and treatment clinic ● Screen for STIs and RTIs (and offer treatment, where indicated) ● Counsel on risk reduction ● Promote and distribute male and female condoms together with the promotion of their correct and consistent use ● Provide surgical care that is safe and of high quality in settings that are adequately equipped and environmentally suitable for minor surgical procedures ● Provide appropriate post-operative care and care of any associated adverse events

Minimum Package for EIMC Services	● Provide information to parents or guardians on advantages and risks of EIMC. ● Offer HIV testing and counselling to parents or guardians to ensure identification of HIV- exposed infants. ● Link HIV-positive parents to HIV care and treatment services and offer prevention services for those who are negative. ● Counsel on the post-operative care of circumcised infants and identification of related complications, danger signs and where to go for follow-up care, if required. ● Provide surgical care that is safe and of high quality in settings that are adequately equipped and environmentally suitable for minor surgical procedures. ● Provide appropriate post-operative care and care of any associated adverse events. ● Refer RoC to appropriate services such as immunization, well baby care, and HIV care and treatment for HIV-exposed infants and/or those infants found to be HIV-positive through Early Infant Diagnosis (EID).

Blood Safety

Unsafe blood transfusion can lead to transmission of HIV and other blood-borne infections. Poor donor recruitment and selection practices, as well as the use of un-properly screened blood, put recipients of blood and blood products at risk of HIV and other transfusion-transmissible infections. The National Blood Safety Program (NBSP) ensures safe blood and blood products are available through a nationally coordinated blood transfusion service.

Healthcare workers should ensure that RoC in need of blood or blood products receive safe blood which has been screened for all transfusion-transmissible pathogens following WHO criteria at the zonal centre. Access to safe blood transfusion is crucial for quality healthcare.

2.1.3 HIV Prevention Services for Key and Vulnerable Populations (KVP)

Key Populations are defined groups who, due to specific higher risk behaviours, are at increased risk of HIV irrespective of the epidemic type or local context. Also, they often face legal and social issues related to their behaviours that increase their vulnerability to HIV and which limit their access to services. Examples of key populations include 1) Men and women at high-risk men 2) people who inject drugs 3) people in prisons and other closed settings. The key populations are important to the dynamics of HIV transmission. They also are essential partners in an effective response to the epidemic.

Vulnerable populations (VPs) are groups of people who are particularly vulnerable to HIV infection in certain situations or contexts. Such groups include adolescents, orphans, street children, people with disabilities, and migrant and mobile workers. These populations are not affected by HIV equally across all countries and epidemics. Vulnerable populations (VP) includes the following groups include:

- Adolescent girls (15 -19) and young women (AGYW) (20-24)
- Adolescent Boys and Young Men
- Mobile populations (long distance truck drivers, fisher folks and fishing communities, miners and mining communities, construction and plantation workers)

- People with Disability in all forms
- Street living or working children and displaced people.

To effectively address the unique requirements of key and vulnerable populations, healthcare providers must offer impartial and inclusive services that extend beyond the healthcare setting. This involves identifying and catering to the specific needs of these groups in a non-judgmental and non-discriminatory manner.

The following list summarizes the key services to be offered to KVP:

- Promote and provide male and female condoms
- Provide VMMC service
- Provide HTS
- Provide ART to HIV infected individuals
- Provide pre-exposure prophylaxis (PrEP)
- Screen and manage STIs, RTIs and cervical cancer
- Counsel and offer Reproductive Health Services (RHS) inclusive of family planning services and dual protection as well as counselling and PMTCT
- Link to facility providing medication-assisted treatment (MAT) and other drug dependence treatments (i.e. harm reduction)
- Provide behavioural change and communication service
- Screen for Hepatitis B and C and provide vaccination for Hepatitis B as appropriate
- Screen for Tuberculosis and manage accordingly
- Screen for sexual violence and provide PEP along with other interventions for gender-based violence (GBV)
- Link with psychosocial support services through targeted campaigns in identified key and vulnerable population settings, use community based outreach, mobile phone technologies, social networking and develop key population friendly services at health facilities; this will facilitate dissemination of behavioural messages, promote follow-up and referral to services, improve adherence to treatment, and increase client participation in their own health care.
- Sensitize and educate health care providers, community health workers, peers, supportive staff and management on issues of specific key and vulnerable populations and on non-discriminatory practices and eliminating stigma, using pre-service and in-service training, job-aids, supportive supervision, and training follow up.
- Ensure confidentiality: Attention should be devoted to protecting privacy and confidentiality, e.g. closing the consultation room door or finding a private place to talk. RoC should be reassured of confidentiality.
- Proper Linkage and referral mechanisms to community support programmes (e.g. psychosocial support, income generating group, spiritual support and legal support etc.

For further details on management of HIV for KVP, refer to the National Guidelines on Comprehensive HIV Interventions for Key and Vulnerable Populations, 2017 Edition.

2.2. HIV TESTING SERVICES

Introduction,

The goals of HIV testing services are to:

- Identify people at substantial risk of HIV and link them to HIV prevention services to reduce HIV transmission e.g., voluntary medical male circumcision (VMMC),

prevention of mother-to-child transmission (PMTCT), pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)

- Identify people with HIV through the provision of quality services for individuals, couples and families;
- Effectively link individuals and their families to appropriate HIV treatment, care and support, as well as HIV prevention services, based upon their status; and
- Support the scale-up of interventions to reduce HIV-related morbidity and mortality, that is, antiretroviral therapy (ART),

HIV testing services, whether conventional or self-testing, should prioritize the RoC needs and interests while adhering to national and international healthcare delivery standards and human rights values. HIV testing should be tailored to the RoC unique risks and needs. To do this, all HIV testing services must conform to the five "C" basic principles of HIV testing services: counselling, consent, confidentiality, correct results, and Connection (linkage).

Note: *Provision of HTS in both settings should comply with Tanzania National Guidelines for HIV Testing Services, 2021.*

2.2.1 HTS Package

The term "HIV Testing Services (HTS)" refers to the entire set of services that should be given in conjunction with HIV testing. When a RoC is diagnosed with HIV, they get the ability to make informed decisions regarding HIV prevention, treatment, care, and support services. Tanzania's HTS package comprises demand generation, pre-test information, HIV testing, post-test counselling, and effective links to prevention, treatment, care, and support services for both HIV positive and HIV negative persons. (Table below 2.5)

Table 2.5: HTS Care Cascade

Intervention	Description
Demand creation	HTS should be promoted through SBCC interventions in mass and social media, information, education, and communication materials (IEC material), signboards, combination, prevention, intervention, advocacy, sensitization and mobilization.
Link to HIV testing pint	Peer educator should link clients to the nearby testing point or client to seek HIV testing service by self-referral.
Screening for eligibility for HIV testing	HTS provider should screen all clients using national HTS screening tool. Clients meeting the HTS eligibility criteria be offered HTS in accordance with national testing algorithm. Screening be conducted in a safe and private area while ensuring confidentiality of clients. Clients who do not meet the eligibility criteria but who insist to be tested for HIV should not be denied the service.

Intervention	Description
Pre-Test information/counselling	HTS provider should conduct age-appropriate pre-test session either through one to one (individual) or group sessions aiming to obtain an informed consent or assent for testing. The sessions can also be conducted through a short, recorded pre-test video clip, or printed materials such as posters and brochures. Children less than 18 years HTS provider shall assess whether testing is in the best interest of a child and if it promotes the child's physical and emotional welfare.
HIV Testing	Rapid HIV Testing should be done with privacy, maintaining confidentiality, adhering to the National HIV Testing Algorithm and good laboratory practices and quality assurance standards for quality results.
Post-test counselling	HTS provider should provide post-test counselling to clients regardless of the outcome of the test. Which may be delivered to individuals, couples or families, depending on what they agreed to, during pre-testing counselling.

Note:

- *HTS providers should encourage couples to receive post-test counselling together to facilitate mutual disclosure.*
- *All HIV positive individuals should be retested for verification before ART initiation. The test should be conducted by a different provider using a different sample and the same testing algorithm. The individual is confirmed positive if the test results remain positive after verification. However, if the test results change, their sample should be referred for additional testing at a nearby higher-level testing site.*
- *Start treatment as soon as possible (preferably within 7 days after a positive result).*
- *Individuals who test negative for HIV should be counselled and linked to prevention services as described in the national HIV and testing guideline 2021.*

2.2.2 HIV Testing Services for Different Populations

a) **HIV-Exposed Infants (HEIs), PBFW and their Partners**. Testing of all infants and children under 18 months born to HIV positive mothers irrespective of mother's ART status. Testing PBFW and their partners is described Chapter V, prevention of vertical transmission from mother to child.

b) **HIV Testing for Children Older than 18 Months up to 15 Years**. HTS providers should identify children at risk of HIV infection using HIV risk Assessment tool, followed by a HIV test using HIV rapid test. Parents or guardians must give their consent to have their children tested.

c) **HIV Testing for Key and Vulnerable Populations.** Conduct HIV testing and counselling for key and vulnerable populations presenting at health facilities or community-based testing; for key and vulnerable populations that test HIV negative, re-testing should be recommended after four weeks and thereafter repeated after six months. Prisoners should be offered voluntary HTS as part of health service whether in prison or in any other setting.

d) **HIV testing for Sexual Partners and biological children of Index Recipient of care.** Individuals who test HIV positive or are known positive should be encouraged to notify their sexual partners and biological children who are under

the age of 18 years, for HIV testing, and linkage to prevention, care and treatment services as appropriate. All PLHIV enrolled in HIV care should receive disclosure counselling and or be supported to disclose their HIV status (assisted disclosure).

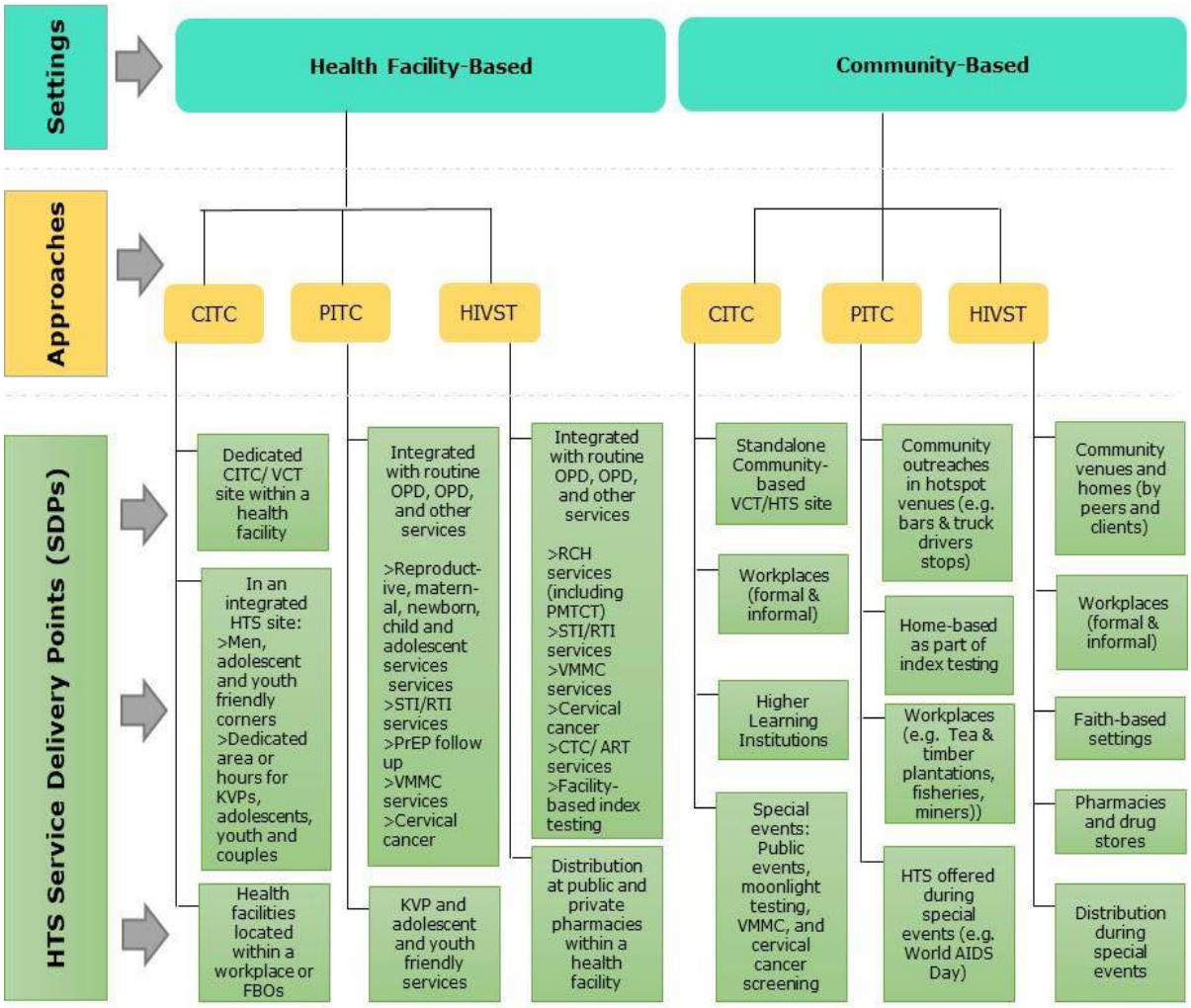
e) **HIV testing for Social Network Partners**. Individuals who test positive or known positive or high risk negative should be encouraged to bring their social partners for HIV testing, and linkage to prevention, care and treatment services as appropriate.

f) **HIV testing in 50+ years.** Low consideration of HIV testing contributes to the late introduction of ART in PLHIV aged 50 years and above. Health care providers should screen for HIV risk factors (e.g., multiple partners, injectable drug use) and offer HIV testing using the modalities indicated in the *HIV Testing Service Guideline 2021*.

HIV positive elders should be linked to care, and HIV negative elders who are at risk of acquiring HIV should be counselled and linked to HIV prevention services (e.g, pre-exposure prophylaxis (PrEP), condom, post-exposure prophylaxis, and GBV as in Fig 2.1).

g) **Recency Testing**: Recency testing is a non-population based testing which differentiates between recent and long-standing HIV infections by testing for an immunologic marker of disease progression in newly identified PLHIV. Establishing a routine HIV recent infection surveillance system, through integration with with routine HTS, is crucial to detect and monitor newly infected individuals. This can help to identify areas with ongoing transmission, inform national efforts to provide care, and pave the way for effective HIV prevention and control strategies. Recency testing should not be used for clinical decision.

Figure 2.1: Summary of the Tanzania HTS



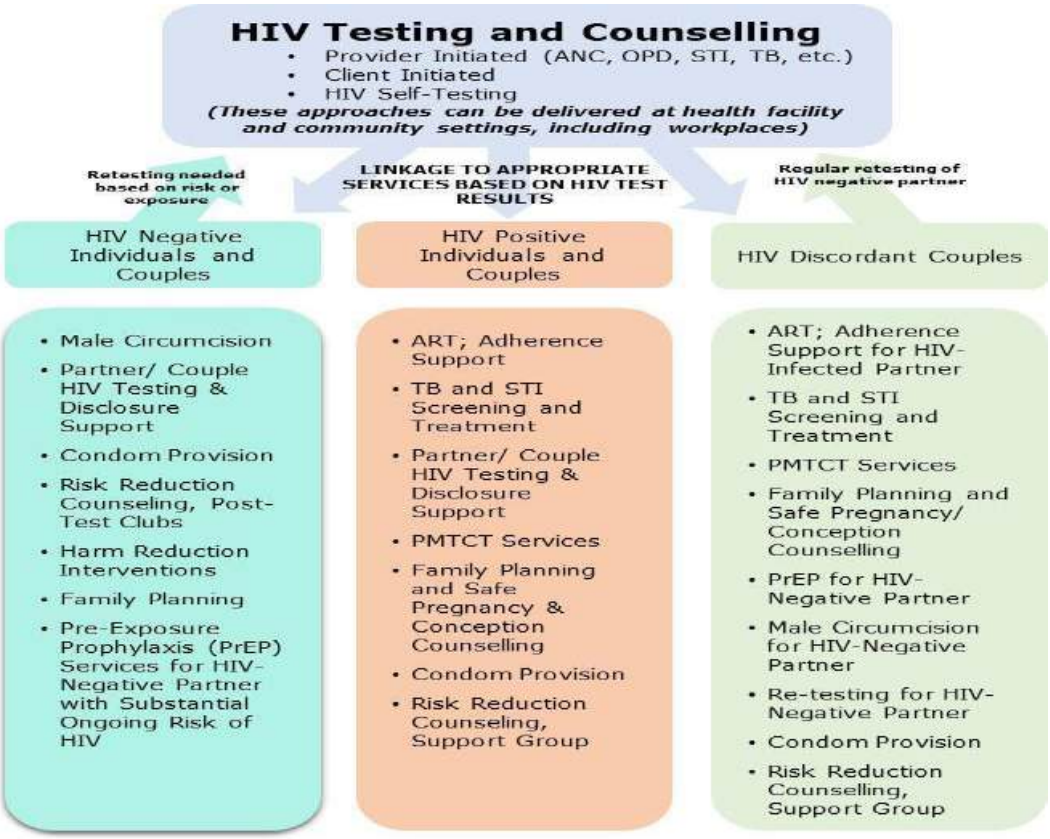
2.2.3 Successful Referral and Linkage Services

Status Neutrality:

Referral and linkages for HTS should deploy the status neutral approach on which whole person approach to HIV prevention and care that's ensures high-quality care to engage and retain people in services regardless of if the services are for HIV treatment or prevention. This approach continually addresses the healthcare and social needs of all people affected by HIV so that they can achieve and maintain optimal health and wellbeing.

Healthcare providers offering HIV testing services should link all who tests positive for HIV is to care and treatment services and initiates ART and any other essential support services, as illustrated Fig 2.1 below.

Figure 2.2: HIV Post-test Linkage to Prevention, Care and Treatment Services



2.2.4 Strategies for Effective Referral and Linkage

- Refer all people who test positive at facility and in community settings to a health facility-based care and treatment services for confirmation of HIV test results and further assessment for care and treatment services.
- Sites offering facility-led community ART initiation for KVP with a 1-month starter pack, should link KVP to the nearest convenient ART site for continued care and follow up.
- Individuals who test negative for HIV should be linked to appropriate prevention services.
- The following strategies have demonstrated benefit in improving linkage to care following an HIV diagnosis:
  - Streamlined interventions to reduce time between diagnosis and engagement in care, including use of Linkage Case Management (LCM) and follow up for the first 6 months;
  - Follow up support to HIV positive RoC opted to care and start ART at other facility than of their choice either via physical visit or virtual.
  - Support for HIV disclosure,
  - Training staff to provide multiple services,
  - Peer support and navigation approaches for linkage,
  - Using quality improvement approaches using data to improve linkage and RoC tracing.

2.2.5 Differentiated HTS services

Differentiated models of HTS delivery should be designed and implemented as a direct response to specific challenges or barriers identified for individuals seeking testing and/or health care workers as described in Chapter I.

CHAPTER III: ANTIRETROVIRAL THERAPY FOR ADOLESCENTS, ADULTS AND THE ELDERLY

3.1 Introduction

This chapter discusses ART management in adults and adolescents aged 15 years and above. All individuals confirmed to have HIV infection are eligible for ART, irrespective of CD4 count, WHO clinical stage, or any other criteria, provided that the individual is willing and ready to take ART and adhere to follow-up visits.

ART should be initiated within 7 days same-day initiation), except when there is an increased risk of IRIS. RoC with advanced HIV disease should be closely screened for opportunistic infections (OIs) and may need ART initiation delay (Table 3.2) to prevent life threatening immune reconstitution syndrome (IRIS).

RoC should be encouraged to reveal and designate a treatment supporter who will assist him/her during treatment and care. In accordance with the needs, the health care providers must refer newly registered RoC to other programs such as PLHIV support groups, Medically Assisted Therapy (MAT), and adolescent clubs.

3.1.1 Goals of Antiretroviral Therapy

Combination antiretroviral therapy aims at achieving:

- Undetectable viral load (<50copies/ml)
- Restoration and/or preservation of immunologic function by attainment of CD4 recovery to normal thresholds ≥500 cells/mm³
- Reduction of HIV-related morbidity and mortality
- Improvement of survival and quality of life
- Prevention of new HIV infection (Undetectable=Untransmissible)

3.2 Initiating ART for Adult and Adolescent 15 years and above

ART should be initiated (to all adult and adolescents who are HIV infected) by qualified Health Care Providers in both facility and community settings after a comprehensive medical history and physical examination, irrespective of CD4 count and WHO clinical staging. All samples for baseline laboratory investigations should be collected at the time of ART initiation, results to be shared once available. ROC should be reviewed within 14 days of initiation. Baseline investigations intend to help in the choice of ART regimen and other drugs, the list of investigation is presented in table 3.1 below.

Table 3.1: Baseline Laboratory tests for Adolescent and adults at ART initiation

Laboratory test	Rationale
CD4 count	Categorization of RoC into Early and Late Presenters To determine eligibility for AHD package of care To determine severity of immune deficiency To determine Eligibility for CPT and CrAg screening
Serum creatinine	To determine kidney dysfunction by eGFR*
Liver enzyme markers (ALAT,ASAT)	To determine liver dysfunction

Laboratory test	Rationale
HBsAg	To determine co-infection with HBV
Haemoglobin (Hb)	To rule out anaemia
Random Blood Glucose	To rule out diabetes mellitus

$$*_e\ GFR\ (ml/min/1.73m^2 = \frac{Height(cm)x\ 40}{Creatinine(umol/L}$$

Table 3.2: Conditions that require delay of Antiretroviral Therapy Initiation

Opportunistic Infection	Immunological Status	Action
TB Meningitis	Any CD4 cell count	● Initiate ART within 4 weeks of starting TB treatment, when the client's symptoms are improving, and TB treatment is tolerated. ● Corticosteroids should be given for 4 weeks as adjuvant treatment for TB meningitis
Pulmonary TB and Extra pulmonary TB other than TB Meningitis	Any CD4 cell count	● Initiate ART within 2 weeks of starting TB treatment, when the client's symptoms are improving, and TB treatment is tolerated
Cryptococcal Infection (CI)	CD4 <200 cells/mm3	● Initiate ART 2 weeks after completion of induction phase of Pre-emptive Fluconazole treatment
Cryptococcal Meningitis (CM)	CD4 <200 cells/mm3	● Initiate ART 5 weeks following initiation of treatment for Cryptococcal Meningitis (beginning of 4th week of consolidation phase)
Pneumocystis Jirovecii Pneumonia	Any CD4 count	● Do not delay ART initiation

Note:

- *Delay of ART initiation prevents development of IRIS (a paradoxical inflammatory disorder characterised by worsening of pre-existing infections following the initiation of ART)*
- *Switching a failing clients to a new regimen who has concurrent TB/Cryptococcal diagnosis requires delay of ART as per recommendations to prevent development of paradoxical worsening IRIS.*
- *IRIS definition: Refer section 3.5*

To provide person centred care, RoC should be categorized to different groups based on clinical and laboratory findings as shown in table 3.3 below.

Table 3.3: Recipient of Care Categories during ART initiation and management

Category	Management package
1. Early presenter	• Screen for TB • Provide TPT if no active TB
2. Late presenter	
a) Without Advanced HIV Disease	• Provide CPT • Screen for TB • Provide TPT if no active TB • Perform CD4 testing after 6 months
b) With Advanced HIV Disease	• Provide CPT • Screen for TB • Provide TPT if no active TB • Screen for cryptococcal infection/meningitis • Perform CD4 testing after 6 months • Screen for other severe infections (toxoplasmosis, CMV) if feasible • Offer other components of AHD package as appropriate (refer to Chapter IX)

Note: TPT should be initiated two weeks after ART initiation

3.2.1 First Line ART

Dolutegravir in combination with NRTI backbone is recommended as first-line regimen for adults and adolescents 15 years and older living with HIV, regardless of previous ART exposure (PrEP, PEP, Neonatal HIV prophylaxis) as shown in table 3.4 below:

Table 3.4: Recommended first line regimens for adults and adolescents.

Recipient of care group	Default 1st line Regimen	Alternative Regimen
Adults and adolescents (≥15 years), Pregnant and Lactating mothers, HIV and HBV co-infection ≥30kg	TDF/3TC /DTG (TLD)	ABC/3TC+ DTG *TDF/3TC/EFV (TLE400) **Special situation** **TDF/FTC + LPV/r
Elderly (≥ 50 years), RoC with CKD, co-morbidities (DM, HTN) with increased risk of renal dysfunction & post-menopausal women	TAF /(3TC or FTC) + DTG	ABC/3TC+ DTG
HIV and TB co-infections	TDF/3TC/DTG (Double dosage of DTG)	TDF/3TC/EFV (TLE400)
		ABC/3TC+ DTG (Double dosage of DTG)
People who Inject Drugs (PWID)	TDF + 3TC +DTG	ABC/3TC+ DTG TAF /(3TC or FTC) + DTG TDF/FTC +ATV/r

Note:

- **TDF/3TC/EFV (TLE400) should only be used in cases of DTG intolerance because NNRTI based transmitted drug resistance is reported to be ≥10% in East Africa which is above the recommended threshold for using NNRTIs.*
- ***LPV/r should be used in the first line if DTG can't be used due to intolerance and when there is resistance to EFV*
- *TAF is contraindicated in TB/HIV co-infection as Rifampicin lowers TAF concentration below the therapeutic level.*
- *TAF use in pregnancy is currently not recommended due to limited data on its safety.*
- *For recipients of care with weight <30kg, avoid TDF and use ABC based regimen.*
- *Consider PI based ARV if unable to use DTG and EFV*
- *DTG does not interact with methadone; therefore, it is a suitable drug for regimens in PWID. Initiate treatment after the RoC has been stabilized, usually 2 to 3 months after starting MAT.*
- *Administer DTG 50mg twice a day for RoC on Rifampicin based regimen to reach DTG therapeutic levels.*
- *ARV drugs have the potential to decrease the bioavailability of hormonal contraceptives especially with oral contraceptives. Dual contraception with condoms and injectable contraceptives is therefore recommended.*

3.2.2 Second-line antiretroviral therapy in adults and adolescents

A combination of a Protease Inhibitor (PI) and at least one new NRTI not previously used in first-line therapy are recommended for second-line treatment for adults and adolescents PLHIV aged 15 and above, as shown in Table 3.5. Lamivudine (3TC) or Emtricitabine (FTC) should be continued in subsequent regimens as it lowers viral fitness and increases susceptibility to AZT.

Table 3.5: Recommended second line regimens for adults and adolescents.

Population	Preferred 2nd line regimen	Alternative 2nd line regimen
Adults, adolescents (>15 years),Pregnant women / breastfeeding mothers and PWID	AZT/3TC+ATV/r	AZT/3TC+LPV/r
HIV and TB co-infection	AZT/3TC+ LPV/r* *Double dose of LPV/r to 800/200 mg	

Note:

- *Addition of DTG to failing PI based 2nd line regimen is not recommended because the client is considered to be on DTG monotherapy leading to development of DTG resistance, which compromises DTG efficacy and its future use*
- *Delayed diagnosis of treatment failure results in accumulation of resistance associated mutations (RAMs). Some of these RAMs compromise efficacy of drugs with similar resistance patterns for future use such as cross resistance between Abacavir (ABC) and TDF, and Atazanavir (ATV) and Darunavir (DRV). HCP should therefore exercise early*

detection and manage treatment failure.

- *RoC who received a PI-based regimen as their first line of treatment can be switched to a DTG-based regimen as a potential option for their second line of treatment.*

3.2.3 Third-line Antiretroviral Therapy

RoC failing second line may have substantial NRTI and NNRTI-associated resistance mutations (RAMs), limiting their usage in the third line regimen. Third-line regimens should include at least two, preferably three, effective drugs, constructed using second-generation formulations of preceding antiretrovirals with low or no cross-resistance. These second-generation drugs have a greater genetic barrier to resistance, and their efficacy is rarely jeopardized by RAMs associated with first-generation formulations.

Third line ARVs recommended regimens include:

- Integrase Strand Transfer Inhibitors (INSTIs): Dolutegravir (DTG) and Raltegravir (RAL)
- Second generation PI: Boosted Darunavir (DRV/r)
- Susceptible NRTI after Genotypic Antiretroviral Resistance Testing and
- Recycled Lamivudine or Emtricitabine regardless of presence and level of RAMs selected by these ARVs

Table 3.6: Recommended third line regimens for adults and adolescents.

Population	Preferred 3rd line regimen	Alternative 3rd line regimen
Adults, adolescents (>15 years),and Pregnant women / breastfeeding mothers and PWID	DRV/r + DTG + 3TC or FTC+1NRTIs **(Based on genotypic antiretroviral resistance testing results)**	DRV/r + DTG /3TC(Dovato) +1 NRTI (Based on genotypic resistance results) 2 NRTIs + DTG e.g.: TDF/3TC/DTG
HIV and TB co-infection	LPV/r + DTG +3TC or FTC +1NRTI **(Based on genotypic antiretroviral resistance testing results)** *Double dose of LPV/r to 800/200mg	LPV/r + RAL + 3TC or FTC +1NRTIs (**Based on genotypic resistance results**) *Double dose of LPV/r to 800/200mg 2NRTIs + DTG e.g.: TDF/3TC/DTG (Double dose of DTG)

Note:

- *For TB and HIV co-infected RoC on LPV/r should be switched back to DRV/r after completion of TB treatment*
- *For second- and third-line regimens which are non TDF/TAF based, in case of new Hepatitis B co-infection TDF/TAF should be added to the new regimen as treatment of Hepatitis B. If single tab TDF/TAF is not available, a fixed dose combination of TDF/FTC or TAF/FTC can be used.*

3.3 Changing Antiretroviral Therapy

There are multiple reasons that may prompt the need to change antiretroviral therapy. These can be grouped into two major categories:

- ARV specific adverse events (toxicity)
- Treatment failure

When changing treatment, the following should be observed:

If changing due to toxicity

- Change/substitute only the ARV suspected to be causing the toxicity.

If changing due to treatment failure

- It is never recommended to switch to monotherapy
- Change at least two ARVs, preferably change all three ARVs (DO NOT RETAIN THE BACKBONE)
- When making ARV selection, opt for drugs that haven't been previously used and don't have cross-resistance, overlapping toxicities, or drug-drug interactions
- Lamivudine has the advantage of reducing HIV viral fitness and increasing susceptibility to AZT and therefore should be retained when changing the failing regimen

3.3.1 Changing antiretroviral therapy due to treatment failure

Individuals receiving ART should be regularly monitored in order to detect and address treatment failure promptly, identify factors that may hinder adherence, and assess the client's eligibility for a regimen switch.

Treatment failure can manifest as virological, immunological, clinical, or a combination of these factors (Table 3.7). However, virological criteria should be used as the earliest marker for diagnosing treatment failure. Early detection of treatment failure through virological criteria prevents accumulation of RAMs, thus preserving future treatment options of ARVs in the same class. On the other hand, late diagnosis of treatment failure based on immunological (CD4) or clinical criteria can result in the accumulation of RAMs, which reduces future treatment options of ARVs in the same class.

Table 3.7: WHO definitions of treatment failure in chronological order of occurrence

Failure	Definition	Comments
Virological	Plasma viral load above 1000 copies/ml with a log drop <0.5 based on two consecutive viral load measurements after three months, with enhanced adherence support.	An individual must be taking ART for at least six months before it can be determined that a regimen has failed.
Immunological	CD4 count at 250 cells/mm3 with stage 3 or 4 WHO clinical condition. OR CD4 cell count consistently below 100 cells/mm3	Without concomitant or recent infection or steroid use to cause a transient decline in the CD4 cell count

Failure	Definition	Comments
Clinical	New or recurrent clinical manifestations/conditions indicating severe immunodeficiency (WHO clinical stage 3 or 4 conditions) after six months of effective treatment	The condition must be differentiated from IRIS

Note:

- ***Virologic blip*** *is an isolated detectable transient rise in viral load after attaining virologic suppression, followed by a return to virologic suppression. It is not due to treatment failure and should not raise any concern.*
- *Treatment failure should be distinguished from IRIS which is a paradoxical reaction which occurs in RoC starting or restarting ART with advanced disease. In IRIS there is clinical deterioration while on ART but improving CD4 count.*

3.3.2 Switching to second line ARV regimens

- Switching to second-line ART should be done to all RoC on first-line ART who have
  - Unsuppressed viral load (≥1,000 cp/ml) after 3 or more successful EAC sessions, as per algorithm). Recipient of care should have good adherence (>95%) before they are switched.
  - Genotypic Antiretroviral Resistance testing is not required when switching from first line to second line ARV regimen as it doesn't improve HIV viral re-suppression rates[3].

3.3.3 Switching to third line ARV regimens

Before a 2nd line regimen is confirmed to have virological failure, a Multidisciplinary Team (MDT) must convene to rule out other causes of high viremia, including suboptimal adherence. The MDT will plan for EAC and support to resolve adherence barriers. In-case of poor adherence, if adherence barriers are fully addressed re-suppression will occur, averting unnecessary switch to a third line regimen.

When the decision to switch to a third line regimen is made, GART should be done to rule out cross resistance between 1st and 2nd generation ARVs and assist in confirming drug resistance as a cause of treatment failure. GART will also inform the selection of an effective third line regimen including the possibility of recycling drugs used in previous regimens (1st and 2nd Line).

3.3.4 Criteria for switching RoC to Third line ART

A comprehensive evaluation should be conducted to determine the cause of treatment failure, including assessing and optimizing adherence and ruling out drug interactions and adverse effects. If there is evidence of treatment failure, a regimen change should be made consisting of at least two effective ARVs. The Central Third Line Committee reviews GART results, and sends third-line regimen recommendations to the respective health facilities.

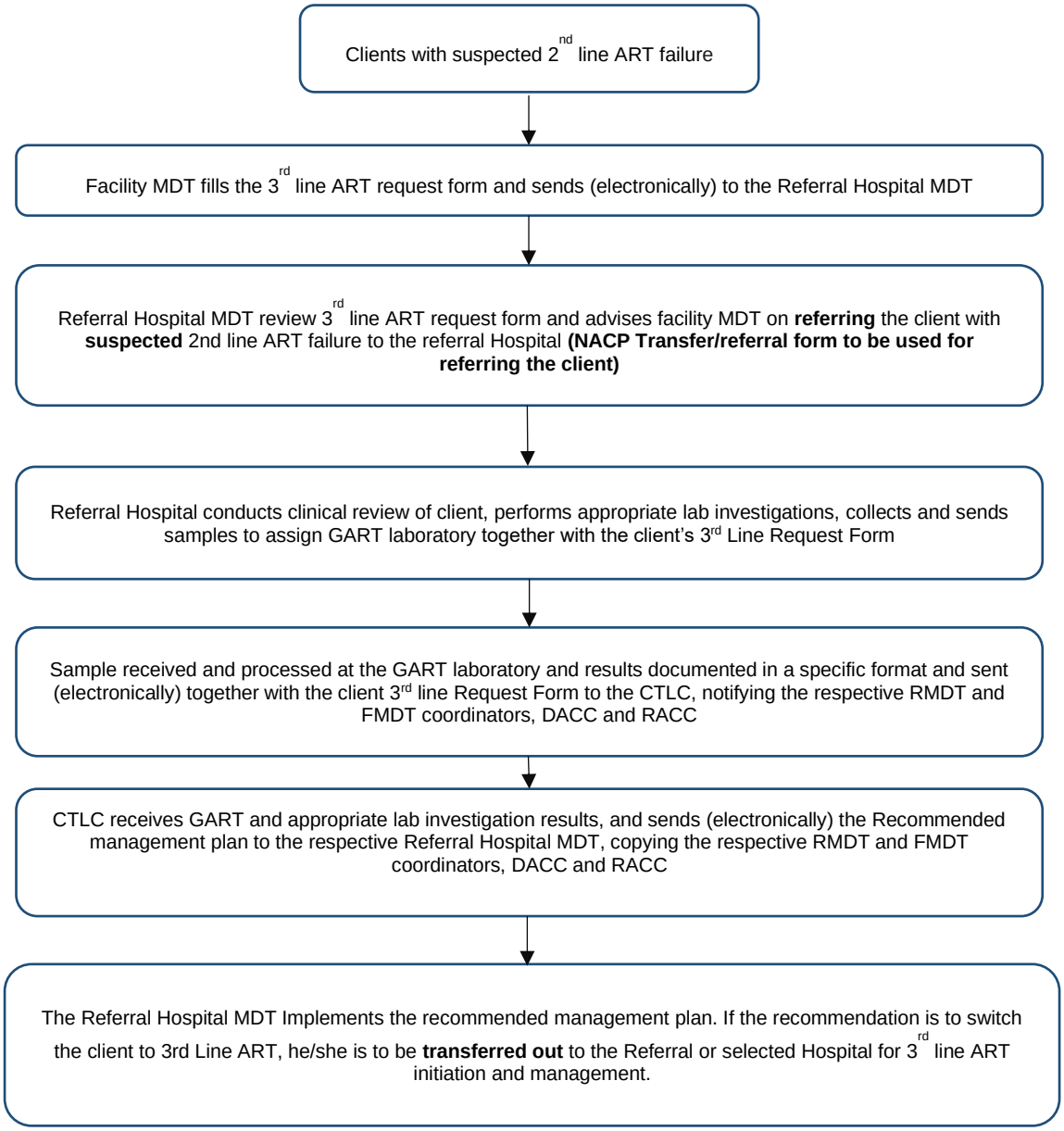
[3] Mark J, siedner et al: Resistance Testing for Management of HIV Virologic Failure in Sub-Saharan Africa : An Unblinded Randomized Controlled Trial

a) Requirements for switching RoC to Third Line

- RoC should be failing 2nd line ART
- RoC should have completed EAC and have good adherence.
- There should be documented virological failure (VL ≥1000) post EAC on a PI based regimen.

b) Process flow for Third line ART Initiation

Figure 3.1: Process flow for Third line ART Initiation



NB: GART is recommended for RoCs on a second line regimen for more than 2 years with Persistent Low-Level Viremia (> 500copies/ml) and good adherence.

3.4 Monitoring of RoC on ART

3.4.1 Clinical Monitoring:

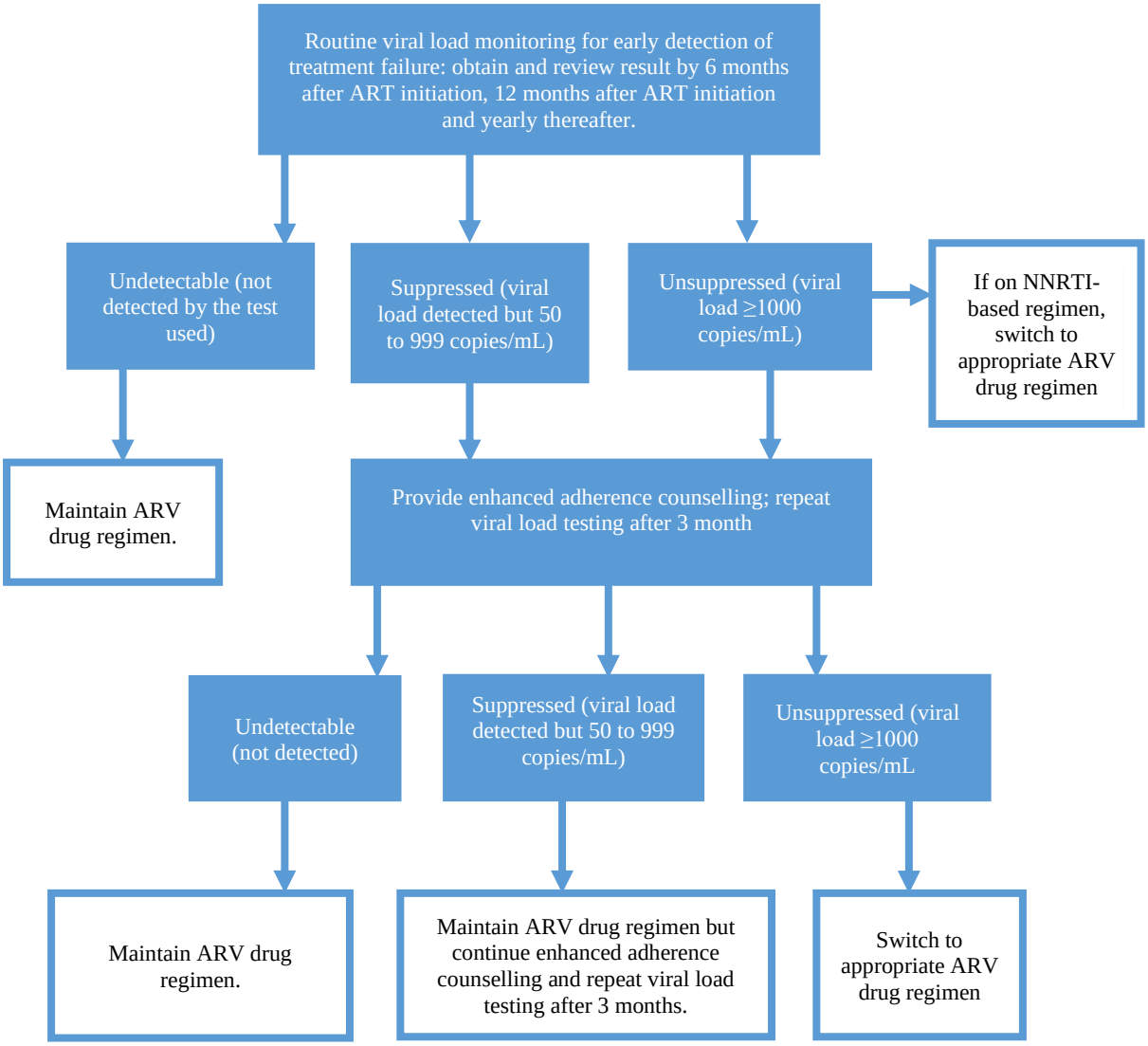
RoC should receive a comprehensive assessment including history and physical examination during each visit, with documentation in their medical record. Any new or persistent opportunistic infections should be evaluated further as they could indicate treatment failure as outlined in Table 3.7. Treatment success results in reduced morbidity from opportunistic infections, and better quality of life.

3.4.2 Laboratory Monitoring:

The gold standard for monitoring treatment failure is viral load (VL) testing. Viral load provides an early and accurate indication of treatment failure, reducing the accumulation of drug resistance mutations and enabling prompt switching to subsequent ARV regimens. This, in turn, improves clinical outcomes and preserves future ART options. All RoC should have access to viral load testing as per the national HVL testing algorithm. Successful treatment is when VL is less than 50 copies/ml.

- The CD4 cell count should be done at baseline to determine if ROC may have advanced HIV and monitor immunological response. For recipient of cares with CD4 cell count less than 350 cell/mm^3 at baseline, the CD4+ T lymphocyte count should be repeated after six months, until the RoC is established on ART and CD4+ T lymphocyte count > 350cell/mm^3. However, in cases of suspected IRIS or treatment failure, CD4 can be tested at any time.
- For other laboratory monitoring investigations, refer table 3.8.

Figure 3.2: HVL Algorithm



Note:

- *RoCs on second line regimen for more than 2 years with Persistent Low-Level Viremia (>500copies/ml) after two consecutive EAC cycles and good adherence, GART is recommended. Choice of the subsequent regimen will be informed by GART. If HVL <500copies/ml RoC should continue with the same regimen with HVL monitoring after every 6 months.*
- *RoC on first line regimen with Persistent Low-Level Viremia after two consecutive EAC cycles, should continue with the same regimen with viral load monitoring after every 12 months. No regimen change should be affected until confirmation of virological failure.*
- *RoCs on MMD should be dispensed 1 month of ART after HVL testing while awaiting HVL results. This is to allow re-evaluation and categorization of establishment in care and prompt initiation of EAC if HVL ≥ 50copies/ml.*
- *It's encouraged to conduct same-day VL testing using point-of-care viral load testing for a repeat viral load test, where available, to expedite the clinical decision. If not*

available, viral load specimens and results for a repeat viral load test should be given priority across the laboratory referral process (including specimen collection, testing and return of results)

- *PROBE assessment; Refer Chapter VI, "Adherence Preparation, Monitoring, retention and Support".*

Table 3.8: Summary of Laboratory Monitoring of Adolescent and adults on First and Second-Line ART Regimens

Monitoring Tests	Frequency	Rationale
HVL (All Recipients of care)	• Refer to HVL algorithm	ART monitoring
CD4 (All Recipients of Care)	• At Baseline (All) • After every six months till CD4 count is above 350 cells/mm^3 • Suspected treatment failure • Development of AHD	ART monitoring
FBP/Hb (All Recipients of Care)	• At Baseline,	Hb monitoring
	If a RoC has Hb,8.5g/dl • At one month, thereafter • Every Six months	Avoid AZT if Hb<8.5g/dl
Serum Creatinine (for Recipients of Care on TDF or TAF)	• At Baseline, after every six months and whenever symptomatic	Screening for early renal toxicity
ALT (For recipient of cares on DTG)	• At Baseline, one month, after every six months and whenever symptomatic	Screening for early Liver toxicity
Cholesterol and RBG	• At 6 months then yearly	Identify/detect TAF, DTG or PI adverse effects
Bilirubin (for all Recipients of Care on ATV/r	• At 6 months • Whenever symptomatic	Indirect hyperbilirubinemia
Urinalysis (proteinuria, glycosuria)	• Every six months	Monitor Renal dysfunction

Note: -

- *Frequent laboratory tests will be determined by clinical evaluation.*
- *The frequency of CD4 and viral load monitoring may be less than six months when IRIS or treatment failure is suspected.*

Discordant viral load and CD4 cell count response to ARV

Concordant HIV viral load and CD4 response to ARV; is when the client has optimally suppressed HIV viral load (<50 copies/ml) and robust CD4 cell count gain.

A discordant response occurs when there is optimal HIV viral load suppression without an

associated robust CD4 cell count gain. This type of response is associated with increased morbidity and mortality.

Risk factors for Immuno-virological discordance response include age more than 50 years at ART initiation, comorbidities such as Hepatitis B, CMV, TB, high viral load at ART initiation, low baseline CD4 cell count and late treatment initiation (ART initiation at WHO clinical stage 3 and 4). This also occurs more often in highly treatment-experienced RoC with drug-resistant HIV.

In such scenario HCP should,

- Make sure the RoC is receiving appropriate prophylaxis for OIs including Cotrimoxazole;
- Examine the RoC medication list for medications that can suppress the bone marrow e.g. consider switching from an AZT-containing regimen to a regimen that does not contain AZT;
- Evaluate for any clinical manifestations, such as systemic symptoms or pancytopenia, which suggest a marrow infiltrative process and lastly continue ART, even if the RoC does not have a good CD4 cell count response.

ARV refill models for RoC

The table below describes different recommended refill models for RoC on ART. HCPs should assist the RoC to choose the model which suits the care requirements.

Table 3.9: Refill Models for RoC who are Established on ART (Stable)

	At facility	**At Community**
Individual models	● One monthly ART refill tied with clinical review, adherence counselling and lab tests according to algorithm. ● Monthly ART refill ● 3MMD ART refill fast-tracked. ● 6MMD ART refill to be done at health facilities and it's tied with clinical reviews, adherence counselling and annual viral load test ● Expanded hours (evening and weekend) ● Synchronized VL sample collection with ARV refills and VLs collected. ● Case management using an early warning dashboard (e.g. early or late missed appointments) ● Welcome back to care after interruption in care	● Facility-based mobile outreaches to some individual RoC who have special needs such as those who are bedridden. ● Community ART Distribution Points, Private pharmacies, MSD community pharmacies, Private hospitals, Vending machines

	At facility	At Community
Group models	• Family-centred models with alignment of children and caregiver appointments • Adolescent clinics • Operational triple zero clinics (Peer-based)	• Facility-based outreaches to smaller health facilities • Facility-based groups ART refill at selected places such as WEO, VEO, churches • Group ART delivery by expert patients or CBHSPs to stable patients

3.5 Immune Reconstitution Inflammatory Syndrome (IRIS)

IRIS is a phenomenon associated with the occurrence or worsening of opportunistic infections/malignancies which can occur early after initiation of ART or at later (several months to years) in the course of ART. IRIS occurs in 10 to 25% of people living with HIV starting ART.

RoC who are treatment naïve, have advanced HIV disease with CD4 cell count <50 cells/mm^3, and/or have undiagnosed and untreated opportunistic conditions. Any OI, malignancy and autoimmune diseases may present as IRIS

IRIS has been reported to occur in as many as 30% of TB-HIV Co infected RoC. Although IRIS in PLHIV who have TB is self-limiting, severe cases may require the use of a brief course of corticosteroids to reduce inflammation for those CNS manifestation or those with severe respiratory symptoms.

Cryptococcal IRIS occurs among 10–50% of people with cryptococcal disease in 3 to 12 weeks (range of 1 to 10 months) of ART initiation and is associated with high mortality.

Initiation of ART can also unmask previously undiagnosed infections such as hepatitis B or C viral infections as it improves the inflammatory response while repairing the immune system.

Graves's disease can occur 8 to 33 months as an autoimmune IRIS after initiation of ART in certain HIV-1-infected individuals. It should be suspected in individuals who present with clinical features suggestive of hyperthyroidism or worsening of clinical features despite good virological and immunological response to ART.

Table 3.10: Clinical presentations of IRIS

Organism	Clinical features
Mycobacterium Tuberculosis	Pulmonary TB: Cough, shortness of breath, increased work of breathing. Extra pulmonary TB: Tender lymphadenopathy, cutaneous lesions. Systemic symptoms: Malaise, fever, chills, unintentional weight loss, night sweats.
Pneumocystis Jirovecii	Systemic symptoms: Fever, chills, malaise, unintentional weight loss. Pulmonary symptoms: Worsening shortness of breath, cough.

Organism	Clinical features
Cryptococcus Neoformans.	The central nervous system (CNS): Confusions, seizures, raised intracranial pressure. Pulmonary symptoms: Cough, shortness of breath.
Mycobacterium Avium Complex	Tender lymphadenopathy.
Cytomegalovirus (CMV)	Ocular symptoms related to immune reconstitution mediated uveitis such as blurred vision, decreased visual acuity, ocular pain. Extraocular symptoms: Shortness of breath due to pneumonia, diarrhoea due to CMV colitis.
Hepatitis B and C Viruses	Fever, chills, lack of appetite, unintentional weight loss, nausea, jaundice.
Kaposi Sarcoma	Worsening of skin and mucosal lesions with increased tenderness and swelling, peripheral edema.
Herpes Zoster	Cutaneous manifestations: Herpetic lesions in typical dermatomal distributions. Ocular lesions: Eye pain and red eye due to keratitis or iritis.
Graves' disease	Development or worsening of clinical features i.e. exophthalmos, excessive sweating, heat intolerance, irritability and weight loss

The criteria for making a diagnosis of IRIS are described in Table 3.11 below:
Table 3.11: Immune Reconstitution Inflammatory Syndrome diagnostic criteria

Diagnosis of IRIS would require both major (A plus B) criteria or Criterion A plus 2 minor criteria
Major criteria **A.** A typical presentation of "opportunistic infections or tumours" in RoC responding to ART includes: ● Localized disease e.g. lymph nodes, liver, spleen ● Exaggerated inflammatory reaction e.g. severe fever, with exclusion of other causes of painful lesions ● Atypical inflammatory response in affected tissues e.g. granulomas, suppuration, necrosis, perivascular lymphocytic inflammatory cell infiltrate ● Progression of organ dysfunction or enlargement of pre-existing lesions after definite, clinical improvement with pathogen specific therapy prior to commencement of ART and exclusion of treatment toxicity and new diagnoses ● Development or enlargement of cerebral space occupying lesions after treatment for cerebral Cryptococcus or toxoplasmosis ● Progressive pneumonitis or the development of organizing pneumonia after treatment of pulmonary-TB or PJP ● New onset or worsening of uveitis/ vitritis after resolution of CMV retinitis. ● Fever and cytopenia after treatment for disseminated Mycobacterium avium complex (MAC) disease
● Enlargement of Kaposi's sarcoma lesions and subsequent resolution or partial regression without ● Commencement of radiotherapy, systemic chemotherapy or intralesional therapy

B. Significant drop in HIV viral load count
Minor criteria ● Increased blood CD4+ cell count after initiation of ART ● Increase in immune response specific to the relevant pathogen e.g. delayed type hypersensitivity to mycobacterial antigens (PPD conversion) ● Spontaneous resolution of disease without specific antimicrobial therapy or tumour chemotherapy with continuation of ART.

Table 3.12: Management of IRIS

Mild to moderate forms:
• Reassure the patient
• Do not stop ART
• Provide specific treatment for the opportunistic infections/malignancies or other diseases
Severe life-threatening IRIS
• Reassure the patient
• Stop ART temporarily
• Provide high doses of Prednisolone 1mg/kg for 4 weeks then taper down the dose. In case of severe cryptococcal meningitis IRIS, a short course of Steroid may be prescribed (Refer to cryptococcal meningitis management, in Chapter IX).
• When using high-dose steroids, it is important to rule out *Strogyloides stecolaris* infection to avoid disseminated strongylodiasis.
• Provide other appropriate supportive measures such as management of fever, oxygen therapy, i.e. fluids
• Restart ART when the RoC is clinically stable

3.6 HIV and AIDS among old persons/Elderly

3.6.1 Epidemiology

Globally, the burden of HIV and AIDS among the elderly is increasing due to increased survival rates for those living with HIV (aging with HIV) and lack of tailored prevention interventions for older adults resulting in new infections among those older than 50. Many Older people acquire HIV due to misconceptions that they are not at risk, and diagnoses are often missed or made very late. Men aged 50 and above still engage in sexual activity and intergenerational sex, while postmenopausal women have an increased biological risk of acquiring HI. About 21% of all PLHIV globally are 50 years and above. The prevalence of HIV among individuals aged 50 or above is not well-documented in Tanzania, and subsequent national HIV indicator surveys should include this age category.

3.6.2 Characteristics of HIV in the elderly

Elderly people living with HIV (PLHIV) often experience rapid disease progression and are

late presenters with high rates of comorbidities, including infectious and non-communicable conditions such as tuberculosis, pneumonia, malignancies, hypertension, diabetes melitus cardiovascular disease, and cognitive disorders.

Infectious comorbidities include Tuberculosis, atypical pneumonias, PJP, CNS related OIs i.e. Cryptococcal meningitis and CNS toxoplasmosis. Non-communicable co-morbidities include AIDS related Malignancies (Cervical cancer among women, Prostate cancer among men), Lymphomas (Primary CNS lymphoma), Cardiovascular and metabolic conditions i.e. Hypertension, Stroke and Diabetes Mellitus. Neurological conditions include HIV Associated Neurocognitive Disorders (HAND), Depression, Psychosis and Frailty.

Age-related decline in organ function can affect medication dosages, risk of toxicity, and response to treatment.

3.6.3 Clinical management Challenges in the elderly

When managing elderly PLHIV the following should be observed.

- Early initiation of ART is recommended if there are no opportunistic infections requiring deferral because of fast disease progression and predominantly late presentation. However, HIV in elderly is associated with high risk of IRIS, slow and blunted immunological response, hence increased risk of discordant ART response (optimal viral suppression with low CD4 cell count).
- Prescriptions of ARVs and other medications should aim at reducing toxicity/adverse effects because of renal/hepatic dysfunction, drug-drug interactions and overlapping toxicities because of polypharmacy,
- Regularly screen for non-communicable diseases such as hypertension and other cardio-vascular co-morbidities, diabetes mellitus and mental health. Once diagnosed such co-morbidities should be treated adequately to improve the quality fo life for the elderly.
- Laboratory work-up of elderly PLHIV will include the recommended investigations for PLHIV and screening of NCDs and monitoring of their parameters.
- One of the challenges among elderly PLHIV is increased risk of poor adherence due to polypharmacy and concurrent neuropsychiatric disorders. Therefore, in order to optimize adherence, screening and treatment of mood disorders including anxiety and depression and identifying adherence support from trusted family member or buddy is critical.

3.6.4 Choice of ARVs among elderly PLHIV

- Because of increased risk of renal dysfunction, osteoporosis and pathological fractures, TAF should be the preferred ARV and in its absence, ABC should be prescribed.
- ABC should be used with caution in elderly PLHIV with risk for or existing coronary artery diseases. In this population it can be replaced with TAF
- In case of neuropsychiatric manifestations or history of mental illness, EFV should be avoided.
- In case of metabolic syndrome and severe hepatic dysfunction DTG should be used cautiously or replaced with EFV in first line and ATV/r in second line

Co-medications with ARVs

- For PLHIV with type 2 Diabetes mellitus on Metformin on concurrent DTG based ARV regimens, the dosage of Metformin should not exceed 1g per day. Regularly check the blood sugar as the risk of hypoglycaemia is higher for such patients.
- DTG should also be used cautiously in Diabetics or replaced with EFV in first line ARV regimen and in second line replaced with ATV/r (Refer to Chapter XII for more information on comorbidities and medications).

CHAPTER IV: PAEDIATRIC HIV AND AIDS-RELATED CONDITIONS

4.1 Diagnosis of HIV Infection in Children

4.1.1 Diagnosis of HIV Infection in Children below 18 Months

Children aged below 18 months born to HIV-infected mothers should undergo DNA PCR to confirm HIV infection. Maternal antibodies persist in children's blood for 9 to 18 months after birth, impeding confirmation of HIV infection using rapid HIV antibody tests. However, children aged more than 9 months may be screened for HIV infection using antibody tests followed by a confirmation of positive results with DNA-PCR as per algorithm.

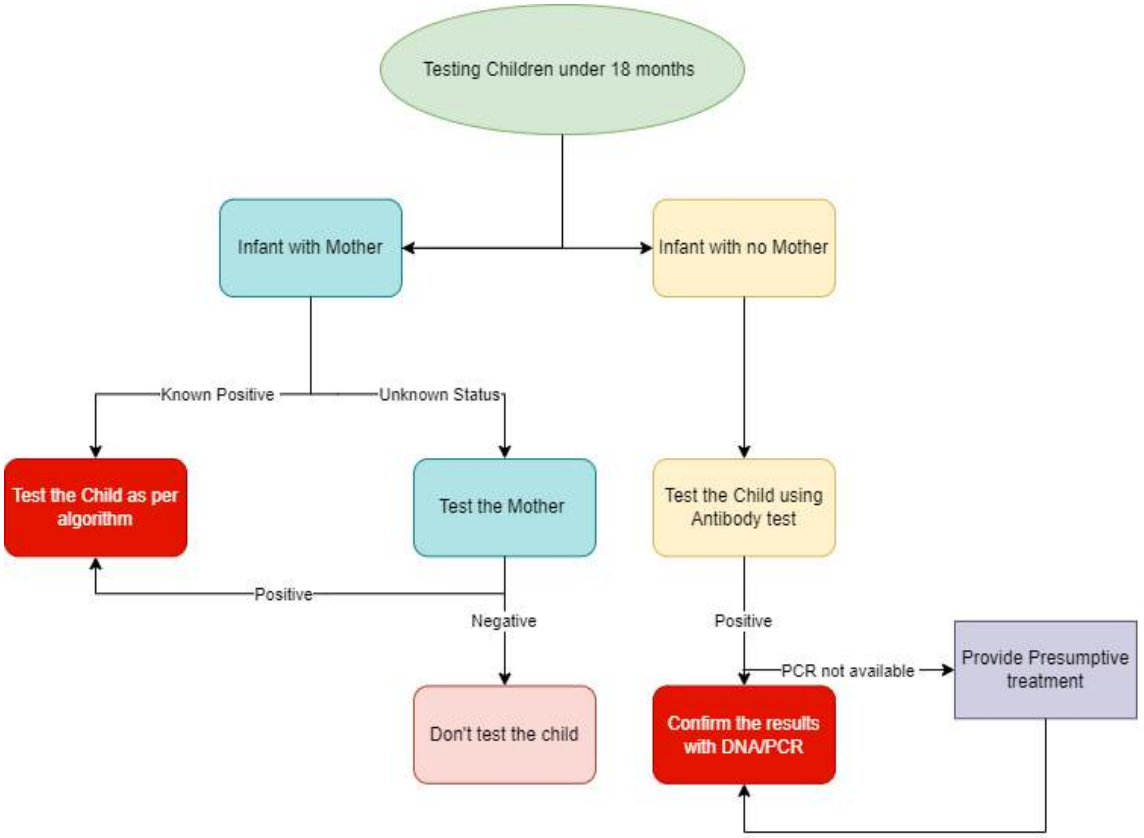
Table 4.1: Summary of Diagnosis of HIV infection in children <18 Months who are being breastfed by a mother known to be HIV Positive

● Do HIV DNA-PCR at birth to all exposed babies; if positive, take another sample immediately for DNA PCR confirmatory test and initiate the child on ART. ● Children with negative results for HIV should have DNA-PCR test at 6 weeks, 9 months of age. Another test should be performed 12 weeks after cessation of breastfeeding using antibody test. At 18 months of age, a final rapid antibody test should be done. Any positive results for a child below 18 months of age should be confirmed by DNA-PCR test and initiated on ART if positive.

***Note**:*

- *If the second (confirmatory) DNA-PCR is negative, following a first positive DNA-PCR results, then a third DNA-PCR should be performed before considering ART interruption. (Refer PMTCT Chapter on 'Managing discordant test results and treatment interruption in HIV Exposed Children').*
- *A child who has never and will never breastfeed, a second negative DNA-PCR test at the age of 6 weeks excludes HIV infection.*
- *For a child that has completely stopped breastfeeding for more than 12 weeks prior to DNA PCR testing, a negative DNA PCR test excludes HIV infection.*
- *All positive antibody tests should be confirmed with a DNA PCR test. However, if DNA PCR test is not readily available and the child is symptomatic and is in WHO stage 3 or 4 (Table 4.2), a positive HIV antibody test, a presumptive HIV diagnosis should be made, and ART started. The diagnosis should be confirmed when the DNA PCR becomes available.*

Figure 4.1: Flowchart for Diagnosis of HIV Infection in Children <18 Months



Note: *HIV Exposed Infants (HEI) should receive routine medical check-ups during their first year of life and thereafter, and healthcare providers should closely monitor their growth and developmental milestones. Poor growth and delayed development may indicate HIV infection*

a) Presumptive Diagnosis and Treatment

A presumptive diagnosis of HIV infection should be made if the child fulfils the criteria in Table 4.2.

Table 4.2: Criteria for Presumptive Diagnosis of Severe HIV Infection in Infants and Children <18 Months

A presumptive diagnosis of severe HIV should be made if:		
1. A child has a positive rapid HIV antibody test result	AND	2 a. The child is symptomatic with two or more of the following: Oral thrush, Severe pneumonia, or Severe sepsis. OR 2 b. Any child who is fulfilling WHO stage 3 or 4 criteria
History of maternal high viral load and /or an HIV-related maternal death supports the presumptive diagnosis of HIV infection in a child with appositive antibody test. ART should be initiated immediately, and HIV confirmed as soon as possible.		

b) Managing discordant results and treatment interruption in HIV Exposed Children

A confirmatory DNA-PCR should be collected immediately after ART initiation owing to an initial positive DNA-PCR test. If the second (confirmatory) DNA-PCR is negative; a third DNA-PCR should be performed before considering ART interruption.

The following should be considered when assessing patients for ART interruption after discordant test results; a positive first test, a negative second test, followed by a third test with a negative result:

1. The infant in question, is ought to have no clinical signs or symptoms suggestive of HIV infection
2. There should be an active follow-up plan agreed upon with family/caregiver(s) and health-care provider to ensure that a potentially infected infant is retained and re-initiated on treatment if virological rebound occurs.
3. Contact information (phone, address, etc.) of the family/caregiver(s) should be collected and confirmed.
4. Infants who develop signs and symptoms indicative of HIV infection should undergo immediate testing.

Note:

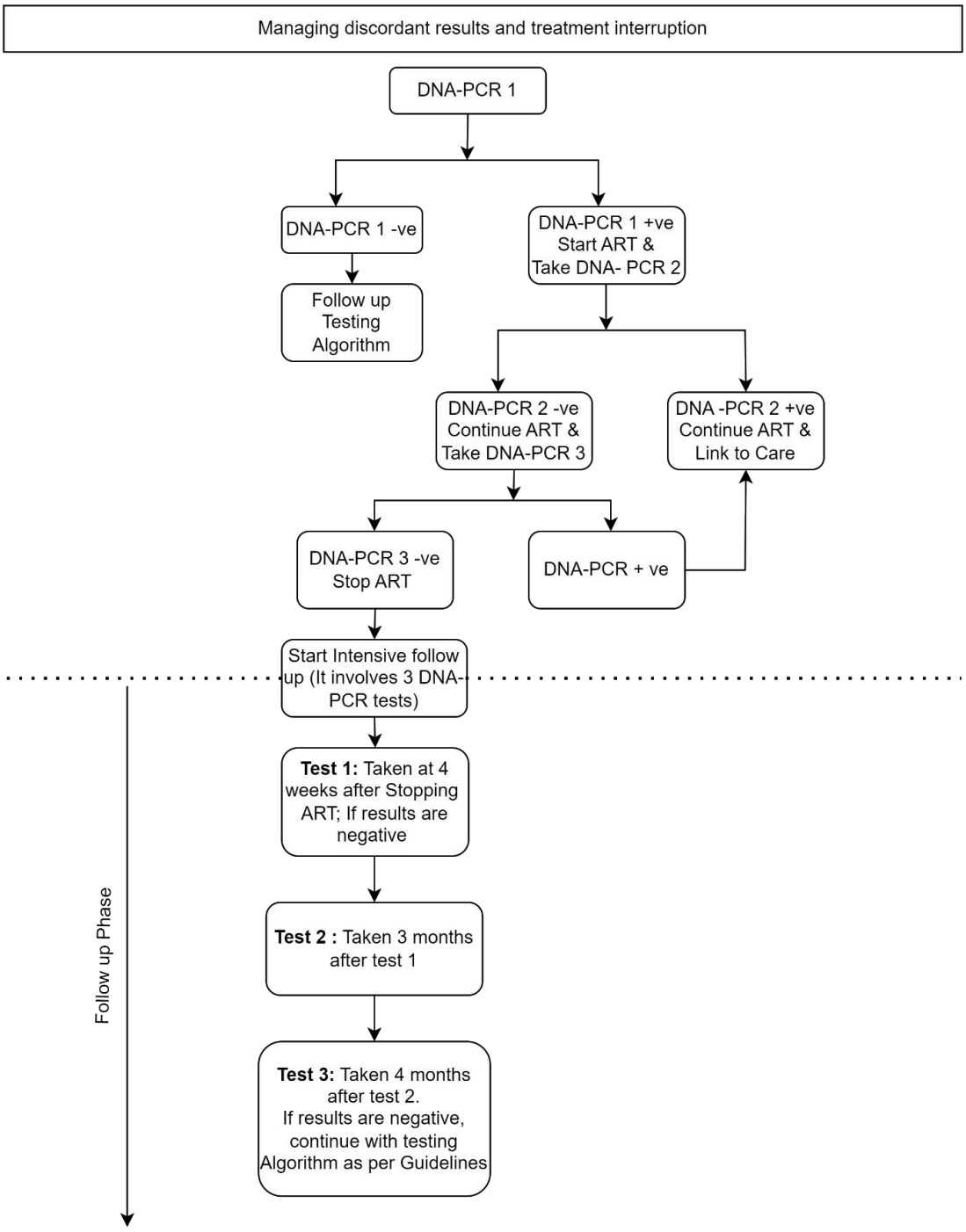
Virological rebound in HIV-infected infants starting treatment early is expected to happen within 8 months of interruption in >99% of HIV-infected infants

c) Follow up of an Infant with ART interruption

In settings where both EID (qualitative) and VL (quantitative) tests are available, tests should be performed at 4 weeks, 4 months, and 8 months after treatment interruption.

Infants who test positive on follow-up test should be re-initiated on treatment as per current guidelines and a confirmatory sample taken.

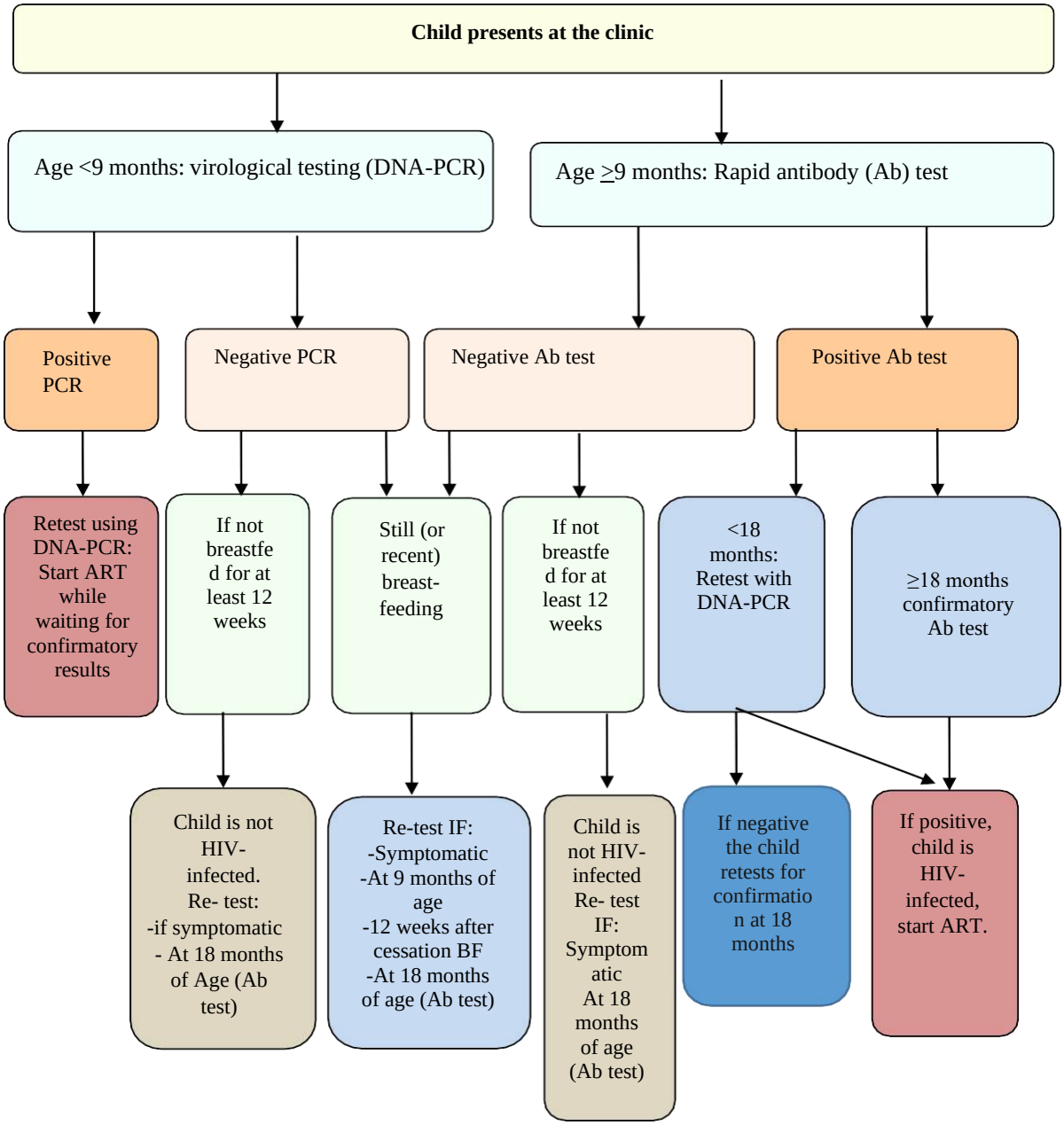
Figure 4.2: DNA-PCR test before and after ART Interruption



Follow up on ART interruption should consider the continuous risk of transmission resulting from breastfeeding and, once the intensive follows up is completed (that is 8 months after treatment interruption), the national infant testing schedule for HIV-exposed infants should be applied to ensure an appropriate final diagnosis.

If breastfeeding has stopped prior to the end of the intensive follow up, final HIV status can be defined with DNA-PCR performed at least 12 weeks post cessation of breastfeeding.

Figure 4.3: HIV Testing Algorithm for Infants and Young Children



Note: *If the HIV DNA-PCR results are inconclusive, a repeat HIV DNA-PCR and viral load should be done the earliest possible.*

4.1.2 Antiretroviral Therapy in Children Living with HIV

4.1.2.1 Goals of Antiretroviral Therapy in Children

The goals of ART:

- Maximally and durably suppress plasma HIV RNA (to <50 copies/ml)
- Restore and preserve immunologic function.
- Reduce HIV-associated morbidity and prolong the duration and quality of survival.
- Prevent HIV transmission.

4.1.3 Initiation of ART for children under the age of 15 years

All children with a confirmed or presumptive diagnosis of HIV infection are eligible for ART,

regardless of their age, CD4 count/percentage, clinical stage, co-infection status, or risk group. Provided the caretaker/parent is willing and supportive to the child and ready to adhere to follow-up care recommendations, ART should be initiated as soon as possible, preferably within 7 days of confirmation of the HIV status.

Note:
Severe acute malnutrition, opportunistic infections e.g., tuberculosis, cryptococcal infection, and other acute medical conditions should be screened for and treated before initiating ART.

a) First-Line ARV Regimens for Children under the age of 15 years

Both weight and age, (preferably weight) should be considered when deciding on the dosage for children under the age of 15 years (Table 4.3). For dosing of ARV regimens see Annex 3, Paediatric Dosing Charts 1- 3.

Table 4.3: Summary of first line ART Regimen for children under the age of 15 years' old

Age	Weight	Preferred first line	Alternative
Neonates	<3kg	AZT/3TC + NVP syrup (Titrate according to weight)	
Infant ≥ 4 weeks	3-5.9Kg	ABC/3TC +DTG10mg	ABC/3TC+ LPV/r (Granules)
	6-9.9Kg	ABC/3TC +DTG10mg	ABC/3TC+ LPV/r (Granules)
	10 – 19.9Kg	ABC/3TC +DTG10 mg	ABC/3TC + LPV/r (Granules/Tabs) **In Special Circumstances:** AZT/ 3TC + LPV/r (Granules/Tabs)
	20 – 29.9Kg	ABC/3TC+DTG50 mg	ABC/3TC + LPV/r (Granules/Tabs) **In Special Circumstances:** AZT/3TC +LPV/r (Granules/Tabs) AZT/3TC +DTG
	≥ 30Kg	TDF/3TC/DTG (TLD)	ABC/3TC+ DTG *TDF/3TC/EFV (TLE400) **Special situation** **TDF/FTC + LPV/r (Granules/Tabs)
HIV and TB co-infections		Double dosage of DTG and or LPV/r	

Note

- *Children weighing 6 to 24.9kg who are on the current pediatric regimen of pDTG + pABC/3TC should be transitioned to the fixed-dose combination (FDC) dispersible tablet of pediatric ABC/3TC/DTG 60/30/5 mg (pALD) when available. The introduction of pALD aims to provide a convenient, single-tablet option for pediatric patients living with HIV, reducing pill burden, simplifying dosing, and enhancing treatment adherence.*
- *TAF is contraindicated in TB/HIV co-infection as Rifampicin lowers TAF concentration below the therapeutic level.*

- *Consider PI based ARV regimen if unable to use DTG and EFV*
- *When a child is taking a Rifampicin-based TB regimen, the DTG dose should be administered twice daily to reach therapeutic levels.*
- **TDF/3TC/EFV (TLE400) should only be used in cases of DTG intolerance as NNRTI associated transmitted drug resistance is reported to be above the recommended threshold (≥10%) for not using NNRTIs.*
- ***LPV/r should be used in first line only if both DTG and EFV cannot be tolerated.*

Special Considerations for LPV/r granules and tablets

- LPV/r granules should be prescribed for infants with HIV infection who develop drug reactions to DTG.
- LPV/r tablets must be swallowed whole and should not be split or crushed as it loses effectiveness.

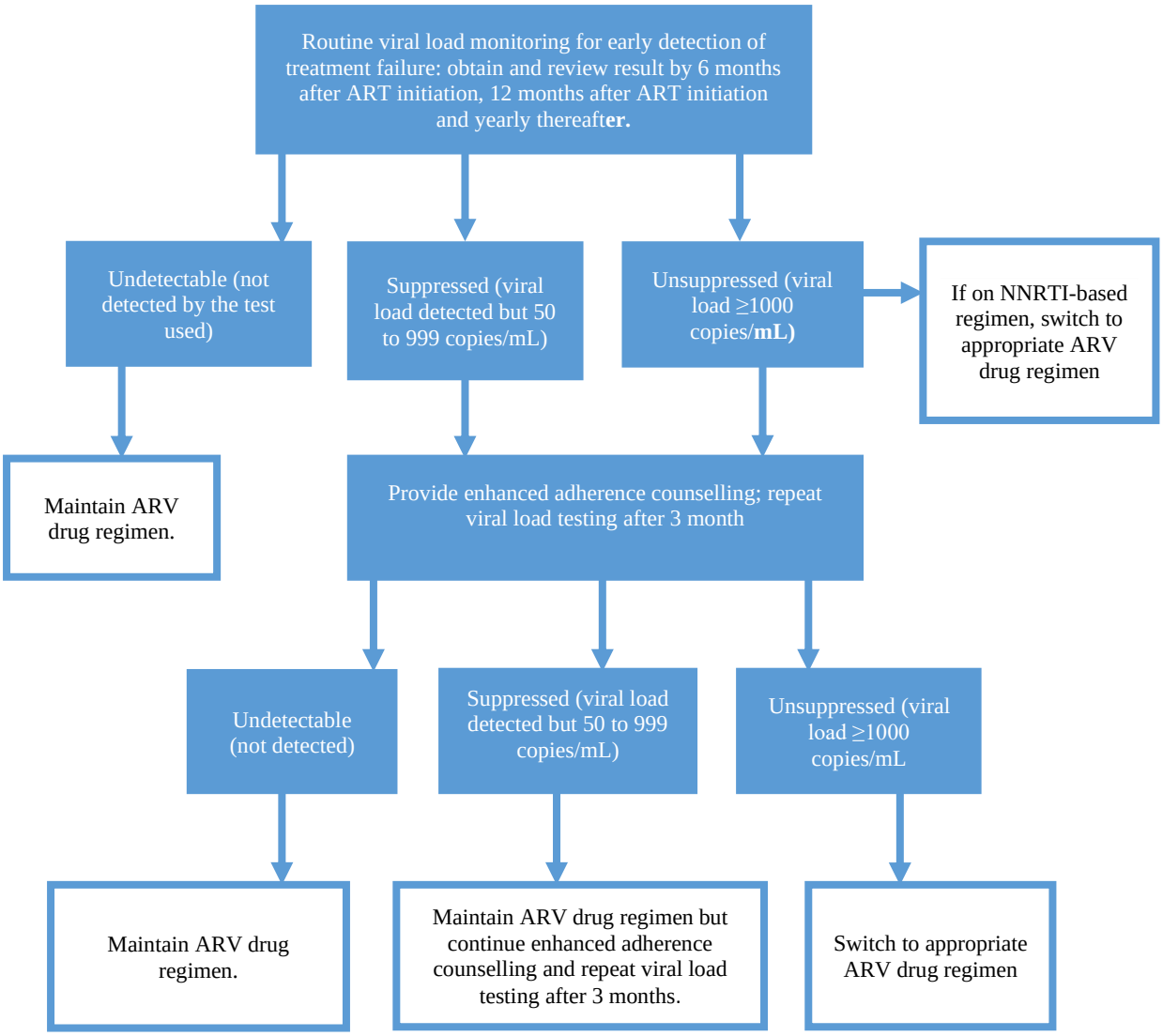
b) Second-Line ARV Regimens in Children under the age of 15 years

Children have lower rates viral load suppression as they respond more slowly to ART. However, with optimized ART and good adherence, children are able to achieve and maintain good viral suppression. Health Care Providers should ensure caregiver/parents and children are properly educated on the frequency and dosage of ART, and the benefits of good adherence to avoid treatment failure.

Treatment failure in children

Virological treatment failure in children is confirmed if the child is adherent to current ART regimen for six months or more and has two consecutive viral load measurements over 1000 copies/ml at three months intervals. The threshold for children under 2 years of age is 0.7 log and for children over 2 years is 0.5 log. Before switching to a new ART regimen, healthcare providers should elicit any adherence to a child as poor adherence is the most common cause of virological failure.

Figure 4.4: HVL monitoring algorithm



Note:

- *EAC for recipient of care with low level Viremia: aims to attain undetectable Viral load ≤50 copies/ml*
- *The use of point-of-care viral load testing is encouraged for repeat viral load testing, where available, to facilitate same-day delivery of results. If point-of-care testing is not available, repeat viral load specimens and results should be prioritized throughout the laboratory referral process, including specimen collection, testing, and result delivery.*

Immunological treatment failure: If adherence is good, immunological criteria indicating that a change to second-line therapy is warranted where/when HVL test is not available includes the following:

Table 4.4: CD4 criteria suggesting immunological failure

Immunological failure is recognized as developing or returning to the following age-related immunological thresholds after at least six months on ART, in a treatment-adherent child:	
<5 years of age (Use Percentages)	CD4 count of <200 cells/mm^3 or CD4 <10%
≥5 years of age (Use absolute Counts)	CD4 count of <100 cells/mm^3
[a] Preferably, at least two CD4 measurements should be available Use percentage CD4 in children <5 years and absolute CD4 cell counts in those ≥5 years of age. If serial CD4 values are available, the rate of declines of CD4 cell count from the peak, CD4 cell count reached should be taken into consideration. *CD4 cell percentage should not be measured during an inter-current infection but can be determined when the child has recovered. If there is a modest decline in CD4 cell count or percentage (<5%); and if there is no failure to thrive do not change medication, instead maintain close monitoring.*	

Clinical treatment failure; occurs when new or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4 with the exception TB) after six months of effective treatment. Healthcare providers should consider switching to a second-line treatment after evaluating the viral load results and in the presence of good adherence to treatment.

Table 4.5: Recommended second-line ART regimens for children under the age of 15 years

Body weight	**If is on the following regimen**	**Preferred 2nd line regimen**	**Alternative 2nd line regimen**
3-5.9Kg	ABC+3TC +DTG10mg	AZT+3TC +LPV/r (granules)	
6-9.9Kg	ABC+3TC +DTG10mg	AZT+3TC +LPV/r (granules)	
10 – 19.9Kg	ABC+3TC +DTG10mg	AZT+3TC +LPV/r (Granules/Tabs)	
20 – 29.9 Kg	ABC+3TC+DTG50mg	AZT+3TC +LPV/r (Granules/Tabs)	AZT+3TC +ATV/r (if weight ≥25Kg)
≥ 30Kg	TDF+3TC+DTG50mg (TLD)	AZT+3TC+ATV/r	AZT+3TC +LPV/r (Granules/Tabs)
			ABC+3TC +ATV/r
			ABC+3TC +LPV/r (Granules/Tabs)
For TB/HIV co-infection already on LPV/r	ABC + 3TC +LPV/r (Granules/Tabs)	If < 20Kg give AZT+3TC+ LPV/r (Granules/Tabs) (double dose LPV/r)	
		If ≥ 20Kg AZT+3TC+DTG (Double the dose of DTG)	
			If ≥ 30Kg TDF+3TC+DTG (Double the dose of DTG)
For TB/HIV co-infected on TLD	TDF+3TC+DTG	AZT + 3TC + LPV/r (Granules/Tabs) (double LPV/r dose)	ABC+3TC+LPV/r (Granules/Tabs) (double LPV/r dose)

NB: Children on rifampicin based TPT medication should receive double dose of DTG or Lopinavir.

4.1.4 Third-Line ARV Regimens for Children under the age of 15 years

Children on second line ART should be closely monitored both clinically and through laboratory investigations to identify treatment failure. Criteria for diagnosing treatment failure among children on 2nd line are similar those on first-line failure. Efforts must be made to assess and optimize adherence and rule out any significant drug interactions. When this has been done and there is still evidence of failure, children should be switched to third line regimen.

Third line initiation and management will be done at the referral hospital for the first three months. Thereafter, consultation and refills can be at the nearby health facility with the dispensing of the third line regimen from the referral hospital to the client's facility monthly

Eligibility criteria for switching children to third-line regimen.

All children on LPV/r or DTG-based regimens with confirmed HIV genotypic drug resistance by GART and have Good ARV adherence; Optimal ARV dosage; correct frequency and appropriately administered; Unsuppressed viral load (>1,000 cp/ml) after 3 successful EAC sessions, with a log drop <0.5 for children from 2years; and <0.7for children less than 2years.

Table 4.6: Recommended 3rd line ART regimen in children

Client group	Third line options
Children < 20kg	DTG 10mg + DRV/r* + 3TC + other NRTI**
Children > 20kg and above	DTG 50mg + DRV/r* + 2NRTI**

*Darunavir/ritonavir (DRV/r) should be used for children ≥ 14kg

**2NRTI will be guided by GART

Practice points

Confirmed HIV-positive infants born to mothers with confirmed PI or DTG resistance mutation should have GART done to exclude transmitted mutations to formulate an appropriate first-line ART regimen. While awaiting for GART results, newly confirmed positive infants should be initiated on the default first-line regimen.

The genotypic resistance test should be used to determine the third-line regimen to be used.

4.1.5 Follow up of Children on 3rd line Regimens

Children on third line regimens must be supported as the regimens are complex, have increased pill burden, drug intolerance and side effects, and are likely to cause treatment fatigue and emotional stress.

- HVL testing will be done at 6 and 12 months after initiating third-line, and then annually thereafter or as clinically indicated
- If CD4 count is ≤350cells/mm^3 at initiation of 3rd line, monitor CD4 count every 6 months until the CD4 count is >350cells/mm^3. Then continue with CD4 and HVL monitoring as recommended,
- After 6 months of 3rd line ART, if HVL >1000copies/ml follow the HVL algorithm from the top.

4.2 Monitoring of children receiving ART

CLHIV on ART should be assessed clinically and monitored through laboratory investigations to ascertain their response to ART.

Drug toxicity: when toxicity is related to an identifiable drug in the regimen, the offending drug should be replaced with another drug that does not have similar side effects.

Clinically.

- Children living with HIV needs routine assessments of nutrition, growth, and developmental milestones at every visit. Medication plans, including OI prophylaxis and ARV therapy, should be discussed intensively with parents or guardians. (*Clinically, monitor weight, height, mid-upper arm circumference, head circumference, feeding practices, nutritional status, neurologic symptoms, and developmental milestones at every visit*).
- *Children using ARVs should be closely monitored for signs of toxicity and adverse events, while providing age-appropriate counselling and psychosocial support, including disclosure sessions. Conduct recommended regular laboratory investigations as indicated in Table 4.7 to assist in making informed decisions about HIV care management for the child.*
- *Where possible, Point of Care (POC) (Gene Xpert) should be used for viral load testing as it is recommended to monitor treatment among specific populations including children, pregnant and breastfeeding women suspected of failing treatment.*

Table 4.7: Laboratory parameters for monitoring children under 15 years at baseline and during ART

Laboratory tests for diagnosis and monitoring	Baseline	At Switching to 2nd and 3rd line	Every 6 months	Symptom directed
HIV diagnostic testing	√[a]			
Haemoglobin	√	√		√
WBC and differential count	√			√
%CD4+ or absolute CD4 cell count	√	√	√[b]	√
Pregnancy testing in adolescent girls		√		√
Full chemistry (including, but not restricted to, liver enzymes, renal function, glucose, lipids, amylase, lipase and serum electrolytes)		√	√[c]	√
HIV VL measurement		√	√[d]	√
OI screening (where possible)	√	√	√	√

a) HIV re-testing for verification before ART initiation
b) For children of <5 years continue CD4 monitoring every six months. CD4 cell count should be taken on emergence of WHO stage 3 or 4 disease
c) Regular monitoring (every six months) of full chemistry, particularly lipid levels, liver enzymes and renal functions, should be considered for infants and children on ART
d) Viral load monitoring is done annually if the first two VL results 6 months apart are <50 copies/mL

4.3 Differentiated service delivery models in children

Children have lower rates of HIV diagnosis, treatment and viral load suppression, therefore there is a need to use children specific DSDM to meet the evolving needs according to age. Child Cantered Family Care Approach (CCFCA) provides an opportunity for involvement of parents, caregivers, and other family members in the care of children living with HIV. This approach improves access and uptake of HIV services by parents and their children as a family, enhancing disclosure and reducing stigma and discrimination.

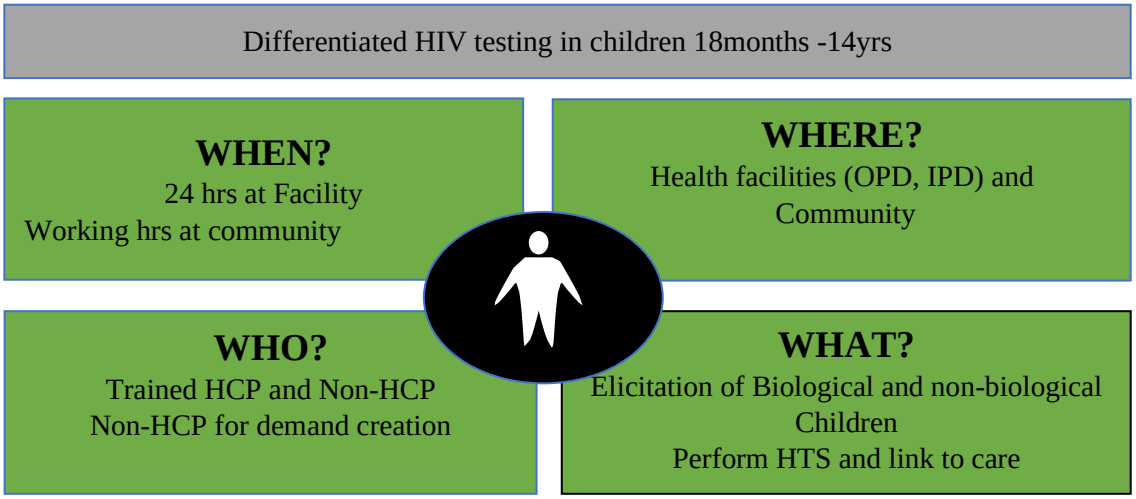
a) Differentiated HIV testing and linkage for children.

It is important that children who are exposed to or living with HIV are identified early and receive HIV testing and treatment services timely. HCPs need to put more emphasis on EID, index testing and optimized PITC for children. This will require educating parents and caregivers on the benefits of timely diagnosis. HTS should be available 24 hours a day, seven days a week in facilities which have out- and in-patient departments (OPD and IPD). The timing of community-based HIV testing services should be adapted depending on the specific population and context of the population being targeted.

Pediatric index and family testing testing: All Children <19 years of age (biological and non-biological) living with HIV positive caregiver/caretaker/parent should be offered HIV testing services.

Pediatric Enhanced PITC (Universal Testing for Children): All children seeking medical care at all sick entry points of the health facility should be offered HIV testing irrespective of screening status.

Figure 4.5: Differentiated Testing for children<18 months



If possible, HIV-positive children should be escorted to the care and treatment centre (CTC) for immediate linkage, and those testing negative should be referred to relevant prevention services based on age. A referral form must be completed.

Linkage to OVC services

All children infected and affected by HIV should be linked to the OVC program and other psychosocial services for vital psychosocial support and targeting household economic strengthening interventions that improve socio-economic capacity among OVC families.

b) Differentiated ART Delivery for Children not established on ART

Children and any HIV positive parent should have the same appointment date for clinical review (despite the stability status of the parents) in order to provide a family centred approach to care. In addition, booking families on the same appointment date will provide support to children and their care givers.

Figure 4.6: Differentiated ART

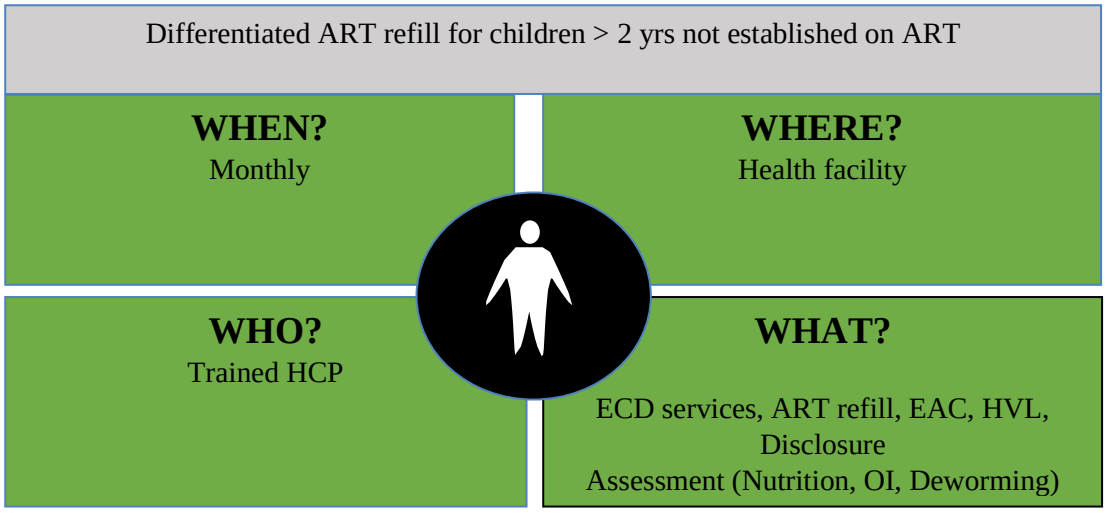
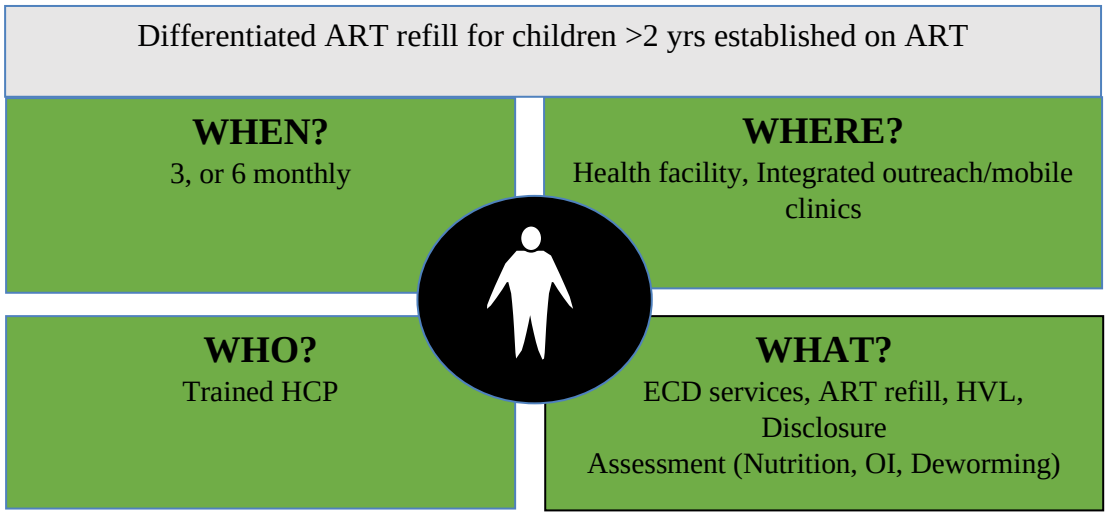


Figure 4.7: Differentiated ART refill for children > 5yrs established on ART



Note:

- *All children below 2 years of age are considered not established on ART. Irrespective of the caregiver's status of establishment on ART, and appointments (for both the parent/caregiver and a child) should be set on a monthly basis. Community Models should be selected from Chapter III.*

4.4 Models to support improvement in the quality of care for children.

4.4.1 Clinical audit, morbidity and mortality review

Healthcare providers should conduct regular morbidity and mortality audits and reviews in order to improve the quality of care provided to children. They should follow the principles of conducting pediatric morbidity and mortality reviews, which include identifying cases, reviewing clinical data, conducting interviews with caregivers and staff, identifying contributing factors, and making recommendations for improvement.

4.4.2 Transitioning of CLHIV in care and treatment clinics

As HIV children living with HIV (CLHIV) grow into adulthood, it becomes necessary for them to transition to adult care settings and take responsibility for their own health and disease management. To ensure desirable outcomes the transition process requires flexibility, interaction, and prior planning by health teams, CLHIV and their care givers.

The transitioning process occurs in 2 steps:

- Step 1 – Involves the transitioning from Paediatric to Adolescent HIV services (8-10 years old)
- Step 2 – Involves the transitioning from adolescent (19 years old) to adult HIV services.

Note:

For more details, refer to the *"National Standard Operating Procedures on Transitioning Children Living with HIV in Care and Treatment Clinics".*

4.5 Prophylactic Treatment of Common Opportunistic Infections in Children

- Children who are under five years old should be given Cotrimoxazole prophylaxis irrespective of their symptoms or percentage of CD4. The cotrimoxazole prophylaxis should be continued until a child reach the age of five, following which symptomatic children and/or children with a CD4 count below 350 cells/mm^3. In children above the age of five years, discontinuation of prophylaxis can be considered if their CD4 count is above 350 cells/mm^3 and have good adherence to ART.
- All children should be assessed for Tuberculosis and offered Tuberculosis Preventive Therapy (TPT) for TB prevention (For further details refer to Chapter VIII).

4.6. Clinical Manifestations of Paediatric HIV Infection/ AIDS- related conditions

4.6.1 Respiratory Conditions in Children with HIV Infection

Pneumonia and chronic lung diseases are common respiratory conditions in immune-suppressed children, and they contribute to increased morbidity and mortality in HIV-infected children.

4.6.1.1 Bacterial pneumonia

Streptococcus pneumonia, Haemophilus influenza, Staphylococcus aureus, and gram-negative bacteria such as Klebsiella pneumonia are the commonest causes of bacterial pneumonia. Recurrent bacterial pneumonia suggests immunodeficiency and requires investigations to exclude Tuberculosis, Lymphocytic Interstitial Pneumonia, and fungal infections.

Diagnosis

The diagnosis of pneumonia is typically based on medical history (presenting as **fever, cough and fast breathing (tachypnoea)**) and physical examination (signs of severe pneumonia (**chest in drawing, cyanosis and lethargy), unilateral or bilateral crepitation (crackles), decreased breath sounds or bronchial breathing, or** bronchial breathing **and hypoxia (**O_2 saturations less than 90% at room air).

Laboratory investigations such as complete blood counts, and blood cultures aid in identifying the causative agent. Chest x-rays may be useful in ruling out complications or other pulmonary conditions, and sputum induction and nasopharyngeal aspirate may help diagnose Tuberculosis or Pneumocystis Jirovecii Pneumonia.

Management of pneumonia at OPD

Management should follow national/ IMCI guidelines but include the following:

- Oral Amoxicillin 40mg/kg/dose BD for 5 days.
- Consider atypical pneumonia (e.g. mycoplasma) for children above 5 years; give Azithromycin 10mg/kg orally OD 5 days or Erythromycin 12.5mg/kg orally QID for 5 days.
- Give paracetamol for fever.
- Co-trimoxazole is not recommended for the treatment of pneumonia unless Pneumocystis jirovecii pneumonia (PJP) is suspected, in which case high-dose Co-trimoxazole should be administered.
- Cough syrups have no added value and are **not indicated.**

Management of severe pneumonia

Severe pneumonia should be managed in hospital and should include both supportive and specific therapy.

Supportive Care

- Use Pulse oximetry to monitor O_2 saturations and administer Oxygen therapy if below 90%. If pulse oximetry is not available, children presenting with chest in-drawing, cyanosis or hypoxia should be put on Oxygen therapy.
- Ensure adequate hydration either intravenously or orally depending on the severity of the condition, and observe for symptoms of dehydration or excessive hydration.
- Administer paracetamol for fever and pain.
- Make sure the child is receiving enough nutrition, and if necessary, use a nasogastric tube to assist with feeding.

Specific therapy:

- Give Ampicillin 50 mg/kg IV or IM every 6 h for at least 7 days and Gentamicin 7.5 mg/kg IV or IM once a day for at least 7 days.
- If the child does not show signs of improvement within 48 hours switch to ceftriaxone (80 mg/kg IV or IM once daily)
- It is recommended that HIV-infected children receive prolonged antibiotic therapy for 7 to 14 days.
- For infants who are either exposed to or infected with HIV and are suspected of having PCP, high-dose Cotrimoxazole can be added to their treatment regimen. This can be given orally or intravenously at a dosage of 8mg/kg of Trimethoprim and 40mg/kg of sulfamethoxazole every 8 hours for a duration of 21 days. In cases of severe respiratory distress, steroids may be prescribed.
- Children treated for PCP should continue taking CPT prophylaxis until the diagnosis of HIV infection has been excluded and all HIV exposure has ended.
- In cases where pneumonia is accompanied by Staphylococcal skin lesions, a positive blood culture for Staphylococcus aureus, poor response to initial antibiotics or recent measles infection, it is necessary to consider staphylococcal pneumonia. A chest X-ray can reveal small cavities called pneumatoceles. Treatment in such cases should include clindamycin or vancomycin in addition to other antibiotics.

4.6.1.2. Lymphocytic Interstitial Pneumonitis

Lymphocytic Interstitial Pneumonitis (LIP) usually occurs in children more than one year of age and is often mistaken for pulmonary TB. Diagnosis is usually by exclusion. The following are common clinical symptoms:

Diagnosis

History of Chronic cough, difficulty in breathing, poor response to TB therapy, with Cyanosis, digital/finger clubbing, and a characteristic radiological picture can aid diagnosis. LIP may be associated with parotitis, generalized lymphadenopathy, and hepatosplenomegaly.

A chest X ray may indicate diffuse bilateral reticulonodular infiltrate similar to miliary TB, consolidation, cystic lesions, bilateral hilar or mediastinal lymph node enlargement making it

difficult to differentiate from TB.

Management
Management of children with LIP, after exclusion of TB, includes the following:

- Continue or initiate ART
- Steroids are needed when children with LIP having respiratory distress
  - Prednisone 2 mg/kg/day - initially for 2 weeks daily and then decrease the dose over 2 to 4 weeks, depending on the response to treatment.
  - *When giving steroids, monitor closely for symptoms and signs of untreated TB as steroids can reactivate TB*
- Oxygen therapy during episodes of hypoxia
- Bronchodilators such as salbutamol when there is wheezing.
- Antibiotics during episodes of concurrent superinfection with pneumonia
- Chest physiotherapy and postural drainage if there is secondary bronchiectasis.
- Supportive care including correction of anaemia with iron supplementation.
- Consultation or referral to specialist care if the child shows poor response to treatment.

4.6.1.3 Pneumocystis Jiroveci Pneumonia (PJP)
Pneumocystis Jiroveci Pneumonia (PJP) is the primary cause of severe pneumonia and death among infants with HIV, particularly during the first year of life, even if they appear healthy and do not show any symptoms of HIV infection.

Diagnosis
When diagnosing PJP, clinicians must have a high index of suspicion since the diagnosis primarily relies on clinical presentation. Therefore, prompt initiation of therapy, along with treatment for bacterial pneumonia, is crucial.

PJP in HIV-infected infants may present with no or low-grade fever, but with marked respiratory distress characterised by chest in drawing, cyanosis, and inability to drink. On auscultation, the chest may be clear or have diffuse fine crepitations. These infants may have a poor response to standard antibiotic treatment and may also exhibit severe persistent cyanosis/hypoxia (SPO_2< 90%). In addition, they may have other signs of HIV such as hepatosplenomegaly, oral thrush, and lymphadenopathy. Early recognition and appropriate management of severe pneumonia in HIV-infected infants is crucial to reduce morbidity and mortality.

A chest x-ray can reveal hyperinflation, diffuse infiltrates, or appear normal in cases of pneumonia.

Where possible, perform sputum induction with nasopharyngeal aspirate. Stain with Giemsa or Silver or immunofluorescent stains. Broncho alveolar lavage where available can also be used to obtain a specimen for staining.

Management of PJP
Prompt initiation of therapy, along with treatment for bacterial pneumonia, is crucial.

Specific:

- High dose cotrimoxazole (CTX) IV (or oral) TMP 8mg/kg and sulfamethoxazole 40mg/kg given every 8 hours for 21 days.
- The recommended dosage of prednisone is 1-2mg/kg/day for 7-14 days and it should be tapered if given for more than 7 days.
- Secondary prophylaxis using cotrimoxazole after an acute episode of PJP

Supportive:

- Oxygen therapy
- Maintain and monitor hydration
- Antipyretics if there is fever
- Continue therapy for bacterial pneumonia
- Nutrition support

4.6.1.4 Tuberculosis in children

HIV-infected children should be evaluated for TB disease at the time of their HIV diagnosis and any time presented with symptoms suggestive of TB or have a history of new contact with a TB infected individual. There is a considerable overlap of clinical and radiological findings of PTB and other forms of HIV-related lung diseases or malnutrition. TB in children is discussed in detail in Chapter VIII of this guideline.

4.6.2 Diarrheal disease

Diarrheal disease is a leading cause of mortality in children under the age of five, and it is more common, severe, and prolonged (> 14 days) in HIV-infected children, often associated with other co-morbid conditions such as pneumonia and severe acute malnutrition. The causative organisms in HIV-infected children are similar to those in non-infected children. Diarrhoea can be

- *Acute watery diarrhoea – non-bloody diarrhoea lasting <14 days*
- *Dysentery – diarrhoea with visible blood mixed in stools.*
- *Persistent diarrhoea – diarrhoea lasting ≥14 days*

Acute and chronic diarrhoea, with or without dehydration, should be treated in accordance with IMCI guidelines, including rehydration with ORS as the first priority and antibiotics where necessary. Caregivers should be educated on hygiene practices such as hand washing and safe water consumption. If diarrhoea persists, alternative causes should be explored, and a thorough feeding history should be taken into account along with stool frequency, duration, presence of blood, recent antibiotic or drug treatment, and any signs of distress in infants.

Diagnosis

Diagnosis of diarrhoea is usually straight forward, however, Stool microscopy, culture/sensitivities may be particularly useful for persistent diarrhoea.

Management

- Management of diarrhoea in HIV-exposed and HIV-infected children should generally, be the same as for HIV-uninfected children.

- Dehydration status should be assessed and managed according to WHO/IMCI guidelines
- Elemental zinc supplementation is recommended for 10–14 days, with increased fluids and continued feeding, for all children with diarrhoea (10 mg per day for infants under six months of age, 20mg per day for infants and children over six months).
- Emphasize continued or increased feeding during and after the diarrhoea episode
- Ciprofloxacin 15mg/kg BD for three days is recommended for treatment of bloody diarrhoea.
- Daily micronutrients and multivitamins are recommended for two weeks for all infants and children with persistent diarrhoea.

4.6.3 Oral candidiasis

Persistent or recurrent Oral candidiasis or thrush outside of the neonatal period is a WHO Clinical Stage III condition.

Management:

- 2% Miconazole oral gel 5mls BID for two weeks
- Nystatin suspension for minimum of two weeks (Infants –100,000 units in every six hours; Children – 400,000 – 600,000 units in every six hours)

4.6.4 Oesophageal candidiasis

- *Clinical features*
- Usually associated with extensive oral thrush
- Infants and young children - present with refusal to feed and crying during feeds
- Older children – may complain painful swallowing.
- Vomiting

Management

- Fluconazole 3-6 mg/kg orally once daily for 2 weeks
- If the child is not responding to oral formulation or unable to tolerate oral medications or at risk of disseminated candidiasis, IV fluconazole (3-6mg/kg once daily) can be prescribed.

4.6.5 Otitis media

4.6.5.1 Acute Otitis Media

Acute otitis media is defined as having purulent exudates in the middle ear cavity with or without ear discharge lasting less than 14 days.

Diagnosis

- The symptoms of acute otitis media include otalgia (painful ear), ear discharge, fever, and an inflamed and bulging tympanic membrane on otoscopy.
- Perform ear swab for gram stain, culture, and sensitivity in RoC with ear discharge to guide appropriate antibiotic therapy.

Management

- Oral Amoxicillin 40mg/kg BD for 5 days or

- Oral Azithromycin 10mg/kg OD for three days
- Oral Paracetamol 15mg/kg TID for three days.

4.6.5.2 Chronic otitis media (draining ears)

Recurrent/persistent ear infections are a common presentation of HIV- infection in children and should be an indication for HIV-testing in children with unknown status.

Diagnosis

- The diagnosis of chronic otitis media is confirmed when there is an ear discharge, perforated tympanic membrane. Ear swab should be taken for gram stain, culture, and sensitivity.

Management

- Administer Ciprofloxacin 0.3% ear drops three time a day immediately after ear wicking and keep ear upright for 15 minutes after drops
- Give oral cephalexin 12.5mg/kg (max dose 25mg/kg) BID for 10 days.

4.6.6 Skin manifestations

Rashes and other skin problems are a common manifestation of HIV in children. Examples include Papular Pruritic Eruption (PPE), Tinea Corporis, Warts and Herpes Zoster, Scabies.

4.6.6.1 Herpes Zoster

Symptoms include pain and fever followed by vesicular rash over a dermatome. For more details, refer to Section 6.4.1.

Management

The goal of treatment is to inhibit ongoing viral replication, relieve pain, and prevent complications such as post herpetic neuralgia (PHN)

Antiviral Medication

- Acyclovir 20mg/kg/dose po or IV 6 hourly per day for 7 days
- Apply Acyclovir cream 5% to the lesions every 6 hours or apply zinc oxide 5% 12 hourly.

Pain management

Pain in children living with HIV should be managed based on the WHO analgesic ladder based on the pain severity.

- For pain relief, paracetamol15mg/kg every 6 hours or Gabapentin 5mg/kg orally 8 hourly can be given for postherpetic neuralgia for 2 weeks.
- If infected add flucloxacillin po 25mg/kg/dose 6 hourly per day for 7 days

4.6.6.2 Kaposi sarcoma (KS)

Though not as common as in adults, children can present with Kaposi sarcoma. The presentation includes purple plaques on the skin and mucous membranes, especially the palate, nodular skin disease, lymphatic involvement with “woody” edema, and less commonly visceral

and pulmonary presentations. However, children are also likely to present with enlargement of lymph nodes and may have enlarged lymph nodes as their only presenting symptom of Kaposi sarcoma.

Management

- First line treatment in epidemic KS use ART, localized nodular disease-radiotherapy, for rapid progressive disease systemic chemotherapy refer to higher level centres for speciality treatment **(For more details, see Chapter XII)**

4.6.7 Identifying and Managing Malnutrition in Children

Childhood acute malnutrition is highly prevalent among HIV-infected children. HIV-infected children with severe malnutrition have a higher risk of mortality than uninfected children due to the frequency and severity of OIs including TB, therefore children with unknown HIV status, who present with severe malnutrition, should be tested for HIV and screened for TB.

Clinical presentation of severe malnutrition

Severe malnutrition is characterized by the presence of any of the following: weight/height Z score <-3, severe visible wasting or bilateral pitting edema. SAM is also defined by a MUAC of <11.5cm in children of 6-59 months of age, MUAC < 13.5 cm in children 5-9 years of age and <16.0 cm in children of 10-14 years of age.

Management of severe malnutrition

The treatment of severe malnutrition in HIV-infected children is the same as for uninfected children. In HIV-infected children, the initial period of stabilization may take longer due to direct effects of HIV on the gut, appetite suppression or presence of OIs, such as TB that may be hard to diagnose. Management of sever acute malnutrition is therapeutic milk F75, F100 and RUTF.

Note:

- *HCP should ensure that all children are assessed of their nutrition status, and counsel appropriately.*
- *In every visit, children's anthropometric measurements (weight, height and where appropriate, MUAC) should be measured and documented in CTC2 card as well as growth monitoring charts. HCP should ask caregivers/parents of children under 5 years of age, to present their growth monitoring cards at every CTC visit and use it to track nutritional status.*

Please refer to Guidelines for Integrated Management of Severe Acute Malnutrition and Community Based Management of Malnutrition for details.

CHAPTER V: PREVENTION OF VERTICAL TRANSMISSION OF HIV, SYPHILIS AND HEPATITIS B

5.1 Introduction

The PMTCT program aims to eliminate vertical transmission of HIV, Syphilis, and Hepatitis B by using effective interventions such as antenatal screening, treatment, and vaccination. The risks of vertical transmission without intervention are significant, and multiple risk factors increase the chance of a mother transmitting HIV, Syphilis and Hepatitis B virus to her child. The goal is to achieve a MTCT rate of less than 4% for HIV, less than 50 cases of congenital syphilis per 100,000 live births, and less than 0.1% prevalence of HBsAg among children.

To reduce the risk of vertical transmission of HIV, Syphlis, and Hepatitis B from infected mothers to their infants, it's important to consider viral, maternal, and obstetric factors as shown in Table 5.1.

Table 5.1: Viral factors, maternal conditions, and obstetric interventions that may increase the risk of vertical transmission of HIV, Syphilis and Hepatitis B

HIV	Syphilis	Hepatitis B
• High maternal viral load and low CD4 cell count • Viral, bacterial, or parasitic placental infections (e.g., Malaria) • HIV serotype 1 • Chorioamnionitis from untreated STIs or other infections • Premature Rupture of membranes (more than 4 hours before delivery) • Prolonged labour • Oral disease in the infant (e.g., mouth sores) • Breast abscesses, nipple fissures, and mastitis • Duration of breast-feeding • Mixed feeding (i.e., breast-feeding combined with other foods or fluids) before 6 months of age	• Late maternal Syphilis diagnosis • High maternal syphilis titre • Maternal co-infection with HIV and other STIs	• Mothers with high HBV viral load • HBeAg positivity in the mother • Co-infection with HIV or Hepatitis C virus • Invasive procedures during delivery

5.2 Four elements of a comprehensive approach to Prevention of Vertical Transmission of HIV, Syphilis, and Hepatitis B Virus.

Health Care Providers should consider comprehensive approach to PMTCT consisting of four elements that guide interventions:

Four elements of a comprehensive approach
1. *Primary prevention of HIV, Syphilis and HBV infections among women of childbearing age and their partners* 2. *Prevention of unintended pregnancies amongst women living with HIV and HBV and linkage with other Sexual Reproductive Health services including STIs* 3. *Prevention of vertical transmission of HIV, Syphilis and HBV from infected women to their infants* 4. *Provision of treatment, care and support to women infected with HIV, Syphilis and HBV and their partners, infants, and families.*

5.2.1 Primary prevention of HIV, Syphilis, and HBV among women and their partners

Primary prevention is the most effective means to control the spread of HIV, Syphilis and HBV, and minimize its impact on individuals, families, and communities. Preventing HIV, Syphilis and HBV infection in women of childbearing age is the best way to prevent vertical transmission.

Primary prevention begins with HIV, Syphilis and HBV testing which can be achieved through different HIV testing approaches in different settings. Combination prevention which includes PrEP for PBFW safer sex practices, behavioural change, and timely diagnosis and treatment of STIs collectively comprise effective means to achieving primary prevention.

5.2.2 Prevention of unintended pregnancies among women infected with HIV and HBV

Family planning is part of a comprehensive public health strategy to prevent vertical transmission of HIV and Hepatitis B viral infections. All women living with HIV and /HBV and their partners should receive family planning counselling and should be empowered to access and utilize effective contraceptive methods to avoid unplanned pregnancies. A woman's/couple's choice of contraceptive methods should be based on her health status and informed choices.

5.2.3 Interventions to prevent vertical transmission of HIV, Syphilis and HBV.

The PMTCT program offers a range of services and interventions that can reduce the risk of vertical transmission of HIV and Hepatitis B viral infections. These include HIV, Syphilis and HBV education, counselling, and testing for PBFW and their partners, antiretroviral treatment (ART), maternal HBV mono-prophylaxis, antibiotic treatment for syphilis, prophylaxis to HIV exposed infants, universal Hepatitis B vaccine timely birth dose and/ Hepatitis B immunoglobulin. Other interventions include safer delivery practices, counselling on safer infant feeding practices and care of the exposed infant.

5.2.3.1 Treatment, care and support for HIV, Syphilis and HBV-infected women and their families

Providing treatment, care and support is critical for enabling pregnant women infected with HIV, Syphilis and/ HBV to address their health needs and ensure the well-being of their children and families. The PMTCT programme should strive to provide integrated care and treatment services. When this cannot be provided in RCH clinics it is important to strengthen coordinated referral systems to ensure that women and their families have access to integrated care services at appropriate clinics.

All women diagnosed with HIV and HBV should have their viral load, CD4 cell count (specifically for HIV), renal and liver function checked and clinically evaluated to monitor their disease progress. It is important that viral suppression is attained before delivery and syphilis treated promptly to ensure maximal reduction of the risk of MTCT. Care and treatment services to PBFW should be provided in RCH settings or by referral when cannot be provided at RCH. All exposed infants require close follow-up and monitoring on growth and development, immunizations, prophylaxis against HIV infections and opportunistic infections (ARVs and CPT), diagnosis and treatment of congenital syphilis, early testing for HIV, nutritional counselling and support services. All HIV-infected infants should be provided with comprehensive paediatric HIV care and treatment services.

Essential triple eMTCT services

- Testing for HIV, syphilis, and HBV at RCH clinics. All pregnant women with unknown status of HIV or Syphilis and/or HBV should be tested (including maternal retesting) as per testing guidelines.
- Prompt and efficacious interventions to treat women who test positive for HIV, syphilis, and HBV, and prevent transmission of the infection(s) to their children.
- Couple counselling to reduce transmission risk and ensure appropriate treatment.
- Pregnant women are appropriately attended, and safe obstetric practices are observed.
- Appropriate follow-up of Hepatitis B virus exposed infants, including HBV vaccine birth dose, HBV immunoglobin (when available) and other preventive services.
- Infant ARV prophylaxis for HIV exposed infants
- Optimal infant feeding counselling; and other essential services like routine immunization.
- Lifelong treatment and care for mothers living with HIV, HBV or syphilis for eligible women.
- Provision of PrEP services to PBFW according to the national PrEP implementation framework

5.2.3.2 Integrating PMTCT into routine Reproductive and Child Health Services

Integration of PMTCT into RCH services, will enable the National health care programs to improve pregnancy care and outcomes for all clients. Pregnant women should be tested for HIV, Syphilis and Hepatitis B once they start attending the ANC services. Obstetric, and medical care should be expanded to address the specific needs of women living with HIV and for those infected with Syphilis or Hepatitis B.

Pregnant women living with HIV or those infected with Syphilis and Hepatitis B should attend ANC clinic every month according to national RMNCAH guidelines.

Table 5.2: Essential package of Integrated ANC services for pregnant women living with HIV and/HBV and / Syphilis infection

Components of essential packages	What needs to be done by health care providers and pregnant and breastfeeding women
Understanding Client's context	Assess need of psychosocial support, mental health support and tailored scheduling of visits
Disease Screening (History and Physical Examination)	Assess the current signs or symptoms of illnesses including HIV, HBV, TB, malaria, cervical cancer and STIs
Laboratory testing	Conduct routine tests and HIV/ HBV-specific laboratory tests (viral load, LFT and RFT and CD4 cell count for HIV) VDRL if indicated, Confirmatory HIV testing (if indicated), Urinalysis, Full Blood Picture (FBP) (or haemoglobin)
HIV staging	Conduct clinical and immunological staging according to the WHO clinical staging categoris
Treatment readiness and support	Assess readiness to start ART and assist to resolve barriers of care including disclosure and plan for close follow up
Antiretroviral Treatment (ART)	Provide life-long ART to all HIV positive pregnant women and those eligible for HBV treatment or prophylaxis to prevent vertical transmission.
Tuberculosis (TB)	Conduct TB screening, initiate TPT and treat TB accordingly
Opportunistic infection (OI) prophylaxis	Provide cotrimoxazole preventive therapy (CPT) to PBFW with CD4 cell count ≤350 cells/mm3
Malaria	Intermittent Presumptive Treatment of malaria with Sulfadoxine Pyrimethamine should be provided. PBFW on Cotrimoxazole Preventive Therapy (CPT) do not need Sulfadoxine - pyrimethamine prophylaxis for malaria. Treat malaria accordingly
STI prevention and treatment	Assess risk, diagnose, and treat STIs according to the national guidelines. Counsel on preventing STIs. Recommend the use of condom throughout pregnancy and breastfeeding period
Adherence to ART, CPT and TPT	Provide counselling and education on healthy pregnancy, HIV and/or HBV care and treatment and PMTCT. Provide adherence sessions accordingly
Nutrition	Conduct nutritional and dietary assessment and provide counselling and supportive services. Give iron, folic acid and multivitamin supplements according to national guidelines.
Planning Delivery	Plan with the client on the mode and place of delivery. Explain the importance of delivering at health facility and birth preparedness.
Tetanus Toxoid	Administer immunization according to national guidelines.
Safe Motherhood	Encourage care seeking behaviour especially in case of symptoms of pregnancy complications such as bleeding, fever, signs and symptoms of pre-eclampsia, severe pallor, or abdominal pain. For pregnant women who present with miscarriage and abortion, comprehensive post-abortal care should be provided accordingly.

Components of essential packages	What needs to be done by health care providers and pregnant and breastfeeding women
HIV/HBV-exposed Infant	Educate about the importance of timely HIV testing, infant ARV prophylaxis, immunoglobulin and vaccine birth dose for HBV
Infant feeding in the context of HIV	Encourage exclusive breastfeeding for first 6 months of life, followed by complementary feeding with continued breast-feeding until 12 months of age. Counsel for gradual cessation of breastfeeding at 12 months of age
Signs or symptoms related to HIV	Provide information and instructions on seeking healthcare for symptoms of HIV disease progression, such as frequent and recurrent illnesses, chronic persistent diarrhoea, oral and oesophageal candidiasis, fever, severe weight loss or signs of any opportunistic infection. Manage client accordingly.
Mental health, Psychological and social support	Assess and address needs for mental health, psychological and social support and provide bidirectional referrals with existing community structures. Encourage joining community support groups
Effective family planning and safer sex	Counsel about consistent use of condoms during pregnancy and breast-feeding period to avoid acquisition of new HIV infection, re-infection and STIs Discuss long-term family planning options with male partner when possible.
Provision of PrEP	Provide PrEP as per PrEP implementation framework

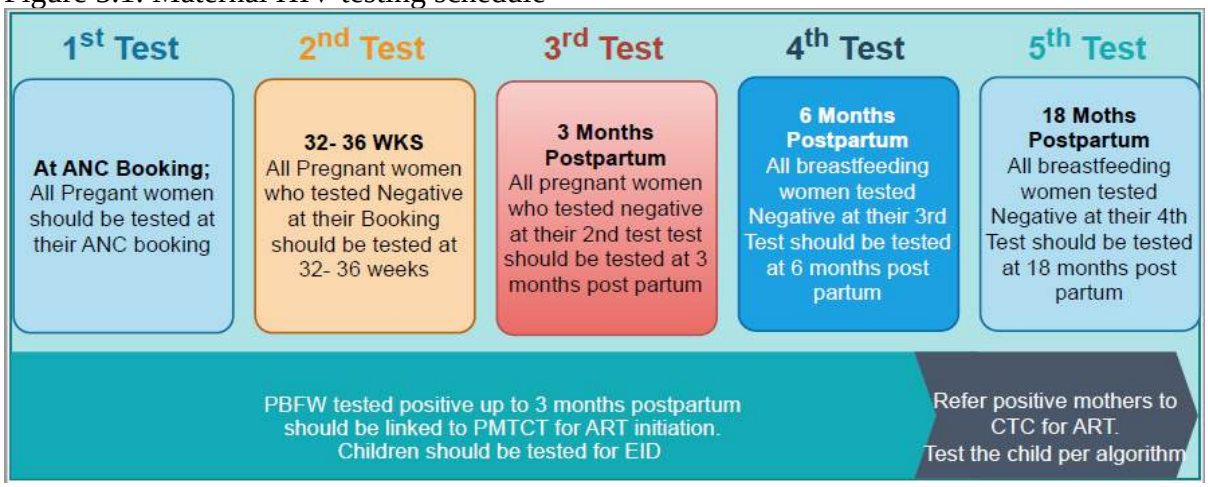
5.3 HIV, Syphilis and Hepatitis B Testing and Counselling for Pregnant and Breast-feeding women

All pregnant women and their partners should be counselled and tested for HIV (unless known to be HIV positive), Syphilis and Hepatitis B during their first ANC visit. If a client is diagnosed positive for any of the diseases i.e, HIV or Syphilis or Hepatitis B manage the client accordingly.

5.3.1 Maternal retesting for HIV and Syphilis negative pregnant women

For those who are HIV and Syphilis negative, repeat test should be done at third trimester between gestation age of 32 and 36 weeks. Follow up repeat HIV tests will be done at 3 months, 6 months and 18 months post-delivery and thereafter testing shall follow guidance for the general population.

Figure 5.1: Maternal HIV testing schedule



Note
All Pregnant women who did not receive their second test during the third trimester should be tested during labour and delivery. If testing at labour and delivery was not done, testing should be done during the immediate postpartum period (within 42 days). In case the first test was done at gestation age of 32 weeks or beyond, the second test will be conducted at labour and delivery.

5.4 Categories of status of PMTCT clients according to risk of vertical HIV transmission

HIV exposed infants can be categorized into two groups depending on the risk of mother to child transmission.

High risk exposed infants: these are the infants with increased risk of transmission, it includes infants whose mother is one of the following:

- Diagnosed with HIV during pregnancy or breastfeeding period
- Known to be living with HIV but not on ART
- Started on ART with less than four weeks before delivery.
- On ART with high viral load (≥50copies per ml of blood)

Low risk exposed infants: these are the infants whose mothers are already on ART and have achieved viral load of <50copies/ml (obtained at least 4 weeks apart or within 4 weeks prior to delivery)

Low risk status can change to high risk and vice versa upon availability of HVL test results. For ARV prophylaxis and the management of HIV exposed infants refer to Chapter IV on immediate post-delivery care.

5.5 Care of women and new-borns during labour and delivery to prevent vertical transmission of HIV and HBV

All labour and delivery services should include interventions to prevent MTCT such as:

- HIV testing for women with unknown HIV status and who were not retested during the

third trimester (32 to 36 weeks of gestation)

- Hepatitis B testing for women without initial Hepatitis B testing
- Administration of ART to pregnant women living with HIV and immediate ARV prophylaxis to HIV exposed infants
- Universal DNA-PCR birth testing for all HIV exposed infants
- Universal Hepatitis B vaccine birth dose for all new-borns within 24 hours
- Hepatitis B Immunoglobulin (where available) to all babies born to mothers with high HBV-DNA viral load (200,000IU/ML) or HBeAg positive within 24 hours
- Implementation of safe obstetric practices
- Appropriate labour and delivery care

The Management of labour should follow obstetric best practices and all HCPs must use Standard Precautions during labour and delivery as highlighted below.

1. Use standard Precautions (good infection prevention practices) for all patient's care.
2. Avoid unnecessary trauma during labour and delivery such as: episiotomy, instrumental vaginal deliveries i.e. forceps and vacuum deliveries,
3. Avoid trauma during the immediate postpartum period such as cord separation using different scissors and conduct gentle suctioning of new-born to clear airway.
4. Minimize vaginal examinations and perform vaginal examinations only when necessary, using sterile techniques.
5. Avoid prolonged labour and artificial rupture of membranes.
6. Minimize the risk of postpartum haemorrhage (PPH)
7. Use safe screened blood and blood products transfusion practices.
8. Avoid extensively delayed cord clamping (not to take place beyond 60 seconds)
9. Provide support and reassurance.

All infants delivered at home should be brought to the health facility as soon as possible, preferably within 6 hours after delivery. HIV exposed infants should be provided with appropriate ARV prophylaxis based on their risk category.

5.6 Immediate post-delivery care

Regardless of the mother's HIV, Syphilis and Hepatitis B status, all infants should be kept warm after birth and dried carefully. Infants should be handled with gloved hands until maternal blood and secretions have been washed off. In caring for new-born, HCPs should observe standard precautions.

5.6.1 Care for HIV-exposed infants

Prophylaxis for Low-risk HIV Exposed Infants: Administer NVP syrup immediately after birth (preferably within 72 hours) and continue until six weeks of age. Nevirapine prophylaxis should not be initiated to infants presenting beyond four weeks (>4 weeks) of age.

Table 5.3: Infant NVP dosing

Infant NVP dosing recommendations from Birth to 6-weeks	
Birth	NVP daily dosing
Birth weight <2000g	2mg/kg once daily as starting dose (0.2ml/kg)
Birth weight 2000–2499g	10mg once daily (1ml)
Birth weight ≥2500g	15mg once daily (1.5ml)

The recommended NVP dosing is based on the dosing required to sustain exposure in the infant of >100 ng/mL with the minimum dose changes.

5.6.2 Prophylaxis for High-Risk HIV Exposed Infants

- In case a high-risk HIV exposed infant is identified, give enhanced postnatal prophylaxis (ePNP) for a total of 12 weeks as described in the table 5.4 below

Table 5.4: Enhanced postnatal prophylaxis (ePNP) for high-risk HEI.

Recommended Regimen	Infant Age	Dosage
AZT/3TC+NVP	Dose 0-6 weeks	AZT / 3TC (60/30mg); ¼ tab twice daily and NVP syrup Once daily (based on body weight).
	Dose 6-12 weeks NVP	NVP - once daily (based on body weight)

5.6.3 Care for Syphilis-exposed infants

All infants born to mothers with Syphilis infection should:

- Carefully be assessed for manifestations of congenital syphilis.
- Ensure proper treatment to infants diagnosed with congenital syphilis (Refer section 5.8.2.1 for management of Congenital Syphilis)

5.6.4 Care for Hepatitis B-exposed infants

All infants born to mothers with HBV infection should receive.

- A birth dose of HBV monovalent vaccine within 24hours post delivery
- If available, a single dose of 100 IU HBIG intramuscularly should be given together with HBV vaccine birth dose. This should be given to all exposed infants born to mothers with high Hepatitis B DNA viral load (More than 200,000 IU/ML) preferably within 12 hours.
- Subsequent 3 doses of HBV vaccine during immunization schedule at 6, 10 and 14 weeks of age
- Verify if:
  - Mother with high HBV DNA viral load (>200,000IU/ml) is on Tenofovir prophylaxis.
  - Mother with HIV/HBV coinfection is on Tenofovir based regimen

5.7 Management of HIV-infected women and their infants in the immediate postpartum period

Immediate post-delivery care:

Standard Precautions should be adhered by Health Care Providers when assessing vaginal bleeding and should safely dispose the blood-stained linens and pads.

Postpartum care for women with unknown HIV status

Women whose status is unknown and those with negative results who were not retested previously should strongly be encouraged to test for HIV and advised to breastfeed exclusively as per National infant and young children feeding recommendations. Partners and other siblings of HIV exposed infants should be encouraged to receive pre-test information, counselling and

5.7.1 Counselling for safer infant feeding:

- All women, regardless of HIV status, should receive infant feeding counselling during pregnancy (ANC) and postpartum care according to the guidelines.
- All HIV positive mothers should be encouraged to exclusively breastfeed for the first 6 months, then introduce complimentary feeding while breastfeeding up to 12 months of age.

Note:

Mothers who opt for exclusive replacement feeding, should be assessed for AFASS criteria (Acceptability, Feasibility, Affordability, Sustainability and Safeness) and counselled that replacement feeding is a permanent option i.e. they cannot use alternate feeding options.

5.7.2 HIV testing and CPT prophylaxis in HIV exposed infants:

Women who are HIV positive must be counselled on the importance of infant testing and be scheduled for testing prior to discharge.

HIV testing

All HIV exposed infants should have an initial DNA PCR test at birth (within 48 hrs). For those who are HIV negative they should receive a second DNA PCR test at 6 weeks of age, a third DNA PCR test at 9 months of age followed by an antibody test 3 months after cessation of breastfeeding and a confirmation test at the age of 18 months using antibody test.

All HIV exposed infants below 18 months of age who test HIV positive by DNA-PCR initiate ART and immediately collect another DBS for repeat HIV DNA PCR test.

In settings where DNA-PCR is not available but antibody test is positive, and the infant has any of the following signs or symptoms.

- Oral thrush
- Severe pneumonia
- Severe sepsis
- Lymph nodes enlargement
- Stunted growth
- Any child fulfilling WHO stage 3 or 4 criteria,

Presumptive HIV diagnosis should be made and initiate ART to infant.

For HIV exposed infants at 18 months of age and above, those who test HIV positive with antibody test initiate ART.

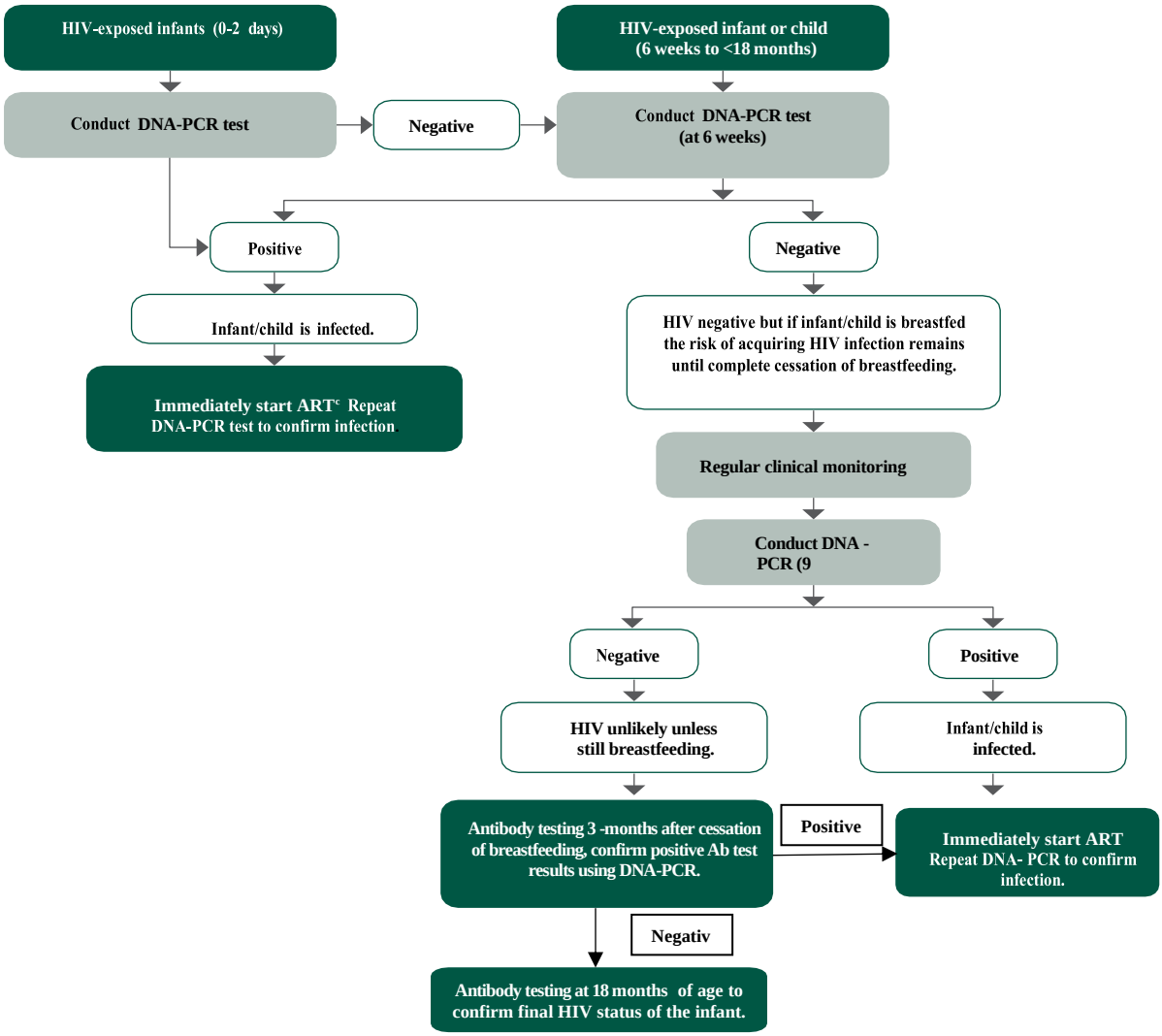
Cotrimoxazole Preventive therapy

All HIV-exposed infants should begin Cotrimoxazole Preventive Therapy (CPT) at the age of six weeks until the end of HIV exposure. Cotrimoxazole should continue up to seven days after being confirmed HIV negative. Table 5.5 below provides recommended infant cotrimoxazole dosing:

Table 5.5: Infant Cotrimoxazole PT Dosing recommendations

Age	Co-trimoxazole syrup dose
6 weeks - 6months	2.5mls Once a day
6 months – end of exposure	5mls Once a day

Figure 5.2: HEI testing algorithm



NB: Point of Care testing for HEI using GeneXpert machine at birth using fresh whole blood is recommended whenever available to enable early detection for timely management. HIV exposed infants delivered at home, or any other place outside the health facility should be tested within 48 hours.

5.7.3 Comprehensive care schedule for the mother and infant:

Mothers who are infected with either HIV, HBV and /or Syphilis and their families will need uninterrupted care, treatment and support services. Healthcare workers should prepare a follow up plan together with the client and ensure the mother knows the time, location, contact person and purpose of all follow-up appointments. In case, the services required are not available at the health facility, healthcare worker should facilitate successful referrals and linkages to treatment, care and support services.

5.8 Treatment of Mother to Prevent Vertical Transmission of HIV, Syphilis and Hepatitis B

5.8.1 Maternal HIV Care and Treatment

PBFW living with HIV should be started on lifelong ART at the time of diagnosis. The recommended first line regimen is once a day fixed dose regimen of Tenofovir disoproxil fumarate (TDF) +Lamivudine (3TC) + Dolutegravir (DTG). Alternatively, Tenofovir disoproxil fumarate (TDF) +Lamivudine (3TC) + Efavirenz (EFV 400mg) may be an option for use on events of or DTG side effects and adverse events.

Before ART initiation, health care provider should discuss health benefits of lifelong ART, including ART impact in preventing mother to child transmission of HIV. A client should understand and comprehend all possible side effects of ARVs. For clients on 2nd and 3rd line ART regimens should continue with their current regimens.

Table 5.6: Maternal HIV Care and treatment

Pregnant and Lactating women	1st line therapy	2nd line therapy
Preferred Option	TDF + 3TC+ DTG	If TDF was used as first line, use ABC plus 3TC plus ATV/r or LPV/r
Alternative Options	ABC + 3TC + DTG TDF+3TC+EFV (400mg)	If TDF was used as first line, use ABC plus 3TC plus ATV/r or LPV/r If ABC was used as first line, use TDF plus 3TC plus ATV/r or LPV/r If TLE was used as first line, , use ABC plus 3TC plus DTG

Note:

- *Tenofovir alafenamide (TAF) is not recommended in pregnancy due to unknown safety profile.*
- *It is recommended that all women on DTG should routinely receive high dose Folic acid (5mg) pre- conception and during pregnancy. Clients with DTG intolerance such as severe liver diseases should not be given DTG containing regimens.*

Whenever possible all women on ART should receive routine LFT and RFT as per guideline on monitoring of individuals on ART

5.8.1.1 Monitoring of PBFW on ART

Successful ART results to suppression of viral load, immune recovery and therefore an increase in the number of CD4 cells. This results into lower transmission risks, improved maternal survival linked with improved HIV free survival for her baby. CD4+ Lymphocytes count should be done at baseline to determine immunological stage and establish need for CPT. Clients with CD4 count of <350 cell/mm^3, the test should be repeated every 3 months. When CD4 >350 cell/mm^3, stop CD4 monitoring and continue with HIV VL monitoring.

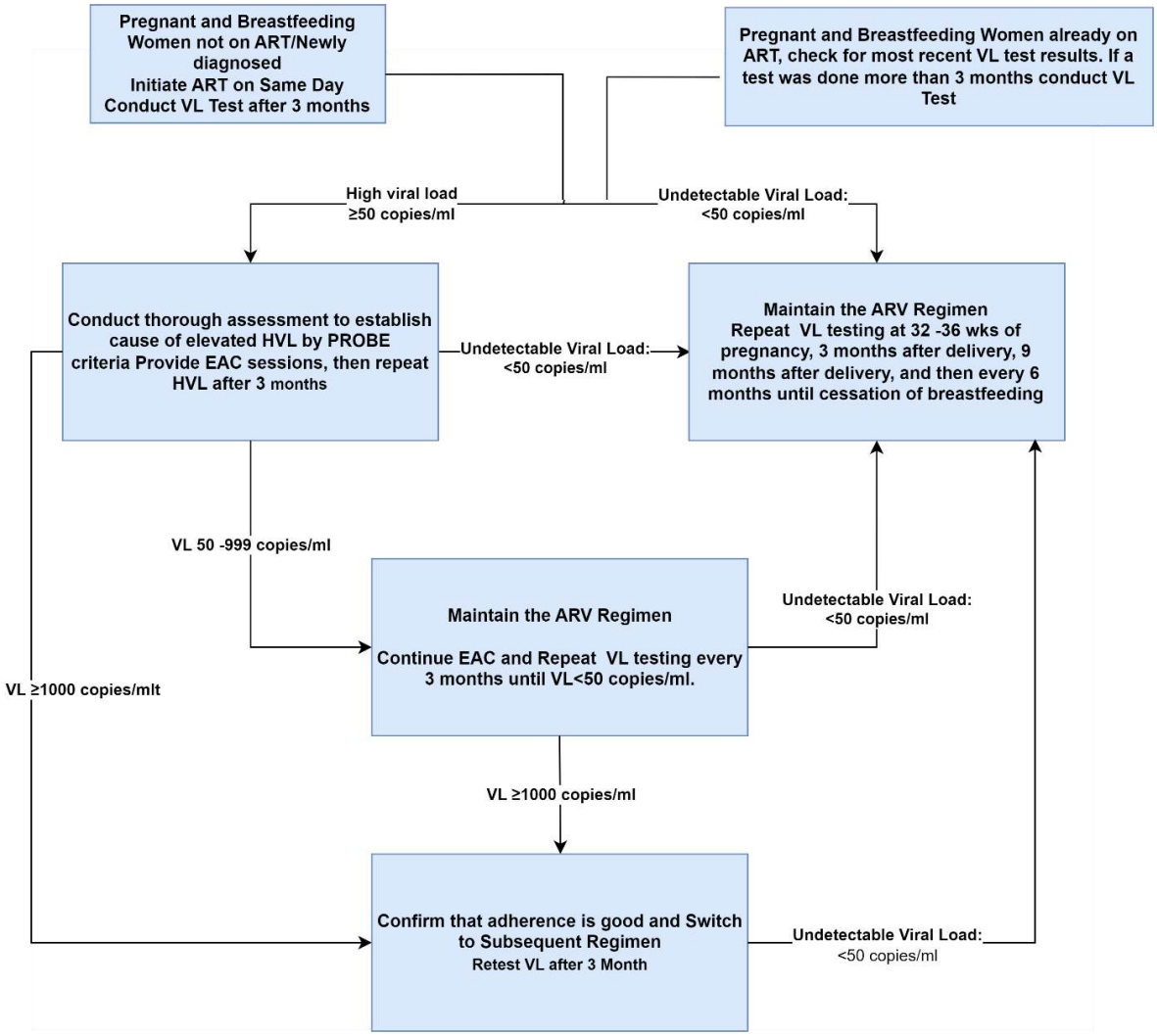
HVL Testing Algorithm during Pregnancy and Breastfeeding

The algorithm is aimed at enabling early identification and management of adherence challenges and treatment failure and hence minimizing the risk of MTCT due to high maternal HIV Viral Load.

a) **For pregnant and breastfeeding women already on ART:** *Conduct VL on first ANC visit, review results with the RoC in 2 weeks upon receiving them.*
b) **For pregnant and breastfeeding women not on ART or newly diagnose:** *Conduct VL after 3-months of ART initiation, review results with the RoC in 2 weeks upon receiving them*

Figure 5.3 below shows HVL testing algorithm for pregnant and breastfeeding women already on ART and newly diagnosed:

Figure 5.3: HVL testing for Pregnant and breastfeeding women already on ART and newly diagnosed



*The goal of EAC in pregnant women is to achieve undetectable viral load (HVL <50copies/mL) to prevent mother to child transmission of HIV. EAC Sessions for Pregnant and Breastfeeding women should be conducted for three consecutive days followed by one session every two weeks for 3 months.

NB: *Point of Care HIV viral load testing is recommended to PBFW in addition to optimization of conventional platform.*

5.8.1 Maternal Care and treatment of Syphilis

Any pregnant woman identified positive for Syphilis should be treated for syphilis. The pregnant woman diagnosed with Syphilis should be managed as shown below.

Table 5.7: Maternal Care and treatment of Syphilis

Disease Stage	Preferred treatment	Alternative treatment
Early	Benzathine Penicillin 2.4MU I.M STAT **OR** Procaine Penicillin 1.2 MU OD 10/7	Tabs Erythromycin 500mg QID 14/7 **OR** IM Ceftriaxone 1G OD 14/7 **OR** Tabs Azithromycin 2G STAT
Late	Benzathine penicillin 3 doses of 2.4MU IM once weekly for three consecutive weeks	Erythromycin 500 mg QID 1/12 Doxycycline* 100 mg BD 28 days **OR** Tetracycline 500 mg QID 28 days
Neuro-Syphilis	Aqueous crystalline penicillin G 24 MU per day (administered as IV 4 MU four hourly or as continuous infusion for 14 days)	Procaine penicillin IM 2.4MU once daily PLUS Probenecid 500 mg orally 4 times a day 14/7

*Doxycycline is not recommended in Pregnancy.

5.8.1.2 Congenital Syphilis

All infants born to sero-positive mothers should be treated with a single intramuscular dose of benzathine penicillin, 50,000 IU/kg whether or not the mothers were treated during pregnancy (with or without penicillin).

Treatment regimens for early congenital syphilis

Children under 2 years of age

- Aqueous benzyl penicillin 100,000–150,000 IU/kg/day administered as 50,000 IU/kg/dose IV 12 hourly, for the first 7 days and every 8 hourly thereafter for a total of 10 days

Children 2 or more years of age

- Aqueous benzyl penicillin, 200,000–300, 000 IU/kg/day by intravenous or intramuscular injection, administered as 50,000 IU/kg every 4–6 hours for 10–14 days
- The alternative regimen for penicillin allergic patients, after the first month of life is Erythromycin, 7.5–12.5 mg/kg (PO) 4 times daily for 30 days.

5.8.2 Hepatitis B Virus Testing and management in pregnant women and exposed infants.

All pregnant women should be tested for Hepatitis B and managed as in the flowchart below.

Figure 5.4: Testing and management of Hepatitis B in pregnant women and infants

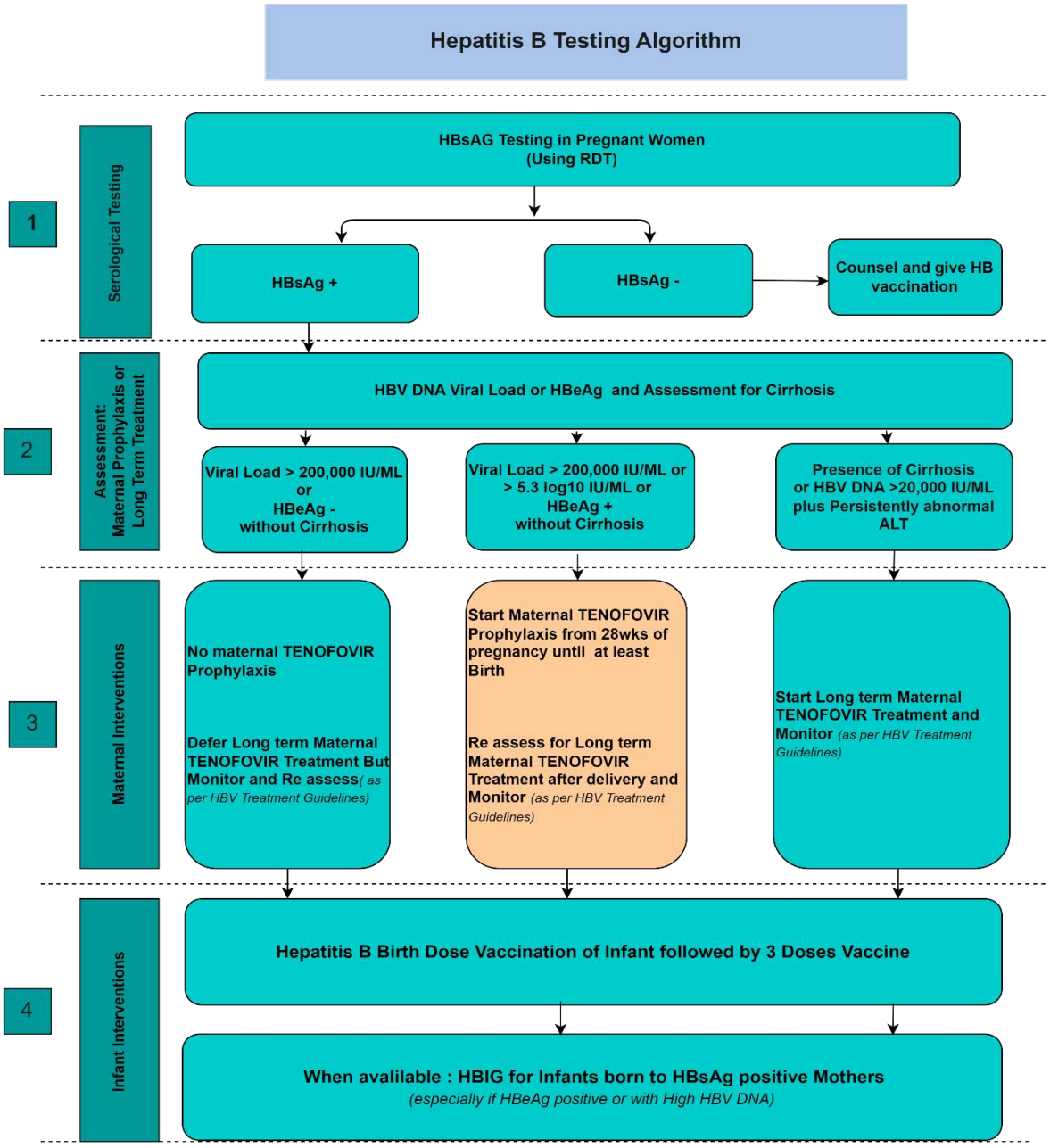


Table 5.8: HBV disease progression tests,

Tests	ALT, AST, FBP, Ultrasound and AFP	HBV DNA, HBeAg,	RFT and risk for renal diseases
Purpose and Frequency	Detection of HCC in patient with Liver cirrhosis or family history of cirrhosis	Adherence and staging of Liver disease	Toxicity Monitoring for RoC on treatment
Frequency	Every 6 months.	Every 12 Months	Annually

Note: For further details on HBV and HCV please refer chapter X.

CHAPTER VI: ADHERENCE PREPARATION, MONITORING, RETENTION, DISCLOSURE AND SUPPORT

6.1 Introduction

Recipients of Care are expected to adhere firmly to the prescribed medication, schedules, and recommendations provided and agreed upon with healthcare providers. Over 95% level of adherence is crucial for achieving viral suppression needed for PLHIV on ART. Healthcare providers should seek and apply different approaches to support the RoC in improving adherence. This chapter provides guidance in adherence preparation, retention, monitoring, disclosure and support among children, adolescents, youth, and adults including pregnant and breastfeeding women (PBFW).

6.1.1 Building blocks of adherence counselling

Figure 6.1: Building block for adherence counselling

6.1.2 Factors that influence Adherence

Health care providers should work with the recipient of care to facilitate adherence by emphasizing the following factors.

Table 6.1: Factors that enhance adherence.

Domain	Factors that influence adherence
Recipient of care related factors	Disclosure of HIV status and involvement of a treatment supporter/family member, including couple counselling.
	Readiness to be on life-long medication and following instructions
	living environment
	Age (adults have better adherence)
	support provided, especially for children and adolescents
Health service providers related factors include:	A good treatment plan agreed upon by both the provider and RoC
	A trusting relationship with the Recipient of care
	Supportive, non-judgmental attitudes and behaviour
	Counselling knowledge and skills on adherence and possible side effects associated with ART
Regimen-Related Factors	Use of fixed drug combinations that have a low pill burden
	Minimal drug interactions and side effects (rational drug selection)
	Food requirements and timing of taking ART medications (e.g. with food, without food, etc.)
	Reliability, education, and socioeconomic status of the caregiver

Domain	Factors that influence adherence
Family/caregiver related factors	Family cultural beliefs and practices with regards to HIV
	HIV status of the partner, parents and/or caregivers
	Ability of parents/caregiver to disclose
	Relationship between the caregiver and the recipient of care
Health System related factors	Relationship between the caregiver and the facility staff
	Availability of medications at all refill times
	Community support services and continuum of care

6.1.3 Consequences of Poor Adherence

Consequences of poor adherence to ART include:

- Treatment failure
- HIV drug resistance
- Increased in morbidity and mortality.
- Growth and developmental faltering

6.2 Adherence preparation, retention monitoring and Support.

Adherence preparation must be customized to the (ROC) based on their age, gender, needs and clinical status. Counsellors should use the guide below to prepare RoC for ARV initiation, retention and follow up.

Adherence Preparation and Support for Children, Adolescent, adult, pregnancy and breast feeding women

Table 6.2: Adherence Preparation and Support for Children, Adolescent, adult, pregnancy and breast feeding women

Visit	Standard of Care
At enrolment into care	• Perform a psychosocial assessment to identify potential psychological, emotional and social adherence influencers and barriers • Identify the primary caregiver/treatment supporter as soon as possible after diagnosis of HIV. • In the absence of a caregiver, link the RoC to a community health volunteer or treatment advocates while a more permanent solution is sought. • Discuss benefits of disclosure of HIV status of the RoC and formulate a disclosure plan for children aged 4 years and above. • Conduct readiness assessment to initiate ART; ART should be initiated on the same day or within 7 days • 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 at enrolment, book the RoC to return within 14 Days after initiation of ART. • Link RoC to CBHS, support groups • Document the session results in the Linkage Case Management (LCM) Register • For children and adolescent. • Assess growth and developmental milestones to rule outgrowth retardation, developmental challenges such as autism, deafness and any other physical

Visit	Standard of Care
	challenge. Any child with developmental challenges should be referred for appropriate care • The child/adolescent and their caregiver, if also infected, should be enrolled in the same clinic as that of the parent/caregiver • Provide HIV education and counselling to the caregiver (and child as appropriate for age) • Identify and establish appropriate adherence support interventions (Table 6.4), including linkage to paediatric and caregiver support groups and pediatric and adolescent clubs. • 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 linkage of the ROC to adolescent mentors, peer educators, social worker, nurses or community health wokers, CBHS providers as may be appropriate. An adolescent can have a one on one counselling session with the counsellor or one that includes the caregiver when deemed appropriate • The health care provider should explore Sexual and Reproductive health (SRH) understanding, fears and needs of the adolescent and prioritize interventions as appropriate. ***For adult*** • Identify a treatment supporter (family member, friend, peer educator, community health worker) and involve them in HIV education and adherence counselling • For pregnant and breastfeeding women • Discuss with the mother, how HIV transmission from a mother living with HIV to her baby. Highlight that can HIV transmission can occur during p (Maternal), Labour and Delivery (L&D) and Breastfeeding (post-partum) • Discuss with a mother on the importance of life long ART services • Address family planning especially Dual method (condom) • Provide assessment and nutritional support. • Discuss exclusive breast-feeding as an option to minimize HIV transmission
Two weeks after ART Initiation	• Review and reinforce the messages delivered at enrolment; • confirm the caregiver's understanding of key messages • Review the ART dosing, timing and reminders (including having the caregiver demonstrate how they measure and administer the medication) • Explore any barriers to adherence • Revisit benefits of disclosure and the individualized age-appropriate disclosure plan • Document session in the LCM Register
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 • Document session in the Linkage Case Management (LCM) Register

6.2.1 Common adherence barriers

Table 6.3: Common Challenges and Strategies to Improve Adherence in Children

Challenge	Strategies
• Child not taking medications	• Obtain a detailed history aimed at identification of the specific causes of his/her broad complaint. • Explore with the parent/caregiver on ways to convince the child to take the medications. • Teach the parent/caregiver on the importance of adherence for the child's survival. • Simplify adherence information to ensure the parent/ caregiver understands the treatment regimen
• Medicines make a child sick e.g. nausea and vomiting	• Administer medications with food • Administer medications with liquid to help reduce gastric irritation • Reassure the caregiver/parent that most nausea and vomiting will resolve • If symptoms are severe, seek expert advice on regimen change and timing of medication.
• Fear of ART harming the child e.g. the child is clinically deteriorating despite good adherence	• Ensure that the child is taking the correct dose • Examine the child for other opportunistic infections • Examine the child for side effects of the regimen • Encourage the caregiver/parent to continue the regimen unless the child has severe side effects, in which case seek an expert advice about changing the regimen • Utilize visiting nurses/CBHS providers to assist with adherence assessments and follow up home visits.
• Regimen dosing confusing to a caregiver/ parent	• Provide the caregiver/parent with a written schedule/ illustration of medications • A written calendar could include symbols for the times of the day to aid with understanding, or utilize colour- coded labels to match with drug regimen colours- coded calendar • Where possible, elicit additional support from another family member or other community resource person.
• Parent/caregiver is ill or absent and other family members cannot give medications to the child	• Treat the ill parent/caregiver • Probe and promote disclosure. • Identify another treatment supporter. • Address stigma and discrimination; provide health education to dispel myths on HIV and AIDS. Refer to CBHS.
• Frequently changing or multiple simultaneous caregivers	• Address the effect of frequent changing of caregivers. • Emphasize on the permanent caregiver/treatment supporter
• Lack of affection and support of caregiver to child	• Assist the bond between caregiver and child through psychosocial and emotional support • Consider changing caregiver/treatment supporter

Challenge	Strategies
• Complexity of measuring paediatric formulations e.g.2nd line regimen (LPV/r syrup)	• Provide the parent/caregiver with a written schedule/illustration of medication • Demonstrate procedures; if possible seek additional support from other family members or other community resource persons.
Unprepared Transition process of children living of HIV to adult HIV care clinic	• Assist the transition of children and adolescents start at the right age to ensure that there's provision of *uninterrupted, coordinated, developmental, age-appropriate* and comprehensive care before, during and after the transition • Transfer the children aged 8-10 years to adolescents HIV clinic by 10 years and by 19 years transitioned to adult HIV clinic • Refer to '*National SOP on Transitioning Children Living with HIV in Care and treatment Clinics'*
Lack of knowledge and skills on Children/adolescent HIV services to teachers	• Re-assure the linkage between facility and school • Increase awareness of HIV services to school teachers in order to facilitate adherence in school • Strengthen school health clubs

Table 6.4: Barriers to Adherence and How to alleviate for adult

Key Barrier to adherence	Suggestions to Alleviate
Social economic problems e.g. transportation, food insecurity	Refer /Link to support groups for assistance Refer to other organizations for economic support e.g. Income Generating Activities (IGA) ● Identify nearby CTC sites ● Involve other family members
No disclosure	Counsel on benefits of disclosure
Travels frequently	Plan the travels before Carry pills Collect pills in advance for longer period Walk with your CTC 1 card Visit any nearby health facility for required services Enrol in MMD and DSDMs
Behavioural barriers e.g. Drinking alcohol regularly, not planning refill for travels or not having a reminder	Counsel to stop or reduce alcohol intake Involve other family members for support Plan for drug refill Address the use of reminders
Emotional barriers e.g. Depression or Mental illness	Counsel for psychosocial support Refer to clinician for treatment Involve other family members for support
ARVs issues e.g. side effects, pill burden	• Reassure Recipients of care and address concerns • Discuss effectiveness and safety of drugs
Myth and missconception	• Discuss misconceptions • Discuss drugs side effects and resistance

Key Barrier to adherence	Suggestions to Alleviate
Unexpected hospital admissions	• Carry pills to hospital • Inform healthcare staff that you are on ARV treatment
Stigma and Discrimination	• Link Recipient of cares with support groups • Create awareness in the communities • Refer to CBHS • Provide health education on HIV and AIDS, Positive Health, Dignity and Prevention (PHDP)
Cultural Beliefs	• Provide Health Education on HIV and AIDS • Create awareness in the communities including religious leaders and traditional healers
Gender Based Violence	• Provide couple and family counselling, educate on importance of reporting early to the facility for PEP, Emergency FP and management of other disease in case of rape • Link RoC to clinical psychologist, Social welfare, Human Rights and Legal issues organizations for support
Communication Problems	• Use colours, symbols and pictures for elaboration. • Usage of simple language and sign language where needed • Use treatment supporter

6.2.2 Adherence, monitoring, counselling and support among Key and Vulnerable Populations

In many settings, key vulnerable populations face multiple challenges related to stigma and discrimination that can affect access to health services, all of which may impact negatively on adherence and clinical outcomes.

a) Key factors to consider when providing services to key and vulnerable populations

Assuring access: Create demand for HIV testing and counselling and prevention services through targeted campaigns in identified key and vulnerable population settings, use community-based outreach, online services, mobile phone technologies, social networking and develop friendly key population services at health facilities; this will facilitate dissemination of behavioural messages, promote follow-up and referral to services, improve adherence to treatment, and increase Recipient of care participation in their own healthcare.

Ensure confidentiality: Attention should be devoted to protecting privacy and confidentiality, e.g. closing the consultation room door or finding a private place to talk. Recipients of care should be reassured of confidentiality.

b) Adherence Monitoring, Counselling and Support for Recipients of care with Undetectable Viral Load

Once a Recipient of care has confirmed viral suppression (with VL below 50 copies/ml)

it is a confirmation of adequate adherence to ART

c) Counselling and support to achieve undetectable viral load

- Elicit any concerns the Recipient of care/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 Recipient of care's/caregiver's life or daily routine that could disrupt adherence
- Update Recipient of care locator and contact information
- Encourage the Recipient of care/caregiver to continue with the supportive system

d) Adherence and support to ROCs with Interruption in Treatment (IIT) and Stopped ART

ROC with interruption in treatment is one of the following:

- Who have not received ARVs within four weeks (i.e. 28 days) of their last missed ART pick-up.
- Those who have not received ARVs within 28 days from the last missed documented community visit with a community health worker, HCPs or peer from a scheduled ART refill group.
- Those who previously opted out/stopped ART by any named reason(s). With exceptional of those who reported to be on ART and had ART refill from other facility or were using Spouse/partner's drugs should be excluded.

Table 6.5: Adherence monitoring and support approach to RoC who IIT and Stopped ART

Adherence	Monitoring and support
• Step 1: Provide the welcome Back Package	• Warmly welcoming the RoC, including congratulating them for choosing to come back to care (Avoid scolding or being judgmental)
	• Pledging support: 'I am here to support you through your ART journey"
	• Identify the reason for Interruption In Treatment
	• Ascertain which drugs the RoC was taking, and for how long, the reasons for stopping treatment, check if they had any side-effects
	• Assess presence of chronic and/or Non-Communicable diseases, OIs and link to appropriate services (e.g. cervical cancer screening, AHD etc.)
	• Request for a CD4 if RoC has Interrupted Treatment for >6 months. If CD4 is less than 200, conduct CrAg testing, start CTX and offer other AHD services as needed
	• Review RoC's CTC1 and CTC2 Card/files particularly but not limited to CD4 Cell count, HIV Viral Load test and results, TPT, and update the new contact information if any
• Step 2: Adherence and monitoring	• Verbal consent for linkage case management Services
	• Enrol the RoC to Enhanced Adherence counselling (EAC) monitoring and support for the period of 3 months and test for HIV Viral load (Depending on the HVL Results follow the National HVL Monitoring algorithm)

Adherence	Monitoring and support
sessions	• Discharge the RoC from EAC through community based HIV/AIDS services Program
	• Whenever necessary, encourage the RoC to enrol into PLHIV Support Groups

e) Monitoring Adherence

Effective communication between facility (CTC) and community structures is important to facilitate RoC tracking and follow up to mitigate any reasons for missed visits and Interruption in Treatment.

The following are the strategies for adherence monitoring.

Table 6.6: Adherence Monitoring Strategies

Adherence Monitoring Strategy	Technique	Frequency
Morisky Medication Adherence Scale-4 (Annexes 7)	Assess adherence using a standardized questionnaire, and act as required	Every recipient of care, every visit
Morisky Medication Adherence Scale-8	Assess adherence using a standardized questionnaire, and act as required	Any time a healthcare worker suspects adherence problems (e.g. RoC with suspected or confirmed treatment failure , or who misses an appointment)
Pill counts	Ask the recipient of care 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	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 recipient of care is missing doses equivalent to the number of days late	At every drug pick-up Any time a healthcare worker suspects adherence problems

Adherence Monitoring Strategy	Technique	Frequency
Viral load	Follow the viral load monitoring algorithm. Undetectable VL is the the best affirmation of optimal adherence	Age 0-24 years: every 6 months Age ≥ 25 years: at month 6 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 (refer to Chapter IV; Refer to HVL Algorithm)
Urine Tenofovir Rapid Assay (UTRA) Has shown good results and high acceptability among health care providers and PLHIV.	UTRA assesses tenofovir presence in urine at point-of-care and can be used to identify PLHIV with short-term poor adherence to preexposure prophylaxis (PrEP) or TDF containing treatment regimens. Distinguishes high or low adherence patterns within the last 48 hours, as well as non-adherence extending over one week prior to measurement	The frequency of urine assay for tenofovir is determined based on individual client needs and at provider discretion
Home visit		

Adherence Monitoring Strategy	Technique	Frequency
	Observe where and how a recipient of care stores their medications and assess if they have extra medications signifying missed doses. Home visits may also provide a better understanding of a RoC living situation and specific barriers to adherence. Unscheduled home visits may be more revealing, however, should only be conducted if the RoC consented to home visits previously (preferably at the time of enrolment or initiation).	For RoC with suspected or confirmed treatment failure, RoC who interrupt treatment , or any time the MDT feels a home visit will contribute to RoC management

Formula for Calculating % Adherence:

$$\%\ of\ pills\ missed = \frac{Number\ of\ Pills\ Remaining}{Total\ number\ of pills\ prescribed} x100$$

$$Percentage\ adherence = 100 - \%\ Pills\ Missed$$

Table 6.7: Adherence Support and Retention Interventions

Standard Adherence	Support Interventions
Structural interventions	• Conduct a baseline psychosocial assessment to explore the various aspects of the RoC life that may influence their adherence to treatment and prevention, and their general well-being and identify issues that need to be explored in detail during the counselling session e.g. disclosure, living circumstances • Use a multidisciplinary team approach to develop and implement treatment plans for each RoC • Engage peer educators to lead HIV education and support services • Adequately prepare and assess the RoC's readiness to initiate and continue with ART • Implement a system for identifying and taking action when RoC misses an appointment • Formalize a system for providing health talks and treatment literacy classes for RoC. • Formalize a system for linking RoC to community-based resources, including: community support groups, religious groups, CBOs, groups supporting income- generating activities, organizations providing food

Standard Adherence	Support Interventions
	support, child welfare societies, community health volunteers/units, schools, children's homes

HIV education and counselling	• Remind the RoC about HIV disease, how ART works, the importance of high level adherence and the consequences of non-adherence
	  • Risk disease progression, poor quality of life and death
	  • 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 minimize, recognize and manage them.
	  • Address misconceptions and beliefs about HIV and ART
	• Discuss and agree on a treatment plan with the RoC. Gain commitment from the recipient of care 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

Disclosure and stigma	• Respect RoC privacy and confidentiality • Discuss with the RoC 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 • Conduct stigma assessment and support appropriately
Treatment supporter	• Encourage the RoC to identify a treatment supporter/buddy who will provide RoC encouragement and social support and even remind the RoC to take medication • Invite the treatment supporter to at least one of the adherence counselling sessions • Obtain consent from the RoC to contact the treatment supporter if needed
Support groups	• Develop population-specific support groups when possible (youth groups with peer educators for adolescent's children clubs, caregiver support groups) • Link the RoC to psychosocial support groups and other community-based support mechanisms (preferably through direct introduction) • MDT members should be patrons to the support groups to guide activities in line with intended objectives. More references can be found in *National Guidelines for the Formation and Management of Support Groups, 2013.*
SMS reminder system	• Enrol RoC into an automated SMS reminder system with their consent. • Review the type of messages the RoC may receive, the frequency of messages, and any actions the RoC should take when receiving the message. • Ensure the system and messages maintain RoC privacy and confidentiality

Standard Adherence	Support Interventions
Other reminder strategies	• Encourage RoC/caregiver to set a specific time of day to take ART, and to associate the ART time with a specific event/s in their daily schedule. • Encourage RoC/caregiver to set an alarm on their phone

6.2.3 Readiness to Start Treatment

Before starting medications, the HCPs should conduct a readiness assessment (Annexes 4)

6.3 Enhanced Adherence Counselling (EAC)

Enhanced Adherence Counselling (EAC) is an intensive counselling session aimed at addressing adherence related issues or poor treatment response or failure. It's conducted among RoC who have been on ART for at least six months and has an HIV viral load of more than ≥50 copies/ml. A minimum of three sessions within 12 weeks is recommended for enhanced adherence counselling. It is preferable to have the Recipient of care go through all adherence counselling sessions with the same counsellor in order to provide continuity. All issued identified should be documented to ensure timely follow-up.

6.3.1 The goal of EAC

- Assessing and understanding the barriers that affect the client's adherence
- Developing adherence strategies to overcome barriers
- Providing education on the outcome of their latest clinical assessment and VL results
- To understand RoC knowledge, perception regarding their treatment and importance of VL suppression.
- Correcting any misconceptions and allowing flexibility around the most common barriers to adherence (such as alcohol/ drug consumption, forgetting doses due to a rigid schedule, etc.)

6.3.2 Conducting EAC to different populations groups[4]

EAC to ROC with low viremia (≥ 50 copies/ml to < 1000 copies/ml)

HIV transmission and treatment failure can still occur at low levels of viremia. It is thus necessary to conduct EAC (using PROBE (annexes 5)) in this population so as to attain undetectable viral load (HVL less than 50 copies/ml) and attain untransmittable level. Upon receiving HVL results, all RoC with HVL 50 copies/ml to 999 copies/ml, should be initiated EAC sessions as indicated in the HVL algorithm.

a) EAC to RoC with High viremia (≥1000 copies/ml)

Initiate EAC at-least 3 sessions for the period of three months and re-test HVL one month after the third EAC session. If HVL results are ≥1000 copies/ml proceed with EAC monthly and retest HVL after three months. If HVL results are persistent ≥ 1000 copies/ml refer ROC to facility MDT for discussion and switching to subsequent lines.

[4] *WHO guideline 2021*

b) EAC to pregnant and breastfeeding women

For PBFW with viral load ≥50copies/ml to < 1000copies/ml and those with ≥1000copies/ml, initiate 1 st EAC sessions for 3 consecutive days from day of results and follow up with 1-day session every 2 weeks for 3 month. Repeat HVL on the day of the last session. If HVL is 50-999copies/ml continues with EAC cycle and test for HVL after 3months. If HVL is above 1000 copies/ml despite good adherence, consider log drop and switch to second line regimen and repeat HVL 3 months after switching. For ROC with HVL 50-999copies/ml and HVL persistently above 500 copies/ml, and those with ≥ 1000copies/ml, despite good adherence for 12 months of EAC, conduct GART and switch to appropriate regimen.

c) Special consideration to pregnancy women during EAC sessions

- EAC for PBFW should be done until viral load is undetectable.
- Discuss with the mother, mode of HIV transmission and explain that transmission occurs during pregnancy, labour, delivery and during breastfeeding.
- Discuss and counsel on proper infant feeding practices

d) Special consideration to Children and adolescent during EAC sessions

- Involve the child in the whole EAC process, if still young, involve parents/ caregivers in developing plans and its implementation
- Implement Child Care Family Centered Approach
- Ask the caregiver about how the child tolerates medication e.g., does the child refuse to swallow medicine, spit out or vomit medicine.
- Review the disclosure criteria and encourage parent/ caregiver to disclose to the child HIV status (partial disclosure at age 5 to 9 years and full disclosure at 12years)
- Link the child to age-appropriate peer groups and teen clubs
- Provide adolescent friendly services`

Table 6.8: Components of Sessions for Enhance Adherence Counselling

Component	Enhance Adherence Counselling
Session 1	Explain the purpose of your session, define terms and • Review understanding of viral load (VL) and explain the benefits of VL suppression. • Conduct PROBE assessment. • Assess any barrier result into an increasing in viral load • Address any reported barriers to adherence and discuss effective strategies to overcome. • Update or develop an adherence plan with the RoC • Discuss risk reduction (e.g. for substance abuse) • Mental health screening (screen for depression using PHQ-9, GAD-7, dementia scale etc.) • Discuss Recipient of care's support systems, referrals and linkage to different support groups • Assist Recipient of care to develop adherence plan to address the identified

Component	Enhance Adherence Counselling
	issues
Session 2	• Education on the assessment result • Review adherence plan from the first session and discuss any challenges • Identify other possible gaps and issues emerging. • Referrals and networking • Assist Recipient of care 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 Recipient of care 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 Recipient of care and the health facility • If adherence challenges persist: plan further Enhanced Adherence Counselling sessions before repeating the VL
Assessment session	• Assess the level of adherence • Restart EAC to ROCs with existing barrier repeat HVL test for those with the eligibility criteria's
Session to Discuss Repeat Viral Load Results	• Discuss result of the second VL test • Plan the way forward: o If VL now undetectable: continue current regimen with enhanced adherence, repeat VL after 6 months. - If VL ≥ 1,000: prepare Recipient of care for change of regimen. - If VL is detectable but < 1,000: may continue to monitor or may prepare for change of regimen, pending MDT discussion and consultation with Regional or National HIV Clinical TWG
Case management	• Assign a CBHS provider to all children and adolescents (those not achieving optimum treatment outcomes); pregnant women, orphans, Recipient of cares with alcohol and substance abuse, Recipient of cares with mental illness, Recipient of cares with suspected or confirmed treatment failure, and any Recipient of cares 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 Recipient of care and the MDT • Roles of the case managers include: - Coordinating multidisciplinary management for Recipient of cares under case management - Following up on appointment-keeping for their Recipient of cares - Organizing Recipient of care reminders (SMS, calling the day before) and other support systems - Ensuring appropriate defaulter tracing - Coordinating home visits to their Recipients of care

6.4 Community Led Adherence Support

Established on ART **(**Stable) recipients of care do not need intensive care model. For community led adherence support to be efficient it needs to be monitored as its follow:

- Each recipient of care should be attached to Community Based Health Services providers (CBHS), CHW, and peer educators.
- Roles of treatment advocate
  - Provide adherence support and monitoring of treatment outcomes,
  - Record and share progress.
- Roles of Health Facility
  - Monitor PLHIV progress through the record sent from the Community.
- Role of family/family member
  - Encourage and remind RoC to take medication regularly.

***NB**. RoC whose stability status changes should be referred back to the facility for appropriate care*

6.5 Disclosure

Disclosure is sharing HIV status with someone else to relive the stress living with HIV. Disclosure enhanced adherence on ART, health care worker and lay worker should be equipped with adequate skill, knowledge, and aids to support the disclosure process to provide post disclosure support.

PLHIV with adherence issues should be assessed for their disclosure status, based on the age categories and understanding of the RoC. Several factors influence the decision to disclose an HIV diagnosis to a child or adolescent or spouse. As with other chronic illnesses, age and developmental maturity are the most significant factors for determining whether a child, adolescent or spouse will be disclosed to; generally, disclosure can be categories as follows,

1. Partial disclosure
   Start at age of 4-6 years. To initiate partial disclosure, a child or adolescent living with HIV needs to understand why he or she attends the clinic and takes medications. HCW and caregiver can start to explain that ARV helps put germs to sleep and keep the child health and strong.
2. Full Disclosure
   Start at age of 8-10 years. Provide full information and knowledge about HIV.
3. Accidental Disclosure.
   Telling someone about his/her HIV status without preparing them and disclosing to them by accident. This is strongly discouraged.

Refer to Job aids for comprehensive differentiated delivery of HIV and AIDs services of 2019.

CHAPTER VII: COMMUNITY BASED HIV AND AIDS SERVICES

7.1 Introduction

Due to advancement in the management of HIV and AIDS and the changing needs of ROC, the scope of Community Based HIV and AIDS Services (CBHS) has changed significantly, from taking care of bedridden ROC to providing ambulatory differentiated services.

This chapter describes Community Based HIV and AIDS services which is part of the comprehensive continuum of HIV care services. The chapter identifies and describes the differing needs of PLHIV and their family members and provides recommendations for helping them cope with lifelong ART.

7.1.1 Overall goal

To harness community resources to support ROC through the HIV Care and Treatment cascade, health promotion and prevention of Non-Communicable Diseases (NCDs).

7.1.2 Objectives

- To promote continuum of care through enhanced ART adherence and retention of PLHIV and prevention of NCDs
- To strengthen PLHIV structures at community level for enhanced case identification, bi-directional referrals, and linkage mechanisms.
- To increase demand and utilization of quality HIV services and prevention of NCDs
- Facilitate effective implementation of ART refilling option for PLHIV. and prevent NCDs

7.1.3 Scope of CBHS

CBHS ensures continuity of care provided to PLHIV. Continuum of care means a set of comprehensive treatment, care, and psycho-social support services provided from facility to community level. CBH services are provided by the government, NGOs, Community-Based Organizations (CBOs), Faith-Based Organizations (FBOs), and community members. A continuum of care is achieved through a combination of well-defined strategies and intervention packages to improve health and social well-being through home- and facility-based services throughout the lifecycle of a health or social welfare issue. In provision of CBH services it is important to recognize that PLHIV can play an important role in delivering continuum of care services through sharing lived experiences and strong desire to ensure their peers are linked to treatment and care services.

PLHIV and their affected families and households have a variety of other needs beyond mere clinical needs. Such needs include access to post-GBV services, psycho-social, nutritional, educational, economic, and legal services. It is the CBHS approach that caters for these needs and creates mechanisms for commonly addressing them.

7.1.4 Beneficiaries of CBH services

Community Based HIV services target the general population including people living with HIV including older people, children, pregnant women, breastfeeding mothers, Adolescent Boys and Young Men (ABYM), People Who Inject Drugs (PWIDs), People who Use Drugs (PUDs), High Risk Women, Adolescent Girls and Young Women (AGYW), fisher folks, miners, long distance truck drivers, prisoners as primary target groups and chronically ill recipients of care as secondary target groups. Also, CBHS targets caregivers of PLHIV to enhance continuum of care and treatment, and disclosure to people living with HIV.

7.2 Community Based HIV Services Provider (CBHSP)

The Ministry of Health (MOH) is committed to formalizing the Community Health Worker (CHW) cadre. However, there are several CHW cadre, most of these focus on a few selected areas and are donor funded. The different cadre who support different community activities include: Home Based Care (HBC) Providers, Treatment Advocates (TAs), Peer Educators, Liaison Persons, Client Trackers, Volunteers and Community Based Distributors (CBD). The lack of coordination in recruiting, placement and payment or a uniform stipend causes confusion and duplication in the different programs.

This guideline recognizes the contribution of community members supporting HIV and AIDS services at community as well as at health facility and sets standards for harmonized provision of CBHS at facilities and in the community. In this regard, all providers volunteering to HIV and AIDS services are known as Community Based HIV and AIDS Services Providers. The ministry has formerly designated CHWs as a formal paid cadre to provide health services at the community level. The CHWs will be trained using the approved national training package and certified to support community activities. The CHWs will be of categorised under two groups: (i) Licensed (CHWs) Community Health Professional and (ii) Non-Licensed CHWs). CHWs will work on a voluntary basis but will be eligible for financial and non-financial incentives. The licensed CHWs will work with non-licensed CHWs (CBHS)) to achieve the goals set by the National Health Sector HIV and AIDS Strategic Plan.

7.2.1 Selection criteria of CBHS Providers (Non-Licensed CHWs)

To ensure that competent individuals who can ably work under difficult field conditions and who can be trained to maintain confidentiality non-licenced CHWs (CBHS) will be selected based on the following criteria:

- Willingness to do volunteer work.
- Must be a resident and currently residing in the street/community for at least 3 years.
- Must have completed at least primary school education and is able to read and write.
- Must be familiar with local language, culture and social norms.
- Must have no record of child abuse, mistreatment or any other unlawful conducts.
- Must be committed, hardworking and with a passion to serve the community.
- Must be trustworthy and able to keep client information confidential.
- Priority must be given to those experienced in community-based health and social welfare.
- Must be capable of building good interpersonal relationship.

- Must be reliable and flexible to deal with various community groups, especially youth and children.

7.2.2 CBHS Providers Training

Only CHWs trained using the approved national training package and certified can serve as CHWs. Training will be conducted by national trainers as described in the National Operational Guideline for Community Based Health Program 2021

a) Roles and responsibilities of CBHS providers

Following the evolution in HIV clinical management, CBHS providers need to play new roles and take on additional responsibilities so as to ensure treatment continuity and quality ART service provision. New roles of CBHS providers include the following:

- Provide education on condom use, disclosure, GBV, TB and STIs.
- Condom distribution at the community level.
- Promote stigma and discrimination reduction practices through peer support, escorted referral, treatment literacy sessions and disclosure.
- Promote male involvement in HIV response through forming targeted approaches that increase male uptake to HIV services.
- Identify pregnant and breastfeeding women from the community and refer them to RCH clinics or health facilities at their catchment areas for HIV testing and continue with post-test services to those identified with HIV infection at community level.
- Track and refer to mothers living with HIV enrolled in PMTCT who have delivered and have not come back for DBS results of their new-born.
- Identify and refer key and vulnerable populations including PWIDs, PUDs, and sex workers, AGYW, ABYM, people with disability, miners, fisher folks, long distance truck drivers to health facilities for HIV services including HIV testing, HIV prevention (condoms, PrEP, PEP, and IEC materials), ART and Sexual Reproduction Health.
- Elicitation of index contacts through reaching PLHIV and link to HIV testing for early case identification and linkage to care. Index contacts includes sexual partners prioritizing those newly diagnosed, those with high viral load and those returning after interrupting treatment, biological children of HIV positive women under 18 years and PWIDs.
- Provide health education, treatment literacy and adherence counselling on ART to pregnant and breastfeeding women living with HIV.
- Initiate and facilitate HIV Post Test Clubs/Support groups at the community and supporting them have good leadership, get registration and other documents that formalize their operations.
- Promote youth friendly services to increase uptake of HIV treatment services among youths and adolescents living with HIV.
- Provide nutritional care and support (education, counselling, nutritional assessments, and attention to household food security).
- Deliver treatment literacy messages to care givers, parents, and school administration, religious leaders for treatment adherence to students and pupils living with HIV.

- Support PLHIV who have pain and distressing symptoms by referring them to palliative care services.
- Encouraging PLHIV to adhere to treatment by informing them of possible side effects to ARVs.
- Provide spiritual and emotional support to PLHIV to encourage treatment uptake and adherence.
- Establish and manage community based PLHIV support groups or clubs for enhanced treatment literacy sessions, peer support and viral monitoring.
- Conduct community visits to provide adherence counselling and health education to ensure treatment retention.
- Track treatment interrupters through the CTC Desk and return them to ART s. Activities will include:
  I. Line listing ROC who have interrupted treatment.
  II. Follow up through phone calls or by physical visits to their households; and
  III. Provide report/feedback through the recommended system.

- Facilitate ART DOT to RoC with high viral load
- Advocate for CBHS to the community through meetings
- Facilitate disclosure but supporting PLHIV to choose a primary caregiver who is his/her relative to help by reminding or assisting him/her in taking medication.
- Link newly diagnosed PLHIV to peer empowerment groups. An empowerment group is a platform that brings PLHIV together to share treatment literacy knowledge and receive enhanced adherence counselling from fellow PLHIV. These groups should provide PLHIV with psycho-social support, economic strengthening, linkage and referrals, entrepreneurship skills, and enrolment to health insurance. Through these groups, the newly diagnosed recipients of care will get experience and testimonies from other recipients of care who are on treatment for a long time hence help them with adherence and acceptance of HIV status which will eventually help them in status disclosure

b) Bi-directional referral

A bi-directional referral refers to both information going from the health facilities to the referred community and the information returning from that community to the health facilities.

CBHS services strengthen the continuum of care and t support. An effective continuum of care requires a functional referral mechanism (bi- directional referral) to improve access to quality HIV services. Through an effective and functioning referral system, PLHIV will continue to receive support services within their respective communities and homes and go to the facility for clinical evaluation, viral load testing or when they have issues requiring facility attention. To strengthen this system, the CBHS coordinator should ensure that the national referral forms are available and that CBHS provider complete the following:

- Fill in and issue a referral form to the recipient of care.
- Ensure that the feedback portion is filled and returned to the initial referral provider.
- Refer the recipient of care depending on their needs are and what is available to them in

their community in terms of spiritual, legal, income, nutrition, and food, and socio-economic support.

- Develop and regularly update the referral services directory within their locality; and
- Facilitate referral services to care and treatment clinics for those who test positive in the community through self-test kits.

7.2.3 Contribution of CBHS programs in the HIV response[5]

Community-based health services (CBHS) is a sub-system of the overall health system, a tier between primary facilities and communities. CBHS programs have significant contribution as follows:

- Provide access to services for hard-to-reach populations.
- Untangle HIV services inequalities hence increased utilization of services.
- Decongesting health facilities as some services.[6]

a) Role of education institutions in the HIV response

- Students are expected to receive friendly services for HIV prevention and treatment at school and higher learning institutions. [7]
- School administrations are expected to create an enabling environment for treatment adherence to students and pupils living with HIV.[8]

b) Role of religious institutions in the HIV response

Religious institutions have a significant role to play in the HIV response by its ability to influence behaviour change. Religious institutions may play complex and varied roles in helping parishioners cope with HIV and its complications. Therefore, religious institutions need to:

- Promote and take part in addressing HIV treatment adherence issues.
- Engage in addressing stigma and discrimination against PLHIV and others.
- Abide by national HIV management guidelines and prevention policies.
- Ensure that the HIV response is integrated into religious structures and practices and promotes identification of those living with HIV, helps them adhere to treatment and achieve viral suppression.

7.2.4 Community Led Monitoring

CLM is a PLHIV-centred monitoring approach that seeks to improve availability, access, acceptability, affordability and appropriateness and quality services to PLHIVs in treatment and retention to ART. Is an inclusive and systematic approach whereby service users (PLHIV in this context) take leadership role in collecting feedback (enablers and barriers) from their fellows and from health facilities and later generate a list of recommendations and a plan to track HIV service provision at facility level.

[5] The Role of Community Health Workers in HIV Care Engagement, Blandina Mmbaga et al, 2021
[6] Effectiveness of the PLHIV in tracking LTFU on ART, Joel Mwanga et al, 2021
[7] National Policy on HIV/AIDS, 2001
[8] National Policy for HIV/AIDS Management in schools, 2001

The purpose of CLM is to encourage health workers at all levels and other stakeholders in the HIV response, to develop innovative approaches for quality improvement and implement them, to outline what needs to be done to institutionalize quality of health care at various levels based on recommendations provided by service users, national interests and vision in HIV service delivery. CLM is guided by the UN-Meaningful Involvement of PLHIV (MIPA) Strategy, the Tanzania Quality Improvement Framework in Healthcare (TQIF) realised in October 2011; and the Community Quality Improvement Framework (CQIF) First Edition of 2018. Community-Lead Monitoring will help to identify issues that are of concerns for PLHIV and propose measures based on their experience in ART service delivery. Raising issues of concerns as PLHIVs through their structures will enhance PLHIVs' voices towards improved quality HIV services and hence help to mobilize more people for HTS, ART, Prevention and HVL Monitoring. In this regard, PLHIV need to be engaged to:

- Conduct meeting with their peers to obtain feedback on availability, accessibility, acceptability, affordability, and appropriateness of services provided to them.
- Meet with facility staff, health management teams at council and regional level to obtain clarity and quantitative information related to feedback obtained from their peers.
- Meet with policy and decision makers at ministerial level so as to track policy-level response in addressing long-term HIV challenges resulting from CLM reports.
- Monitor changes as agreed during feedback session with health facilities, district, regional and policy makers.
- Conduct dissemination to key stakeholders about progress made in availability, accessibility, acceptability, affordability, and appropriateness of HIV services delivered to them.

7.2.5 Community ART refill

Community ART Refill Group (CARGs) model is an differentiated service delivery model in recipients of care who are established on ART (stable) voluntarily form into groups, and a group member visits the health facility to collect ART for all group members[9]

Community ARV refills improve retention in ART services leading to effective management of HIV. With the current Human Resource for Health (HRH) gap, community ART refill will allow health staff to serve a reasonable number of recipients of care more efficiently. This guideline provides ways for implementing the CARG model:

- Established on ART (Stable) recipients from the same geographic area for a group and take turns to go to the health facility to collect for the group.
- The person who collects ARV from the health facility distributes them to group members.
- Collection and distribution of ARVs is done rotationally by different CARG members taking turns in each collection period.

[9] Ref: Decroo T, Telfer B, Dores CD, White RA, Santos ND, Mkwamba A, et al. Effect of Community ART Groups on retention-in-care among recipient of cares on ART in Tete Province, Mozambique: a cohort study

- All PLHIV in a group (CARG) eventually have to go to the facility for their scheduled clinical consultation blood draw for HVL testing.
- The coordination of the model should be done jointly by the facility staff and the structures of recipients of care called Konga at district and ward level.

7.2.6 Retention and Tracking of RoC

Retention of RoC is the process of continuously using services, keeping clinic schedules and complying to HCP's instructions. It is a key towards achieving goals of care and treatment. Tracking is a major role that CBHS providers have to play.

In implementing this, CBHS have to:-

- Attend CTC and work at the CBHS desk
- Obtain the list of RoC for tracking
- Identify the location of individual RoC for tracking
- Make follow up/track and provide counselling on the importance of attending clinic.
- Fill in the tracking tools.

CHAPTER VIII TB/HIV CO-INFECTION

8.1 Introduction

TB is the commonest opportunistic infection and the major cause of death among PLHIV. HIV increases the risk of TB acquisition and reactivation and progression from TB infection to active disease. There is a 4 fold increase in the risk developing Active TB[10]. The MoH updated the TB/HIV collaborative policy guidelines in 2022 highlighting priority interventions to address TB/HIV co-infection.

8.2 Collaborative TB / HIV activities

Addressing TB/HIV co-infection requires a collaborative approach involving joint efforts by healthcare providers, community organizations, and government agencies to not only prevent but also identify, diagnose, treat TB and HIV in individuals and communities. The collaboration should aim at joint management in delivering integrated TB and HIV services in coordination, planning, and resource mobilization on TB/HIV activities.

At CTC level, providers should aim at reducing the burden of TB among PLHIV through screening and timely initiation of ART. Healthcare providers should be trained in both TB and HIV case management and offer comprehensive care to RoC who are co-infected. TB infection control measures in HIV care and congregate settings such including proper ventilation, use of masks, and screening of healthcare workers to prevent the transmission of TB within healthcare facilities should be emphasized.

Community organizations also should play a key role in providing education and support to individuals living with TB and HIV, reducing stigma, and encouraging adherence to treatment and where necessary, referring for diagnosis, treatment and other support services. Consult *TB/HIV collaborative policy guidelines third edition, 2022* for further description.

8.2.1 Intensified TB case finding among PLHIV.

- All PLHIV should: be screened for TB on every clinic visit for early identification and treatment of TB. PLHIV without symptoms and signs should be provided with TPT to prevent them from developing active TB.
- PHIV may have an atypical clinical picture, especially those with advanced HIV disease, further complicating the clinical diagnosis of pulmonary and extra pulmonary forms of TB disease.
- Both clinical (signs and symptoms) and laboratory approaches (microscopy, culture or WHO recommended rapid diagnostic test) should be used when assessing for TB infection.

[10] TB Global report, 2022

8.2.3 Clinical evaluation

Table 8.1: Clinical diagnosis involves history taking and physical examination.

Step	History evaluation
History Taking	● Ask the RoC about any existing symptoms suggestive of TB disease among adults (Such as cough of any duration (sputum colour and quantity), night sweats, fever or weight loss) ● Ask about history of TB disease and the outcome of treatment. ● Ask about history of TB among contact(s) of TB patients. ● Ask about history of other risk factors such as tobacco smoking, drugs and alcohol use or occupational history (miners)
Physical examination	Assess the RoC for ● Fever ● Anaemia ● Lymphadenopathy, ● Presence or absence of chest and neurological abnormalities ● Hepato-splenomegaly in order to screen for co-morbidities and rule out EPTB in all RoC.

Table 8.2: Laboratory diagnosis

Molecular tests	Sputum smear microscopy	Culture and sensitivity	Additional supportive diagnostic tests
WHO recommended molecular diagnostics tests (mWRD) ● Xpert MTB RIF/ULTRA ● Truenat **Note: collect spot sputum sample from All presumptive TB case for molecular testing.** Line Probe Assay (MTBDRplus (1st line DST) and MTBDRsl (2nd line DST)	● Spot-Morning Light microscopy (ZN staining) ● Spot-Morning LED Fluorescent microscopy **Note:** ● Diagnose people with active TB in the absence of molecular tests. ● Monitor the progress of treatment. ● Confirm whether cure has been achieved	Solid culture (LJ medium) or liquid culture	● Chest X ray ● Hematology tests (ESR) ● Chemistries

**Refer to the National Manual for Management of TB and Leprosy, 2020 for more on TB diagnosis*

Diagnosis of Tuberculosis in Children

The diagnosis of TB in children can be challenging. Sputum can hardly be obtained from children and is often negative even on culture; and signs and symptoms are atypical to TB. The diagnosis is therefore based on the use of TB score chart. Older children who can cough up sputum should go through the same assessment as adults using Gene-Expert as the "gold standard" test.

8.3 New recommended Tests for TB screening and diagnosis

Tests	Recommended for	Description
Urine for TB Lateral Flow Lipoarabinomannan (LAM-Test	TB screening	Urine lateral flow (LF-LAM) may be used to assist in the diagnosis of active TB in adult patients with advanced HIV disease, with or without signs and symptoms of TB (pulmonary and/or extra-pulmonary).
Computer – aided detection (CAD4TB) of Chest X ray.	TB Screening	This use artificial intelligence technology (CAD4TB) to read chest X ray images (This should not be used for initiation of TB treatment on its own).
TrueNat TB test	TB diagnosis	This is a rapid molecular test for detecting TB and resistance to rifampicin as PoC at lower levels.
Use of stool sample in TB diagnosis among children	TB diagnosis	This is a non-invasive detection of Mycobacterium tuberculosis complex (MTBC) in stool specimens recommended alongside sputum (expectorated or induced), nasopharyngeal aspirate or gastric aspirate (GA) for both Xpert MTB/RIF and Xpert Ultra as the initial diagnostic test for TB and rifampicin resistance in children under 10 years with signs and symptoms of pulmonary TB.

8.3.1 Standard TB Treatment Regimens

- All new or previously treated recipient of cares should receive a six-month regimen containing rifampicin: 2RHZE/4RH as daily observed treatment (DOT) by a health care provider or other designated individual, which could include a family member or friend, throughout the six months as shown in Table 9.3.
- All previously treated TB recipient of cares should provide a specimen for rapid molecular testing (GeneXpert MTB/RIF/TrueNat MTB/RIF), where available, and culture and DST. Recipient of cares with rifampicin resistance should be referred to a designated health facility for MDR TB treatment. Recipient of cares who are rifampicin susceptible should be treated with a first-line treatment regimen containing all four drugs (2RHZE/4RH) while waiting for DST results
- Recipient of Care who failed treatment (treatment failure), should have a sputum sample taken for culture and DST. If a molecular test is not available; RoC should be initiated on first-line TB treatment while waiting for culture and DST results.

Note: *Samples for the molecular test can be referred to the nearest facility with molecular tests capacity.*

Table 8.3: Summary of first-line TB treatment regimens for adults.

Duration of treatment	Drugs	ADULT Pre-treatment weight			
		21 – 30kg	31 - 50kg	51 – 74 kg	≥75kg
2 months intensive phase, daily observed	{RHZE} 150/75/400/ 275	2	3	4	5
4 months continuation phase, daily observed	{RH} 150/75	2	3	4	5

Table 8.4: Summary of first line TB treatment regimens for Paediatric.

Weight (Kg)	Intensive Phase (2 months)		Continuation Phase (4 months)
	RHZ (paediatric) 75/30/150	Ethambutol 100 mg	RH (paediatric) 75/50
2 - 2.9 kg	1/2 tablet	1/2 tablet	1/2 tablet
3 - 3.9 kg	1 tablet	1/2 tablet	1 tablet
4 – 7.9 kg	1 tablet	1 tablet	1 tablet
8 – 11.9 kg	2 tablets	2 tablets	2 tablets
12 – 15 .9kg	3 tablets	3 tablets	3 tablets
16 – 24.9 kg	4 tablets	4 tablets	4 tablets
25 + kg	Use Adult regimen		

*H – Isoniazid; R – Rifampicin; Z – Pyrazinamide; E - Ethambutol

Note:

30 percent of children with a miliary picture on chest radiography have central nervous system involvement and should be treated with a 12-month regimen (See Manual for the Management of TB and Leprosy, 2020).

8.3.2 Tuberculosis-associated Immune Reconstitution Syndrome

- In RoCs experiencing signs of Immune Reconstitution Inflammatory Syndrome (IRIS), (occurrence of features of active TB or a temporary exacerbation TB signs and symptoms, with or without an aggravated radiographic manifestation after the initiation of ART), TB treatment failure should be excluded before IRIS is confirmed.
- If IRIS is diagnosed, continue with both ART and anti-TB treatment. In severe cases, prednisone 1-2 mg/kg for 1-2 weeks can be given (thereafter gradually decreasing dosage).

Monitoring response to TB treatment

A monthly TB smear microscopy should be used to monitor response to treatment of pulmonary TB. TB culture is also recommended in monitoring TB treatment in line with TB

smear microscopy. Details on how and when to collect specimens, transportation, and results feedback are prescribed in NTLP *National Manual for Management of TB and Leprosy, 2020*.

8.4 TB Preventive Measures

8.4.1 BCG vaccination to Children

As recommended by WHO all neonates should be given BCG vaccine immediately after birth, regardless of HIV status. BCG vaccine rarely causes disseminated infection of *M. bovis* in HIV neonates and if it occurs it should be treated with 2RHZE|4RH. The benefits of BCG (including prevention of severe form of TB), outweigh the possible disadvantages. However, BCG vaccine should not be given to children who are immunosuppressed (with clear signs and symptoms of HIV disease or AIDS

8.4.2 TB Preventive Treatment (TPT)

- To prevent the progression of TB infection to active TB disease, all PLHIV should receive TB Preventive Treatment (TPT) once in a lifetime after the exclusion of active TB.
- The recommended TPT regimens are three months of Isoniazid plus rifapentine (3HP) weekly; three months of Isoniazid plus rifampicin (3HR) daily and six months of Isoniazid monotherapy (6H) daily to eligible RoC as shown in Table 8.5.

Table 8.5: Recommended TPT regimen

Age	Preferred Regimen and Duration	Alternative
Children <15 years, pregnant and breastfeeding women, and adult who cannot tolerate 3HP	Daily 3HR (Isoniazid plus rifampicin for 3 months)	Daily 6 months Isoniazid Monotherapy
PLHIV ≥ 15 years (excluding PBFW)	Weekly 3HP (Isoniazid plus rifapentine for 3 Months)	Daily 6 months Isoniazid Monotherapy

Note:

For children <15 years and PBFW *who are on 3HR, the dose of Antiretroviral Therapy (ART) should be double because Rifampicin has potential drug–drug interactions with protease inhibitors-based regimens (lopinavir – ritonavir), nevirapine or integrase inhibitors (dolutegravir).*

6H is the preferred regimen among HIV infected children on protease inhibitor-based regimen (lopinavir–ritonavir), nevirapine, or integrase strand transfer inhibitors (dolutegravir) due to potential drug–drug interactions with other regimens.

Post – treatment TPT among PLHIV

RoC who have successfully finished their TB treatment should promptly begin a course of TPT right after completing their TB treatment as they are at higher risk of recurrence (5 to 7 times) with over 90% of these recurrences associated with reinfection.

a) Eligibility for TPT among children, adolescents and adults

Client Category	Eligibility Criteria
For people with no history of TB treatment	● All HIV positive individuals who screen negative for active TB. ● <5 years household contacts of bacteriologically confirmed TB. ● ≥5years house contacts of bacteriologically confirmed TB clients, prisoners, PWUDs and miners.
For people with history of TB treatment	● People living with HIV who successfully completed their TB treatment should immediately receive TPT *It has been shown that PLHIV who receive TPT immediately after completion of TB treatment have less risk of TB recurrence, relapse and re-infection and mortality*.
Pregnancy and breastfeeding	● TB preventive treatment is not contraindicated in pregnancy and it can be given during any trimester.

Note;

- *TPT should not be offered to PLHIV who abuse alcohol, are non-adherent to long term treatment, have current/past history of hepatitis and/or have medical contra-indication to INH.*
- *Offer a recommended dose for TPT as described in the National Tuberculosis Infection Manual.*
- *Follow up to detect and treat side effects as early as possible.* Refer **figure to 8.1** below for more *clarity.*
- *TPT should be provided where there is quality supportive counselling, capacity for follow-up and monitoring of RoC to encourage adherence and manage side effects.*

Figure 8.1: Algorithm for ruling out TB; for children above 12 months, Adult and adolescent including pregnant women and breastfeeding mothers living with HIV.

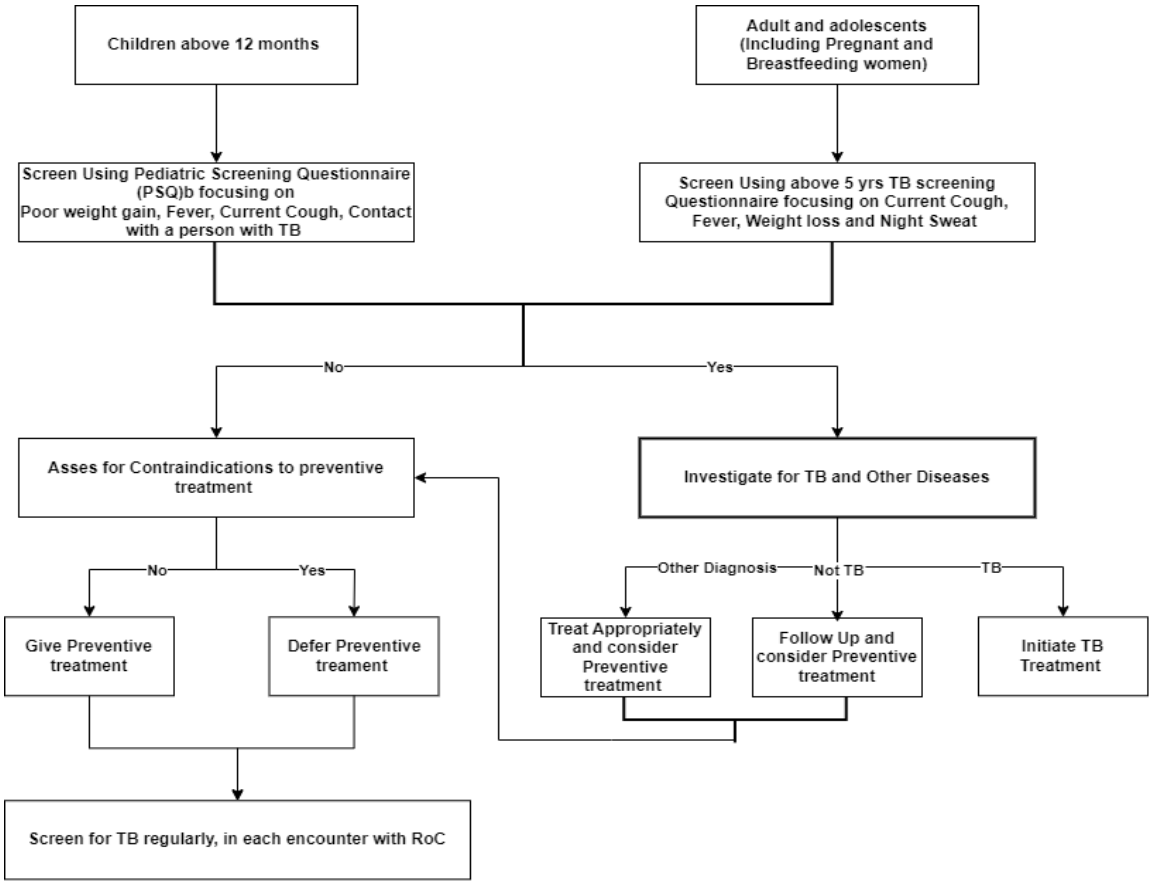


Table 8.6: Recommended dosage for the treatment of tuberculosis infection

Drug regimen	**Population**	**Dose per kg body weight per day**	**Maximum daily dose**
Daily isoniazid Plus rifampicin for three months(3HR)	Children < 10 years	Rifampicin: 15 mg (range 10-20 mg) Isoniazid: 10 mg (range7-15 mg)	Rifampicin: 600mg Isoniazid: 300 mg
	Children ≥ 10 years	Rifampicin: 10 mg Isoniazid: 5 mg	
Three months of rifapentine plus high dose isoniazid (3HP) weekly (12 doses)	≥ 15 years	**Medicine, formulation**	**Number of tablets for body weight more than 30 kg**
		Isoniazid 300 mg	3
		Rifapentine 150 mg	6
		Isoniazid + rifapentine fixed dose combination (300 mg/300 mg)	3
Isoniazid alone, daily for 6 months (6H)	All population groups.	Children 5mg Adult 10 mg (range, 7–15 mg)	300 mg

Note**: For Weight and Age Based Dosing Charts: Refer **Annexes 8.

Table 8.7: Management of potential adverse reactions following treatment with TPT

Adverse event	Stop and consider reintroduction with caution	Stop and do not reintroduce
Flu-like syndrome with fever, chills and malaise, sometimes with headache, dizziness or bone pain	If mild and not increasing continue treatment and observe closely	If moderate to severe symptoms, consider alternative TPT options without a rifamycin (6H)
Drug-associated fever only	Consider re-introduction if fever settles below 39ºC, but stop permanently if fever recurs	If fever more than 39ºC after the previous episode of drug – associated fever
Persistent nausea, frequent vomiting and/or persistent episodes of unformed watery stools	Administer an antiemetic or anti-diarrheal medication and consider reintroducing TPT with caution once the symptoms have resolved	If there is nausea, vomiting or diarrhoea which requires aggressive rehydration
Cutaneous reactions	Diffuse rash (no vesicles) Diffuse rash with limited vesicles	If there are extensive bullous lesions/ulceration of mucous membranes/Stevens Johnson or toxic epidermal necrolysis, contact a specialist and use steroids
Other hypersensitivity reactions (hypotension, acute bronchospasm, conjunctivitis, thrombocytopenia)	Assess the clinical severity of the symptoms and if severe consider alternative TPT options without a rifamycin (6H)	
Hepatitis (early symptoms of weakness, fatigue, loss of appetite, persistent nausea)	ALT/AST < 5 times upper limits of normal and absence of symptoms	ALT/AST ≥5 times the upper limit of normal in the absence of symptoms ALT/AST ≥3 times the upper limit of normal in the presence of symptoms.
Psychosis	Psychiatric evaluation, antipsychotic therapy, pyridoxine.	Attributable to Isoniazid
Seizures	Withhold isoniazid pending resolution of seizures, evaluate possible causes of seizures.	Attributable to Isoniazid

b) **Provision of TPT in DSDM**

All PLHIV on ART, and receiving TPT are eligible for MMD provided they are established on ART/Stable.

Table 8.8: MMD for TPT

RoC Category	Regimen	**MMD Plan for TPT**		
		Month 0	Month 1	Month 2
Not Established on ART/Unstable	3HR	1 Months	2 months	None
	3HP	1 Month	2 Months	None
	6H	1 month	2 months	3 months
Established on ART/Stable (Missed on opportunity)	3HR	3 months	None	None
	3HP	3 months	None	None
	6H	6 Months		

- Health care providers should monitor RoC enrolled on TPT at health facilities or community settings working with CHWs/CBHS.
- PLHIV using TPT and ART should be educated to return to health facilities symptoms of TB or development ADRs.
- Monthly TB screening will be conducted by community HIV based service providers.

NOTE:

- *For TBHIV co-infected individuals who are not on ART at TB diagnosis, TB treatment should be started first, followed by ART as soon as possible, within the first 2 weeks after starting TB treatment.*
- *For PLHIV who are already on ART at TB diagnosis, TB treatment should be started immediately.*
- *In individuals who need TB treatment and who require an ART regimen containing a boosted protease inhibitor (PI), LPV/r double dose (i.e., LPV/r 800mg/200mg twice a day) should be used or with an adjusted, super-boosted dose of RTV (i.e., LPV/r 400mg/ 400mg twice a day). However use of this regimen is frequently associated with toxicity and RoC on this regimen require regular clinical and laboratory monitoring.*
- *When TB is diagnosed in PLHIV who are already on ART and Medical Assisted Therapy using Methadone, Rifampicin decreases Methadone level by 33% to 68% and hence an increase in the methadone dose increase may be required.*

c) **TPT Treatment completion**

A number of endpoints are proposed that could be used to trigger a review of persons on TPT and in some instances, changes to treatment. RoC on TPT are considered to have completed treatment if she/he take the minimum required number of doses in the specified time.

Key Note:

Treatment completion. A person initiated on TPT who completed at least:

- 80% of recommended dose (68/84) consumed within 4 months of planned TPT duration for 3HR.
- 90% of recommended dose (11/12) consumed within 4 months of planned TPT duration for 3HP.

- 80% of recommended dose (144/180) consumed within 9 months of planned TPT duration for 6H.

8.4.3 TPT Treatment interruption

a) 3HP

Weekly schedule of one dose missed:

- If the missed dose is remembered within the next 2 days, the person can take the dose immediately. Continue the schedule as originally planned (i.e., continue to take the remaining doses following the same schedule).
- If the missed dose is remembered more than 2 days later, the person can take the missed dose immediately and change the schedule for weekly intake to the day the missed dose was taken until treatment completion. This will avoid 2 weekly doses being taken less than 4 days apart.

More than 1 weekly doses of 3HP missed:

- If 1–3 weekly doses are missed, treatment is continued until all 12 doses are taken, thus prolonging the treatment duration to a maximum of 16 weeks.
- If, however, 4 or more weekly doses are missed, offer counselling and restart the full TPT course under DOT. If adherence to a weekly routine is not possible, discontinue 3HP and offer a daily regimen.

b) 3HR and 6H

Less than 2 weeks:

- Resume preventive treatment immediately upon return and add the number of days of missed doses to the total treatment duration.
- Do not change the scheduled date of the next follow-up visit but the last follow-up visit will be postponed by the number of extra days to compensate for missed doses.

More than 2 weeks:

- If treatment interruption occurred after more than 80% of the doses (144 of 6H and 72 of 3HR) were taken, no action is required. Continue and complete the remaining treatment as per original plan.
- If less than 80% of doses of 6H or 3RH were taken, and the treatment course can still be completed within the expected time for completion, i.e., treatment duration + 33% additional time (that is a total of 239 days for 6H or 120 days for 3HR), no action is required. Continue and complete the remaining treatment as per original plan. If less than 80% of doses of 6H or 3HR were taken, and the treatment course cannot be completed within the expected time for completion, restart the full TPT course.

8.4.4. TPT Drug Interaction with ARV drugs

Name of ARV	Type of interaction	Recommended action
TDF	No Interaction	No dose adjustment
3TC/FTC	No interaction	No dose adjustment
EFV	Reduced concentration	No dose adjustment
NVP	Reduced concentration	Don't use
DTG or pDTG	Reduced concentration	Double the dose (50mg) and administer in 2 doses 12 hourly apart when using 3HR as TPT **No dose adjustment required when using 3HP**
AZT	No interactions	No dose adjustment
ATV/r	Reduced concentration	Don't use
LPV/r	Reduced concentration	Double the dose to 800mg/200mg
RTV	Reduced concentration	Don't use
ABC	No interaction	No dose adjustment
RAL	Reduced concentration	Double the dose to 800mg
DRV/r	No studies	Don't use

8.5 TB Infection control in health-care facilities and congregate settings

TB infection control should be implemented in health care facilities and congregate settings where people with TB and HIV are frequently confined. Measures to reduce TB transmission include administrative, environmental, and personal protection measures, which are generally aimed at reducing exposure to M. tuberculosis among healthcare workers, prison staff, police officers and their clients and other persons in the congregate settings. Measures are explained in the table below.

Table 8.9: TB Infection control in health-care facilities and congregate settings

Control Measure	Evaluation

Administrative measures	● Early identification of TB clients and reduction of TB transmission.
	● All RoC should be screened for TB as soon as they arrive at the facility to identify those with at least one TB symptom.
	● In outpatient departments, coughing patients should wait in well-ventilated areas.
	● TB suspects need to be examined in a well-ventilated room.
	● Have patients turn their heads and cover their mouths when they cough.
	● Avoid contact between TB and HIV positive patients by separating them.
	● If TB clinic is providing ART, channel PTB and HIV co-infected patients to the TB clinic where they should receive TB and HIV care i.e. anti TB treatment/CPT, ART, adherence counselling;
	  ● Refer them to CTC at the end of the TB treatment to ensure continuum of care (general HIV care, CPT, ARV provision, HBC, etc.)
	  ● If the TB clinic is not providing ART, evaluate PTB and HIV co-infected

Control Measure	Evaluation
	patients at the CTC on separate days to avoid sharing the same waiting area with PLHIV. ● If volunteers living with HIV (e.g. peer educators) are working at the HF level (e.g. CTC), they should be informed about the risk of developing TB and they should avoid accompanying TB suspects/RoC.
Environmental control measures	● Open doors and windows to allow cross air ventilation. ● Waiting places and examination rooms designed in a manner that they have maximum natural ventilation. Fans may also assist in the process of air circulation. ● Collection of sputum for TB should be done in an open environment and away from other people, not in small rooms or other enclosed places.
Personal protective measures	● Respiratory protective equipment is an additional measure to protect HCPs from inhaling infectious droplet nuclei expelled out into the air by a patient with infectious TB disease. ● Personal protective measures should be used by health care providers to protect from risk of TB transmission. ● Respirators are among the equipment and interventions used to protect personnel who must work in environments with contaminated air. In Tanzania they are recommended to be used when providing care to infectious DR-TB patients or people suspected of having infectious smear positive DR-TB. ● The primary way to prevent transmission of TB to health workers and others at the health facility is for TB patients to take their medicines regularly. By doing so, they will become non-infectious in a week or two. Proper ventilation of the place where treatment is provided is also very important.

TB infection control plan:
Every health facility needs to have TB infection plan which is to be reviewed at least once every year. TB infection control plan should contain information regarding TB control in the respective health facility. Moreover, every health facility needs to have TB focal person to oversee implementation of TB infection control measures.

Note:

- *All healthcare workers are at increased risk of developing TB when they are HIV positive. Those working in hospital departments where TB patients are admitted should be advised to test for HIV. If they test positive, they should avoid contact with presumptive TB cases and confirmed TB patients.*
- *Normal masks do not protect medical staff against TB infection*

8.6 Drug Resistant TB

This is a form of TB on which first-line anti-TB drugs have less or no effect. The diagnosis is confirmed through drug susceptibility test (DST) using molecular and/or phenotypic tests of

M. tuberculosis strains.

All MTB detected as rifampicin-resistant cases should have specimens sent to a designated zonal TB laboratory for first- and second-line LPA, culture, and DST.

8.6.1 Identification of presumptive drug-resistant TB patients

The following patient groups are at high risk for DR-TB and should have their sputum specimen sent immediately for molecular testing, culture, and DST:

- Treatment failure after using first-line anti-TB medicines
- Close contact of a known DR-TB case
- Patients who remain sputum smear-positive after completion of Intensive Phase of first-line anti-TB drug regimen
- Relapse and return after loss to follow-up, without recent treatment failure
- HCPs presenting with TB symptoms.
- Vulnerable groups in congregate settings (prisoners, urban poor, miners, people who use drugs)
- Patients who have a contact who died while on DOT for TB
- Residents or migrants from high MDR-TB burden settings who presents with TB symptoms.

Patients found to have RR-TB or MDR-TB at any point in time should be started on an adequate second-line drug regimen. The treatment of DR-TB involves standardized and individualized approaches consisting of intensive and continuation phases. *For further details, refer to Chapter IX in TB and Leprosy Manual 7th Edition, 2020.*

8.6.2 TB/HIV and COVID-19

There is no evidence that TB/HIV co-infected patients who are clinically and immunologically stable and, on both TB, and ART medication have a different risk of infection or complications of COVID-19 as compared to the general population. However, TB/HIV co-infected patients who contract COVID-19 are likely to suffer more severe disease with poor outcomes. PLHIV with unsuppressed viral load and lower CD4 levels and people with active TB might be at an increased risk.

COVID-19 pandemic caused considerable disruption to delivery of essential health services, including TB/HIV services. Therefore, concrete efforts are needed to ensure people can access and utilize TB/HIV and COVID-19 services in an integrated approach.

Policy statements

i) Adhere to COVID-19 protocols in care and treatment facilities.
ii) Use of PPEs in care and treatment facilities.
iii) Proper management of COVID-19 in HIV/AIDS and TB/HIV co-infected RoC
iv) Reduce the risk of contracting COVID-19 among HIV/AIDS and TB/HIV co-infected patients.
v) Provision of support to COVID-19 response by leveraging existing resources.

Priorities in TB/HIV and COVID-19 Response

Below are a number priority strategies to ensure the continuation of critical services for HIV/AIDS and TB/HIV co-infected people. :

a) Rapidly scale up DSDM among all eligible HIV/AIDS and TB/HIV recipient of care including family-centred approach.
b) Strengthen facility-infection control Readiness – Including Infection Control Practices as follows:
    - Implement infection control practices within the facility and screening/separation of those with COVID -19 symptoms including bi-directional screening.
    - Fast track vulnerable patients in facilities.
    - Ensure chronic care service delivery points that are separate from COVID-19 screening, testing and care points that are in open-air environments.
c) Expand Community TB and HIV screening services, DOT, and ART provision.
d) Strengthen in-facility and community processes to support TB/HIV clients on treatment to maintain adherence.
e) Ensure TB and HIV/AIDS messages emphasize the importance of receiving COVID-19 vaccination.
f) Continued treatment for HIV, TB, and other comorbidities

CHAPTER IX: MANAGEMENT OF ADVANCED HIV DISEASE AND COMMON OPPORTUNISTIC INFECTIONS

9.1 Introduction

All PLHIV aged five years and above with baseline CD4 cell count < 200 cells/mm3 or WHO HIV clinical stage 3 or 4 are considered to have AHD. All children younger than 5 years are considered to have AHD, given their increased risk of disease progression and mortality. Individuals presenting to care who are ART naive, have documented ART failure or returning to care after more than 6 months or more of ART interruption should be assessed for AHD. CD4 testing is the gateway to identification of RoC with AHD among PLHIV aged five years old and above.

Adults, adolescents and children aged five years and above identified to have AHD based on CD4 count and or WHO clinical staging should promptly receive the AHD package of care (Table 9.1) which includes, screening and diagnosis of opportunistic infections, prophylaxis and pre-emptive therapy, rapid initiation of ART and Adherence support. Additionally, the STOP (Screen, Treat, Optimize, and Prevent) AIDS approach has been shown to reduce morbidity and mortality among children with AHD.

NB:

Routine cryptococcal antigen screening and pre-emptive therapy are not recommended for children younger than 10 years because of the low prevalence of cryptococcal meningitis in this age group. However, if a child younger than 10 years presents with signs and symptoms of meningitis, cryptococcal meningitis should still be considered and the appropriate investigations and treatment must be done.

Definition of AHD

- *Advanced HIV disease is defined as CD4 cell count < 200 cells/mm3 or WHO HIV clinical stage 3 or 4 in adults, adolescents and children aged five years and above.*
- *All HIV infected children younger than five years old are considered as having AHD.*

Priority Groups for AHD Screening

- *Newly diagnosed individuals*
- *Individuals returning after interruption of treatment for more than 6 months.*
- *Those failing treatment (VL > 1000 copies after EAC)*
- *RoC newly categorized as WHO stage 3 or 4*

9.1.1 AHD screening

CD4 cells progressively decrease as HIV advances and the immune system deteriorates. It is therefore an important immunological marker for the identification of RoC who are at an increased risk of developing opportunistic infections and death. CD4 cell count should be used to identify RoC with AHD. If access to CD4 count is limited or unavailable, WHO staging should be used. The steps for AHD screening are well described in Figure 9.1 below.

In order to optimize and increase access to AHD services, the Hub and Spoke model will be used for both the screening for AHD and delivery of the AHD package of care.

Figure 9.1: AHD screening algorithm

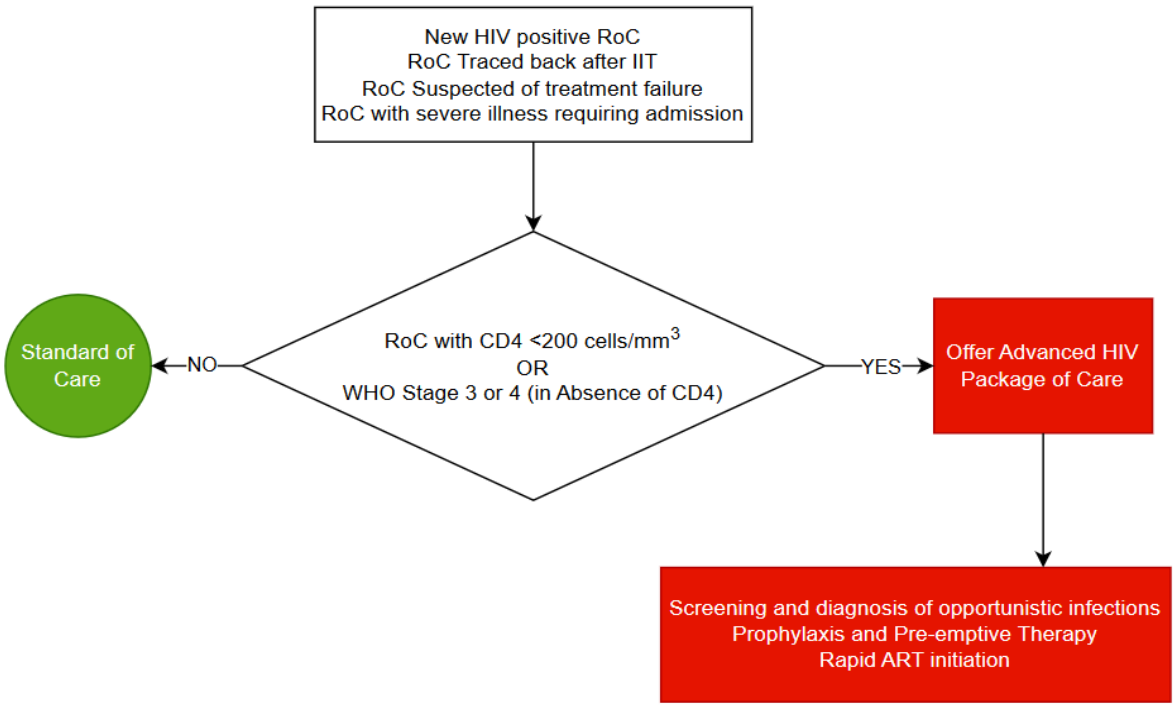


Table 9.1: Advanced HIV Disease package in different age groups

AHD services	Interventions	CD4 Cell count/ WHO HIV clinical staging.	Adults and Adolescents (10 years and above)	Children (0-9 years)
Screening and Diagnosis	• TB screening questionnaires (TSQs) • Chest X-ray where available. • Sputum for microscopy and molecular test (Xpert/TruNat) for TB diagnosis among symptomatic PLHIV.	All PLHIV	YES	YES
	• Urine Lateral Flow-LAM for TB	CD4<200 cells/mm3 or WHO clinical stage 3 or 4	YES	YES

AHD services	Interventions	CD4 Cell count/ WHO HIV clinical staging.	Adults and Adolescents (10 years and above)	Children (0-9 years)
	Cryptococcal antigen Screening (CrAg)	<200 cells/mm3 or WHO HIV clinical stage 3 or 4	YES	NO (unless presents with signs and symptoms of meningitis)
Prophylaxis	Co-trimoxazole prophylaxis	≤350 cells/mm3 or WHO clinical stage 3 and 4.	YES	YES
	TB preventive treatment	All PLHIV	YES	YES
	Fluconazole pre-emptive therapy for serum CrAg – positive PLHIV without evidence of meningitis. *N.B: When Lumber puncture services are available, Pre-emptive therapy among serum CrAg positive should be initiated upon confirmed CSF CrAg negative* ***but should not delay initiation of Pre-emptive therapy.***	<200 cells/mm3	YES	NA
ART Initiation	Rapid ART initiation	All newly diagnosed HIV positive RoC.	YES	YES

AHD services	Interventions	CD4 Cell count/ WHO HIV clinical staging.	Adults and Adolescents (10 years and above)	Children (0-9 years)
	Delay ART initiation if clinical symptoms suggest TB or cryptococcal meningitis	● Start ART within two weeks after starting anti TB treatment/Fluconazole Pre-emptive therapy. ● At least 5 weeks after starting treatment for cryptococcal meningitis	YES	YES
Adherence support	Tailored counselling to ensure optimal adherence to the AHD package, including home visits if feasible	<200 cells/mm3 or WHO Clinical stage 3 or 4	YES	YES

Note:
Lumber puncture should be done in all PLHIV with a positive +ve CRAG test in serum/plasma/blood with signs and symptoms of meningitis. Additionally, lumber puncture is recommended for all PLHIV with a CD4 count of <100cells/mm^3 regardless of signs and symptoms.

Table 9.2: Management of children with AHD: Screen, Treat, Optimize and Prevent AIDS among Children- (0-9 years) (STOP)

Interventions	Diseases	Description
Screen	Tuberculosis	● Screen for TB using available screening tools as indicated. Stages for those who screen positive, use the following diagnostic tests to confirm TB as applicable. ● Rapid molecular diagnostic on (induced)sputum, stool, gastric aspirate, or nasopharyngeal aspirate or other extra pulmonary samples if relevant -LF LAM assay
	Cryptococcal infection among adolescents	● Serum or plasma or blood CrAg screening ● Lumbar puncture if serum CrAg positive and symptomatic
	Malnutrition	● Weight for height ● Height for age ● Mid upper arm circumference among children 2-5 years old
Treat	TB, severe pneumonia, severe bacterial infections, cryptococcal meningitis and severe acute malnutrition	
	Optimize	In accordance with existing national guideline
Optimize	Rapid ART initiation	
	ART counselling	Preferably same day after the diagnosis
	Bacterial infections and *P.Jirovecii Pneumonia*	In accordance with National guideline
	TB	TB preventive treatment
	Cryptococcal meningitis among adolescents	Fluconazole pre-emptive therapy if cryptococcal antigen positive or cryptococcal antigen unavailable
	Vaccinations	
Prevent	Bacterial infections and *P.jirovecii pneumonia*	Co-trimoxazole prophylaxis
	TB	TB preventive treatment
	Cryptococcal meningitis among adolescents	Fluconazole pre-emptive therapy if cryptococcal antigen positive or cryptococcal antigen unavailable
	Vaccinations	● Pneumococcal vaccine ● Human papillomavirus ● Measles ● BCG

9.2 Screening, Diagnosis and Management of Common Opportunistic Infections in RoC with AHD

Opportunistic Infections (OIs) are more frequent and severe among PLHIV because of their weakened immune system from the HIV infection, and they are the leading cause of mortality in this population. The risk of getting OIs increases with lower CD4 counts, especially among those with CD4 <200 cells/mm3.

9.2.1 Screening and diagnosis of Cryptococcal infection and disease

Even though Cryptococcal infection (CI) can also cause pneumonitis and skin lesions, Cryptococcal meningitis (CM) is the most common manifestation of cryptococcosis and is a leading cause of mortality among hospitalized adults living with HIV. However, it is less common among children below 10 years of age living with HIV. The risk of developing cryptococcal meningitis increases with a fall of CD4 count below 200cells/mm3.

***NB**: Not all RoC with Cryptococcal infection develop disease (e.g. meningitis, pneumonitis, skin lesions), some of them remain asymptomatic and CrAg screening with prompt initiation of pre-emptive therapy are key to prevent them from developing CM and other severe forms of cryptococcosis.*

a) Cryptococcal Screening

Serum CrAg testing is recommended for all adults and adolescents living with HIV who have a CD4 cell count <200 cells/mm^3 at any point during their management. If CD4 testing is not available on site, refer the sample/client to a nearby hub/facility for testing. If CD4 testing, sample referral or client referral is not feasible in a seriously sick RoC who is in WHO stage 3 or 4, the RoC should be screened for serum CrAg and managed based on the clinical presentation as plans for virtual consultation are made with the hub facility.

Asymptomatic recipient of care who are serum CrAg positive should be managed as CI while those with signs and symptoms of CM and are serum CrAg positive should be further evaluated for CM.

The most common signs and symptoms of cryptococcal meningitis are:

- Fever
- Severe headache
- Neck stiffness
- Confusion (Altered mental status)
- Cranial nerve palsy
- Focal neurological deficit
  - Blurred vision
  - Photophobia
  - Decreased hearing
  - Difficult in walking

a) Diagnosis

The recommended diagnostic approach for adults, adolescents and children living with HIV suspected of having CM is a prompt lumbar puncture with measurement of cerebrospinal fluid

(CSF) opening pressure and a CSF CrAg test. Alternatives to the CrAg test in CSF are the India ink test and CSF culture for Cryptococcus neoformans.

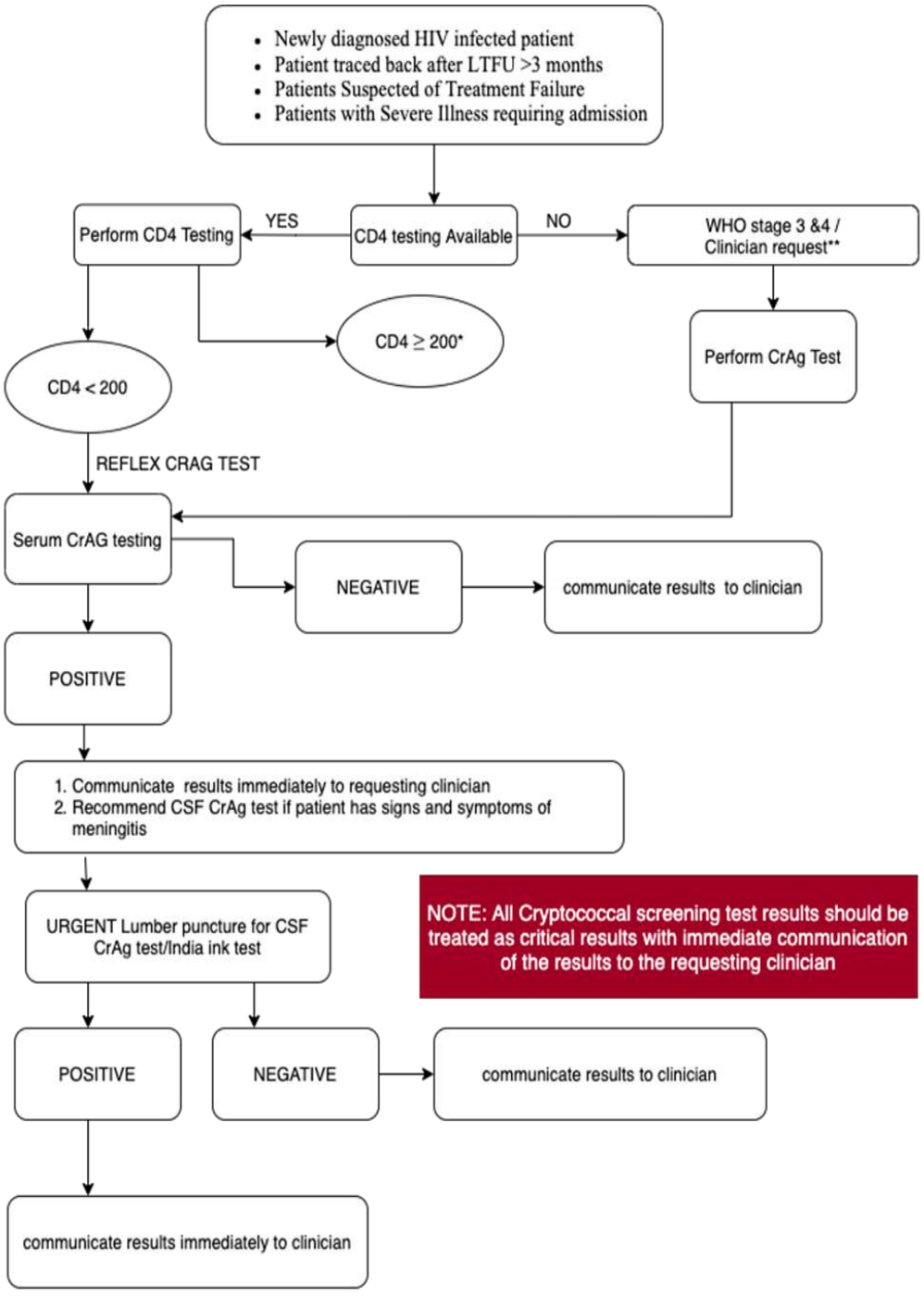
In health facilities where a lumbar puncture cannot be performed or when a lumbar puncture is contraindicated, prompt referral to a nearby health facility following a positive serum CrAg for further investigations and management is recommended.

Common contraindications to Lumbar Puncture are:

- Significant coagulopathy
- Suspected CNS space-occupying lesion based on:
  - Focal nervous system signs (excluding cranial nerve VI palsy)
  - Recurrent seizures and,
  - Where possible, confirmed by computed tomography.

NB. Signs of raised intracranial pressure does not contraindicate lumbar puncture in (suspected) cryptococcal meningitis once a space-occupying lesion is ruled out. Lumbar puncture helps relieve the intracranial pressure and severe headache in CM.
Other diseases that can present with signs and symptoms similar to cryptococcal meningitis (such as viral, bacterial or tuberculosis meningitis) should also be investigated.

Figure 9.2: Algorithm for reflex screening and diagnosis of cryptococcal infection and meningitis



****Clinician may request for a CrAg test if the patient has signs and symptoms of meningitis regardless of WHO stage and/or CD4 count**

b) Pre-emptive therapy for Cryptococcal Infection

Pre-emptive therapy is recommended for asymptomatic CrAg–positive RoC to prevent CM. Initiate fluconazole pre-emptive therapy as illustrated in Table 9.3, if the RoC has no clinical signs and symptoms of CM or has CrAg negative CSF.

Table 9.3: Fluconazole pre-emptive therapy

Infection	Prophylaxis
Cryptococcal infection (antigenemia) (pre-emptive therapy)	Pre-emptive therapy should be done in 3 phases: Phase 1: **Induction phase** Fluconazole 800 mg/day for adults for 2 weeks. Phase 2: **Consolidation phase** Fluconazole 400mg/ day for 8 weeks. Phase 3: **Maintenance phase** Fluconazole 200mg/day for at least 1 year. Discontinue if client is adherent to ART and fluconazole and CD4 ≥ 100 and viral load is undetectable (<50 copies/mL) OR CD4 ≥ 200 cells/mm3 (if viral load monitoring is not available) after being on treatment for at least one year.

c) Treatment of cryptococcal meningitis

Early treatment of CM is a key intervention to reduce mortality from cryptococcal meningitis. This manual recommends the use of triple therapy (amphotericin B, flucytosine, and fluconazole), antifungal medications shown to improve survival in RoC with cryptococcal meningitis.

Table 9.4: Treatment of cryptococcal meningitis

Disease	Treatment
Cryptococcal meningitis	The treatment should be done in 3 phases: **Phase 1: Induction phase** A single high dose (10 mg/kg) of liposomal amphotericin B with 14 days of flucytosine (100 mg/kg per day divided into four doses per day) and fluconazole (1200 mg/daily for adults; 12 mg/kg per day for children and adolescents up to a maximum of 800 mg daily) should be used as the preferred induction regimen for treating people with cryptococcal meningitis. **Alternative induction regimens** ***If liposomal amphotericin B is not available*** A seven-day course of amphotericin B deoxycholate (1 mg/kg per day) and flucytosine (100 mg/kg per day, divided into four doses per day) followed by seven days of fluconazole (1200 mg daily for adults and 12 mg/kg per day for children and adolescents up to a maximum of 800 mg daily).

Disease	Treatment
	If amphotericin B is not available 14 days of Fluconazole (1200 mg daily, 12 mg/kg per day for children and adolescents) and flucytosine (100 mg/kg per day, divided into four doses per day). **Note:** Fluconazole and flucytosine is the only recommended oral combination regimen and has been associated with lower mortality compared with amphotericin B deoxycholate and Fluconazole.
	If flucytosine is not available 14 days of liposomal amphotericin B (3–4 mg/kg per day) and Fluconazole (1200 mg daily, 12 mg/kg per day for children and adolescents up to a maximum of 800 mg daily). ***If liposomal amphotericin B and flucytosine are not available*** 14 days of amphotericin B deoxycholate (1 mg/kg per day) and Fluconazole (1200 mg daily, 12 mg/kg per day for children and adolescents up to a maximum of 800 mg daily). ***Note:*** *flucytosine-containing regimens are superior, and steps should be taken to ensure access to this drug.* **Phase 2: Consolidation phase** Fluconazole (800 mg daily for adults or 6–12 mg/kg per day for children and adolescents up to a maximum of 800 mg daily) is recommended for the consolidation phase (for eight weeks following the induction phase). **Phase 3: Maintenance phase** Fluconazole 200mg/day for at least 1 year. Discontinue if client is adherent to ART and Fluconazole and CD4 ≥ 100 and viral load is undetectable (<50 copies/mL) **OR** CD4 ≥ 200 if viral load monitoring is not available) after being on treatment for at least one year.

NOTE: Routine use of adjunctive corticosteroid therapy during the induction phase is not recommended in treating adults, adolescents and children who have HIV-associated cryptococcal meningitis.

Therapeutic lumbar puncture: Draining 20-30ml of cerebrospinal fluid is recommended to sufficiently reduce the raised intracranial pressure in setting where lumber puncture is possible.

For further information on preparation, administration and management of drug toxicity of amphotericin B therapy, refer to Chapter 3.7 of the "*Advanced HIV Disease Management, A Manual for Health care providers*".

d) Timing of ART

For new RoC, ART initiation should be delayed to at least 5 weeks from initiation of treatment for Cryptococcal Meningitis and 2 weeks from initiation of treatment for Cryptococcal infection. Immediate ART initiation is not recommended because of the risk of increased mortality.

9.2.2 Screening and diagnosis of Pneumocystis Pneumonia

Pneumocystis jirovecii Pneumonia (PJP) is caused by a fungus, Pneumocystis Jirovecii. About 30% to 40% of adult PLHIV get infected with PJP and 13% of them become hospitalized. PJP presents with no or low-grade fever, marked respiratory distress and normal breath sounds or fine diffuse crepitations, severe persistent cyanosis/hypoxia (SPO2< 90%). RoC with PJP respond poorly to standard antibiotic treatment.

a) Diagnosis

Diagnosis of PJP is mainly through clinical examination. Chest x-ray may show hyperinflation, diffuse infiltrates, or normal findings. Nasopharyngeal aspirate obtained from sputum induction or Broncho alveolar lavage can be stained with Giemsa or Silver or immunofluorescent stains to detect the presence of Pneumocystis Jirovecii fungus.

b. Treatment

Management of PJP includes both specific and supportive treatment. See table 9.5

c. rophylaxis Therapy

Cotrimoxazole is used as a prophylaxis against PCP among PLHIV.

9.2.3 Screening and diagnosis of Toxoplasmosis

Toxoplasmosis is a parasitic infection caused by Toxoplasma gondii and it is among the leading cause of central nervous system lesions among adults living with HIV. The prevalence of toxoplasmosis coinfection in in sub-Saharan Africa is high and PLHIV are at risk of developing cerebral toxoplasmosis when their CD4 count falls <200 cells/mm^3.

a) Toxoplasmosis Screening

Serologic tests to detect immunoglobulin G and M (IgG and IgM) can be used to screen for Toxoplasmosis. A combination of IgG and IgM tests can help to determine the timing of infection. Detection of IgG suggests a past infection with T. gondii while IgM is used to estimate active infection, which is of importance particularly for pregnant women.

b) Diagnosis

Diagnosis is predominantly based on clinical findings after exclusion of other common causes of neurological deficit. If available serum IgG/IgM, computed tomography scans (CT scan) or MRI with contrast, PCR or biopsy are very useful for confirmation. The type and severity of the infection will guide the choice of diagnostic method.

c) Treatment

Empirical treatment reduces mortality of hospitalized PLHIV by 15%. Table 9.5 below illustrates the Management of Common Opportunistic Infections among Adults and Adolescents.

d) Prophylaxis Therapy

Cotrimoxazole is used for prophylaxis against toxoplasmosis among PLHIV.

9.2.4 Screening and diagnosis of severe bacterial infections

PLHIV with AHD frequently present with severe bacterial infection commonly affecting the bloodstream, respiratory system, genital urinary system, central nervous system, and gastrointestinal system.

The bacteria most frequently isolated by culture from HIV-infected adults are Salmonella, Shigella, and Campylobacter. Clostridium difficile-associated infection (CDI) is also common in HIV-infected RoC.

a) Common signs and symptoms of severe bacterial infections.

There are no specific signs and symptoms of severe bacterial infections since it depends on the area affected. Fever is present in most RoC with severe bacterial infections, and patients are often very ill in the presence of bacteraemia. Screening for OIs in AHD RoC should be done in every clinical visit to identify the bacterial infections hence prevent complications and improve outcomes.

b) Diagnosis of severe bacterial infection

Diagnosis of severe bacterial infections can be done using full blood count and it is very important to isolate the organisms through culture and sensitivity for appropriate treatment.

c. Treatment of severe bacterial infection

Drug susceptibility patterns are required to aid optimal antibiotic selection. In absence of culture and sensitivity testing, empirical treatment targeting suspected organisms can be offered.

d. Prophylaxis Therapy

Cotrimoxazole prophylaxis (CTX) is the recommended first line regimen for primary prophylaxis.

Table 9.5: Treatment of Choice for Common Opportunistic Infections among Adults and Adolescents

Clinical Condition	Clinical Features and Investigations	Treatment
Pneumocystis jirovecii Pneumonia (PJP)	This condition is common in Tanzania especially among HIV infected children. RoC usually present with non-productive cough, fever, chest tightness and shortness of breath that has evolved over 2-4 weeks. A Chest x-ray may show increased diffuse and symmetrical interstitial markings or diffuse alveolar pattern with infiltrations characterized by asymmetry, nodularity, or cavitations. Normally there is a "bat's wing's appearance". Chest radiograph may appear normal in 10-30% of RoC. Usually in clinical circumstances diagnosis is based on clinical presentation and exclusion of other common causes of severe dyspnoea.	Cotrimoxazole 1920 mg 8 hourly for 21 days and in severe cases give IV cotrimoxazole 15–20mgTMP/75-100mgSMX/kg/day, administered 6-8 hourly, may switch to oral after clinical improvement. For those allergic to sulphur, and if available, give Trimethoprim 12- 15mg/kg/day + Dapsone 100mg/day for 21 days as well as Clindamycin 450mg 4 times/day or 600 mg three times daily + Primaquine 30 mg once daily for 21 days. Adjuvant therapy with steroids may also be beneficial in severe cases. Give Prednisolone 40 mg twice daily for days 1 to 5, then 40 mg once daily for days 6 to 10, and then 20 mg once daily for days 11 to 21 Supportive: ● Oxygen therapy ● Maintain and monitor hydration ● Antipyretic if there is fever ● Continue therapy for bacterial pneumonia ● Nutrition support
Toxoplasmosis	Clinical features include: Seizures, new onset of focal neurologic findings like hemiparesis and signs of cerebral edema such as confusion, altered mental status and lethargy which can progress to coma. Diagnosis predominantly based on clinical findings after exclusion of other common causes of neurological deficit. If available, a CT scan or MRI with contrast is very useful for confirmation.	**Treatment of Active infection** Sulfadiazine tabs 1 gm 6 hourly + Pyrimethamine tabs 100mg loading dose, then 50mg /day + Folinic acid tabs 10mg /day for 6 weeks. OR Clindamycin capsules 450mg -600mg 6 hourly + Pyrimethamine tabs 100mg loading dose, then 50mg /day for 6 weeks. NOTE It is a must to start altogether the three drugs on the same day to prevent bone marrow toxicity. **Alternative therapy** Trimethoprim– Sulphamethoxazole 5 mg TMP/kg bid iv/po, 25 mg SMX/kg bid iv/po for six weeks (consider IV route if oral route

Clinical Condition	Clinical Features and Investigations	Treatment
		not possible) **Maintenance Therapy** After six weeks of treatment (Secondary prophylaxis, Maintenance Therapy) Give prophylaxis therapy with Sulfadiazine tabs 500mg 6 hourly + Pyrimethamine tabs 25-50 mg /day + Folinic acid tabs 10mg /day. For those allergic to sulphur replace Sulfadiazine tabs with Clindamycin capsules 450 mg 6 hourly. Alternative therapy Trimethoprim– Sulphamethoxazole (TMP-SMX) tabs160/800 mg orally twice a day Discontinue maintenance therapy when CD4 count is >200 cells/ml, initial therapy is completed, and the RoC is asymptomatic. Primary prophylaxis therapy for toxoplasmosis can be accomplished with Trimethoprim–Sulphamethoxazole (TMP-SMX) tabs 160/800 mg administered orally/day. For those allergic to sulphur, give Dapsone tabs 50mg/day + Pyrimethamine tabs 50mg per week + Folinic Acid tabs 10mg 3 times a week.
Severe bacterial infections	No specific signs and symptoms of severe bacterial infections since it depends on the area affected	The type of infection, the severity of the illness and the drug susceptibility patterns will guide the choice of antibiotics. In addition to antibiotics, supportive care may be necessary to manage symptoms and prevent complications

9.2.5 Primary Prophylactic Treatment of Common Opportunistic Infections in HIV and AIDS

Cotrimoxazole has a mortality benefit and must be provided in all RoC with AHD. For adults; one double strength tablet (160/800mg) or two single strength tablets once a day and continue until discontinuation criteria are met. For those whose weight is <60kg, refer to the dosing chart (Annex 10). Many opportunistic infections can be prevented by using cotrimoxazole prophylaxis, particularly in the case of: Pneumocystis Pneumonia (PCP), Toxoplasmosis, severe bacterial infections, skin infections.

Table 9.6: Indication for Cotrimoxazole Preventive Therapy Treatment Using Cotrimoxazole

Population	Criteria for initiating cotrimoxazole prophylaxis	Criteria for discontinuing cotrimoxazole prophylaxis
Adults, adolescents and children > 5yrs of age (including pregnant women) living with HIV	Initiate for everyone with advanced HIV disease (WHO clinical stage 3 or 4) or CD4 cell count ≤350 cells/mm^3	Stop when CD4 cell is above 350 cells/mm^3 and HIV Viral load is suppressed (< 50 copies/ml)
Children < 5yrs of age living with HIV	Initiate for everyone regardless of WHO clinical stage or CD4 cell count	Continue until above 5yrs of age, then follow criria for discontinuation for above > 5yrs of age
HIV-exposed infants	Initiate for everyone starting at 4–6 weeks after birth	Until the risk of HIV transmission ends, and HIV infection is excluded with age-appropriate test
People living with HIV and TB	Initiate for everyone with active TB regardless of CD4 cell count	Until the criteria for discontinuation for adults or children are met

Caution should be taken when initiating Cotrimoxazole Preventive Treatment (CPT) during the first trimester of pregnancy because cotrimoxazole causes deficiency in folic acid.

Pregnant women who are receiving CPT do not need sulfadoxine pyrimethamine (SP), an additional medication to prevent malaria.

a) Dosage:

Adults: One double strength tablet (160/800mg) or two single strength tablets once daily.

Use Co-trimoxazole formulations and dosage for infants and children living with HIV or exposed to HIV weighing < 60kg (See Annex 10)

b) Follow-up and monitoring:

Regular follow up is recommended, initially every month for the first three months, then every three months if the medication is well tolerated.

It is mandatory to monitor for side effects and adherence. Monitoring includes assessment of skin reactions, measurements of haemoglobin, and white blood counts every six months and when clinically indicated. Occurrence of severe side effects such as severe cutaneous reactions or fixed drug reactions is among the criteria for stopping cotrimoxazole prophylaxis.

9.3 Management of Other Common Opportunistic Infections

It is very important that all efforts are made to deal with such treatable opportunistic conditions in people with HIV and AIDS, particularly because they are managed at various levels in the health care delivery system. Emphasis should be placed on early detection, treatment and

proper referral where necessary. Table 9.7 shows recommendations on how to identify and treat common opportunistic infections in HIV infected individuals.

Table 9.7: Management of Common Opportunistic Infections among Adults and Adolescents

Clinical Condition	Clinical Features and Investigations	Treatment
Skin conditions		
Scabies	Diagnosis of many skin conditions is usually made on clinical findings. Other diagnostic investigations include: Potassium hydroxide preparation microscopy, Skin scrapings microscopy Pus swab for culture & sensitivity Skin biopsy	Benzyl benzoate Emulsion 25% (twice a day applications after bath for 2-3 consecutive days) Crusted scabies use Ivermectin 20mcg/kg once then repeated in two weeks If secondarily infected Ampiclox500mg TID for 5-7 days or Erythromycin 500mg TID for 5-7 days
Dermatomycoses		Whitefield's ointment twice a day for 2-4 weeks Griseofulvin tablets 15-25mg/kg once daily for 6 weeks for Tinea Clotrimazole or Miconazole cream for Candidiasis twice a day 2-4 weeks Terbinafine 250mg od for at least 2 weeks Fluconazole 150mg or 200mg od for at least 2 weeks
Impetigo		Localized –use topical mupirocin ointment 2% BD for 5 days Extensive – Cloxacillin 250mg TID for 5-7 days Erythromycin 500mg TID for 5-7 days
Pruritic Papular Eruption (PPE)		Antihistamine, e.g., Cetirizine 10mg once daily for 3 days or Loratidine 10mg Topical steroids, e.g. hydrocortisone, Mometasone cream apply twice a day Antibiotics if there is a secondary bacterial infection, e.g. Cloxacillin or erythromycin

Clinical Condition	Clinical Features and Investigations	Treatment
seborrheic Dermatitis		Antifungal Ketoconazole 2% lotion 2-3 times/week for 4 weeks' Systemic antifungal if severe Topical Steroids (careful if concomitant TB is suspected) 3% salicylic acid ointment
Molluscum Contagiosum		ART should be considered as the primary treatment of extensive and/or unusually distributed molluscum contagiosum in HIV-infected RoC. Individual lesion may be treated by: Curettage, Cryotherapy, Electro cauterization
Kaposi's sarcoma (KS)	Cutaneous biopsies using punch biopsy Diagnosis based on clinical criteria and chest X-ray, abdominal USS in cases of systemic KS	This depends on the extent and severity and the options include: Anti-retroviral therapy (preferably PI-based, especially when extensive) Referral for chemotherapy and radiotherapy.
Viral infections		
Herpes simplex	Diagnosis is usually based on clinical history and physical findings. The classical presentation of primary HSV infection includes:	Acyclovir 400mg orally 8 hourly for 7 days for mild and moderate cases of HSV (e.g. cold sores)
	Fever Lymph node enlargement Small painful vesicles	Acyclovir 800mg orally, five hourlies for 5 days for severe and recurrent HSV (e.g. genital infection, gingivitis, pharyngeal tonsillitis)
	Painful ulcers on the mucosa and skin Pain along gluteal and upper thigh muscles (Sacral radiculomyelitis) may occur with genital/rectal HSV	Antibiotics such as Erythromycin should be used when there is secondary bacterial infection Analgesics when pain is severe
	Lesions that usually resolve within 10- 21 days after primary infection. The HSV then becomes latent in trigeminal and sacral nuclei and may reactivate.	

Clinical Condition	Clinical Features and Investigations	Treatment
Herpes Zoster or Shingles	Early symptoms include pain (often severe and radicular) and fever followed by vesicular rash over involved dermatome(s) 2-4 days later. Primary varicella-zoster virus (VZV) infection usually results in chicken pox. Herpes zoster in HIV infected individuals may be more severe, with more recurrences and may involve more dermatomes. The diagnosis of herpes zoster is usually based on findings of characteristic of painful skin lesions at different stages of evolution (e.g. erythema, papule, vesicles, and crusts) in a dermatomal distribution.	Acyclovir 800mg 5 hourly for 7-10 days for mild and moderate cases IIV/oral Acyclovir 10 mg/kg/day 8 hourly for 7 days for disseminated VZV or ophthalmic nerve involvement (If diagnosed within 72 Hrs) Erythromycin or Cloxacillin 500mg 8 hourly for 7 days for bacterial super-infection Amitriptylin 25-50mg nocte for post-herpetic pain (neuralgia) or Carbamazepine start 100mg od Analgesics, e.g., Paracetamol, Aspirin, or Diclofenac to relieve pain Note: Use of steroids (prednisolone) in herpes zoster is not recommended.
Human Papilloma Virus Infection (HPV)	HPV is a family of viruses that cause genital warts in men and women. HPV is also known to cause cellular changes that can lead to cancer of the cervix in women and anal cancers especially in gay men. The association between HIV and invasive cervical cancer is complex, due to a more rapid progression of cancer amongst HIV-infected women.	Primary prevention of cervical cancer involves prevention of infection with HPV, therefore it can be achieved through behavioural change approaches and the use of biological mechanisms, including HPV vaccination and consistent condom use can reduce the risk of HPV transmission. Annual cervical cancer screening is recommended to all sexually active women under the age of 50 years done at Care and treatment centres (CTC) using VIA (visual inspection of the cervix with acetic acid).
		Treatment There is no cure for the virus (HPV) itself. There are treatments for the health problems that HPV can cause, such as genital warts, cervical changes, and cervical cancer. For more details for the treatment of genital warts, cervical changes and cervical cancer, refer to treatment guidelines.

Clinical Condition	Clinical Features and Investigations	Treatment
Fungal Infections		
Oral, Oropharyngeal, Oesophageal, Trachea- Bronchial and Pulmonary Candidiasis	RoC with oropharyngeal and oesophageal candidiasis may complain of pain and/or difficulty in swallowing, which may be due to infection of the oesophagus with Candida. On examination white painless plaque ("curd like") on buccal or pharyngeal mucosa or tongue surface that can easily be scrapped off will be seen. Where available, barium swallow X- ray/oesophago-gastro duodenoscopy (OGD) can be performed.	For treatment, any of the following may be used: Fluconazole oral/IV 150mg/day or 200mg/day for 2-3 weeks (for oro-pharyngeal candidiasis and others) Miconazole oral gel 3-4 times/day after meals for 7 days Nystatin oral suspension 4-6mls 3- 4 times/day continue for at least 2days after oral lesions have disappeared
	Symptoms for trachea-bronchial and pulmonary candidiasis may include fever, non-productive couch, dyspnoea, and tachypnea. Investigations include bronchio-alveolar lavage (BAL) for microscopy and biopsy using bronchoscopy.	Gentian violet solution Note: Treatment should be continued until symptoms resolve.
Vaginal Candidiasis	This is one of the common illnesses presenting with itching and curd-like genital discharge.	Clotrimazole pessaries 100mg Nocte 5 days Miconazole pessaries 400mg nocte 5 days Fluconazole taken orally (in case of pessaries failure)
Cryptosporidiosis	Cryptosporidiosis (*cryptosporidium parvum, cryptosporidium meleagridis and cryptosporidium hominis*) is the common cause of chronic diarrhoea.	Nitazoxanide is the recommended treatment 500mg-1000mg twice daily for 14 days + rehydration, electrolytes replacement and optimized ART. Alternatively Paromomycin 500mg PO QID for 14-21 days can be used.

Clinical Condition	Clinical Features and Investigations	Treatment
	• Diagnosis can be made by microscopic examination of the oocytes in stool or tissue with acid-fast staining or direct immunofluorescence for better sensitivity.	

CHAPTER X: VIRAL HEPATITIS AND CO-INFECTIONS

10 Introduction on Viral Hepatitis

Viral hepatitis is an inflammation of the liver, caused by five distinct hepatitis viruses (A, B, C, D, and E). Hepatitis A, C, D and E contain RNA genome while Hepatitis B contains DNA viral genome. Viral Hepatitis is emerging as a global public health problem. Viral Hepatitis, HIV and STIs shares the similar risks, transmission routes and infects about 5 million people per year worldwide. In Tanzania, it is estimated that, 4% of adults 15 – 49 lives with chronic hepatitis B infection, this burden is high among certain populations, young women 7%, pregnant women 8%, and key and vulnerable populations, 5 – 16%. Despite this pattern that is as high as HIV, and correlates in terms of affected populations and populations at risk, viral hepatitis response is yet to get foothold.

HBV is transmitted vertically (perinatal), or horizontally (percutaneous and mucosal exposure to infectious blood or body fluids, sexual exposure, open cuts, and sores especially among children in high endemic areas). HBV infection is approximately 90% perinatal (with 25-50% occurring under age 5), and less than 5% occurring in adult life.

Majority of the infected people are asymptomatic and are discovered during routine investigation. Symptomatic RoC usually have signs of stigmata of chronic liver disease, Signs of Liver Decompensation or Liver Failure refer Table 10.1

Table 10.1: Signs of stigmata of chronic liver disease, Liver Decompensation and Liver Failure

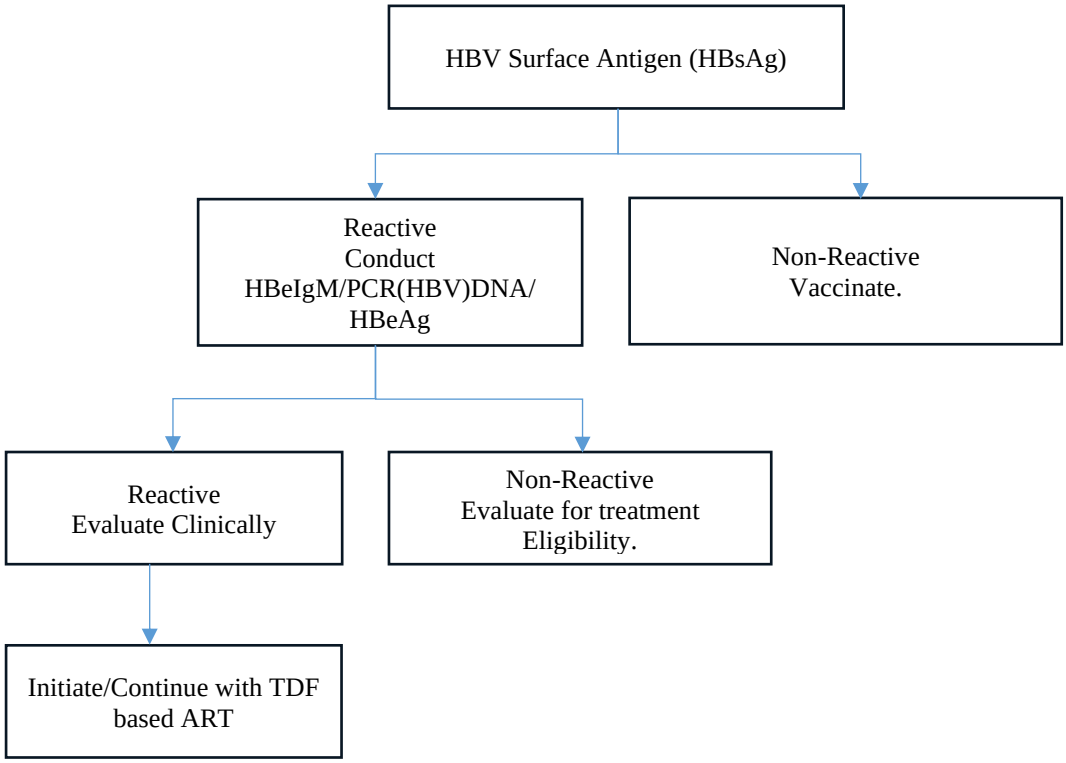
Chronic stigmata of Liver Disease	• Ascites • Testicular atrophy • Splenomegaly • Asterixis • Finger clubbing • Fetor hepaticus • Leukonychia • Caput medusa • Anemia/Pallor • Duputyre contracture* • Axillary hair loss • Xanthelasma • Spider naevi/angiomata • Jaundice • Palmar erythema • Parotid enlargement* • Muscle Wasting • Scratch pruritic marks • Petechial hemorrhage • Body swelling

	• Gynecomastia in males or Breast atrophy in females
• Signs of Liver decompensation	• Ascites • Bleeding tendency • Hepatic encephalopathy • Spontaneous bacterial peritonitis • Hepatorenal syndrome
• Signs of liver failure	• Fatal Hepaticus • Asterixis • Bleeding diathesis • Mental confusion • Testicular atrophy

* Signifies presence of alcoholic liver disease

Clinical evaluation of RoC is based on the following approach as per figure 10.1 below

Figure 10.1: HBV Diagnostic Testing and Linkage algorithm



Laboratory diagnosis and interpretation of the viral markers are described in the table N10.2

Table 10.2: Screening of HBV and its interpretation

Marker	Characteristics
Hepatitis B surface Antigen (HBsAg)/ antibody (HBsAb):	• HbsAg Positive (HbsAg +ve) indicates presence of acute or chronic infection • HbsAg Negative (HbsAg -ve) indicates no past infection or resolved infection
	• HBsAb Positive (HBsAb +ve) indicates clearance of the virus associated with HBsAg loss providing lifelong immunity.
Hepatitis B core antibody (Anti-HBc IgM/ IgG)	• Anti-HBcIgM indicates acute infection that resolve within six months since the onset of acquiring the infection
	• Anti-HBc IgG Indicates past or chronic infection
Hepatitis B envelope antigen HBeAg+ve /Antibody	• HBeAg Positive (HBeAg+ve) indicates high viral replication with high viral loads • Its disappearance (HBeAg –ve) indicates immune control against the virus associated with low viral loads
	• HBe Antibody Positive (HBeAb+ve) indicates establishment of intermediate immune marker after HBe antigen loss
HBV DNA	• Is a confirmatory marker for disease presence, viral replication and disease progression • Is used for therapeutic monitoring and detection of resistant variants

HBV infected RoC should receive a lifelong Tenofovir based regimen

- HBV monoinfected RoC should receive Tenofovir monotherapy (300mg daily) based on eligibility treatment criteria as per National Hepatitis B treatment guideline
- HBV / HIV co infected RoC should receive Tenofovir based ART regimen regardless of eligibility criteria stipulated in Hepatitis B mono-infected RoC
- Entecavir (0.5mg-1mg daily) is an alternative regimen for RoC who cannot tolerate Tenofovir especially those with Kidney associated diseases and Children below 12 years of age

Note

- Where there is evidence of chronic liver disease with cirrhosis and other associated disease such as Diabetes, Tuberculosis, and Chronic Kidney Disease RoC should be referred to the next level of care.

10.1 Hepatitis B Co-infection

HBV co-infection among HIV-infected adults according to recent local surveys ranges from 6.2% to 7.3%. Younger males with low CD4 count and advanced immune suppression appears to have increased risk of being co-infected RoC who are co infected with HBV exhibit rapid clinical deterioration and poor outcomes as compared to their HIV or HBV mono infected counterparts.

The progression may include high rate of HBeAg sero positivity, increased HBV-DNA, occurrence of liver fibrosis, and increased risk of mortality

Additionally, they have increased risk of developing chronic hepatitis infection, reducing the chances of spontaneous clearance and increased rate of HBV replication or reactivation with rapid HIV progression, poor ART outcomes, complications of hepatotoxicity, drug interactions and hepatitis related immune reconstitution.

It is recommended that all HIV infected including the newly diagnosed should be screened for HBsAg and immunized if not co infected.

Pregnant and Breastfeeding women, PWID and other KP's should be prioritized for screening, testing and treatment as they have shown to have higher rates of HBV and HIV co-infection.

10.1.1 HBV Treatment among PLHIV

HBV / HIV co infected RoC should receive Tenofovir based ART regimen regardless of eligibility criteria stipulated in Hepatitis B mono-infected RoC. Entecavir is an alternative regimen for RoC who cannot tolerate Tenofovir especially those with Kidney associated diseases and Children below 12 years of age.

10.1.2 HBV Prevention

- HIV-infected infants, children, adolescents and adults without evidence of hepatitis B infection (HBsAg negative) should be vaccinated against hepatitis B with the standard vaccination regimen.
- Neonates and Infants born to Mothers with HBV/Co Infection should receive at birth dose of HBV vaccine plus Hepatitis B immunoglobulin (HBIG) when available and scheduled for catch up doses at 6,10,14 weeks as EPI schedule.
- HIV positive Pregnant Mothers should be tested for HBsAg and follow recommended immunization protocol for both mother and infant.
- For newly diagnosed co infected HIV Positive mothers should receive Tenofovir based ART for Prophylaxis of Mother to child transmission of viral hepatitis B irrespective of HBV viral load and gestation age.
- For mono infected (HIV Negative) pregnant mothers in inactive phase but with viral load of 200,000IU/ml or more; or HBeAg Positive without cirrhosis at 28 weeks of gestation age, should receive Tenofovir or Entecavir until 6-months after delivery and when the child is fully immunized.
- After six months, HIV negative post-natal mothers she should be reassessed for treatment eligibility or follow up protocol as indicated in the National Viral Hepatitis guideline.

10.1.3 HBV monitoring

RoC with confirmed HBV should perform ALT, AST, Creatinine FBP, Alpha Feto Protein (AFP), Abdominal Ultrasound (AUS)) twice yearly for hepatorenal toxicity monitoring and Hepatocellular Carcinoma surveillance.

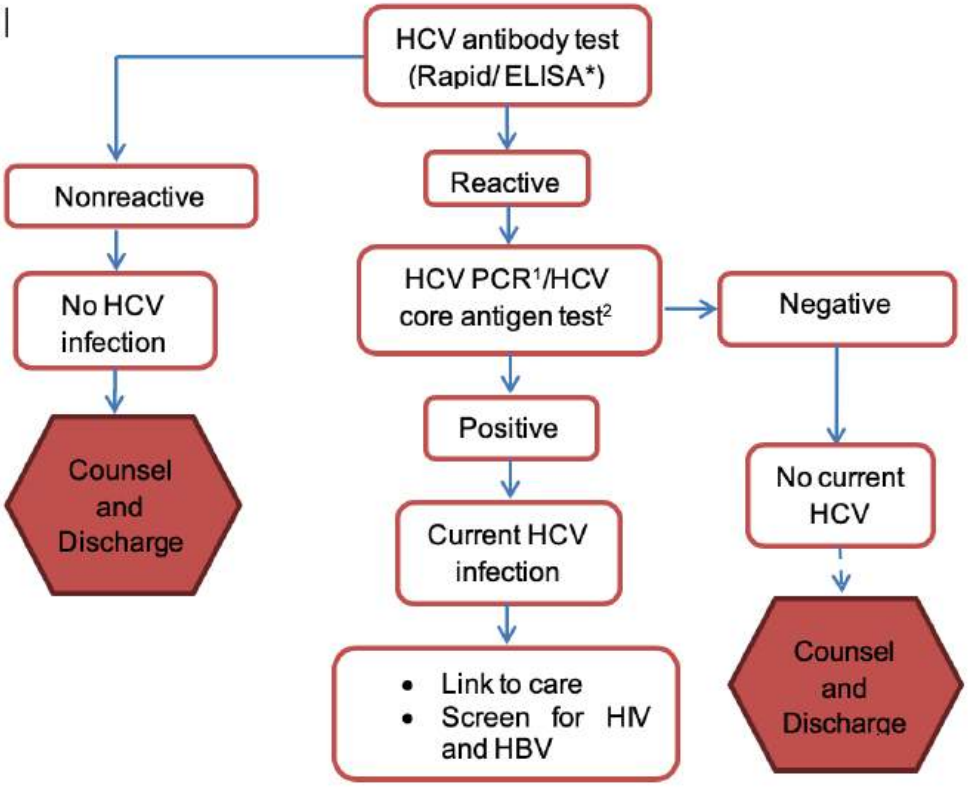
Annual monitoring of Hepatitis B viral load (PCR DNA) and Hepatitis B envelope antigen (HBeAg) loss are recommended for evaluation of disease progression.

10.2 Hepatitis C Co-infection

- Global prevalence of HCV is estimated at 2-3 % HCV with geographical variations ranging from 0.6 to 22% and being the lowest in Sub Saharan African Countries general population (0.7% to less than 2%).
- However, it is highest among KPs with prevalence ranging between 30%-70% in (PWIDUs) irrespective of HIV status.
- Based on serological screening of HCV core antibody (HCVcAb) both HBV/HCV and HCV/HIV co infections has a prevalence of 5.4% and 3.9% among the KP's respectively in sub-Saharan African countries, while the global prevalence of HCV co infection among people living with HIV (PLWHIV) is 6.2%.
- HCV transmission is majorly through percutaneous injections and unscreened blood or blood products; and much less common through sexual intercourse utero or peripartum routes.
- 80% of mono infected RoC who are chronically infected will develop liver cirrhosis or liver cancer compared to 20% and 5% of those with Hepatitis B respectively.
- Like HIV/HBV co infection, the HIV/HCV co-infected patients tend to exhibit rapid clinical deterioration and poor outcomes as compared to their HIV or HCV mono infected counterparts. This include disease progression to liver fibrosis with decompensation, HCC occurrence and increased risk of mortality.
- Rapid HCV serological antibody (anti-HCV) or HCV core antigen testing should be prioritized and offered at point of care (POC) to the following individuals:
    - Adults and adolescents from population most affected by HCV-KPs (e.g. PWID) and those with history of exposure or high-risk behaviour.
    - Adults, adolescents and children with clinical suspicion of stigmata of chronic viral hepatitis.
- Currently, there is no vaccine for prevention of HCV infection and therefore all preventive measures are geared towards primary prevention in general population through health education and awareness creation, Blood and injection safety and Harm Reduction.

10.2.1 HCV and Co-infection Clinical evaluation

- Diagnostic evaluation is supported by adequate history taking, baseline laboratory testing (ALT, AST, Creatinine FBP, Alpha Feto Protein-AFP); Abdominal Ultrasound (AUS),) and confirmed by HCV testing algorithm as follows:



- Linkage to care involves performing baseline assessment, staging of disease severity and planning for specific treatment.

10.2.2 HCV Treatment

- Treatment of HCV is curative irrespective of HIV status
- Use of fixed combination of anti HCV based therapy is recommend based on age, weight (table 10.2.1) and history of past treatment exposure.
- **Sofosbuvir 400mg+Velpatasivir 100mg** daily for 12 weeks up to 24 weeks is recommended regimen of choice for treatment naïve and treatment experienced RoC's respectively
- Depending on availability other fixed combination regimen (**Sofosbuvir 400mg+ Ledpasivir 90mg OR Sofosbuvir 400mg + Daclatasvir 60mg)** daily for 12 weeks up to 24 weeks may be used (table 10.2.1)
- All RoC completing anti HCV dose duration should have their viral load (HCV RNA PCR) done at three (3) months after treatment completion to establish sustained viral remission (SVR)

Table 10.3: Anti HCV based therapy

Recommended pan genotypic Direct acting antiviral agents (DAA) regimens		Non-pan genotypic DAA regimen
SOF/VEL	SOF/DCV2	SOF/LED
>30 kg 400/100 mg od (FDC tablet)	>26 kg 400/60 mg od (film-coated tablets)	≥35 kg 90/400 mg od (FDC tablet)
17–29 kg 200/50 mg od (FDC tablet or granules)	14–25 kg 200 mg/30 mg2 (as single tablets, SOF preferred as smaller, 100 mg tablet)	17– 35 kg 45/200 mg (tablet)
<17 kg 150/37.5 mg od (coated granules)		<17 kg 33.75/150 mg (FDC granules packets)

Note

- HCV/HIV Co infected patients should receive concurrent treatment regardless of CD 4 count and fibrosis stage.
- Due to potential drug-drug interactions and presence of hepato-renal toxicity, selection of antiviral regimen should be considered, and duration of treatment extended from 24 weeks up to 48 weeks (Table 10.2.3)
- For individual with CD4 count less than 200cells/ml, its recommended to defer HCV therapy until the individual stable (CD4 count greater than 200cells/ml) on ART with HIV RNA suppressed levels of less than 1000 copies/ml.

Table 10.4: Drug–drug interactions between antiretroviral and direct-acting antivirals

DAA	ABC	ATZ/r	DTG	EFV	DRV/r	LPV/r	NVP	TDF	RAL	TAF	3TC	FTC
Sofosbuvir/ ledipasvir												
Sofosbuvir/ Velpatasvir												

Adopted and Modified from WHO guidelines for the care and treatment of person with chronic Hepatitis C virus infection Pg 34

Key:

	Do not co-administer
	Possible toxicity/interaction/dose adjustment, as specified
	No interaction; can be co-administered

ABC: abacavir; ATZ/r: atazanavir/ritonavir; DRV/r: darunavir/ritonavir; DTG: dolutegravir; EFV: efavirenz; LPV/r: lopinavir/r; NVP: nevirapine; RAL: raltegravir; ZDV: zidovudine; TDF: tenofovir disoproxil fumarate; XTC: emtricitabine/lamivudine; TAF: tenofovir alafenamide

10.2.3 HCV Treatment Monitoring

- Baseline and three months post treatment HCV RNA PCR testing should be perfomed
- Evaluation of ALT of AST should be done at baseline and repeated every 4 weeks until end of treatment
- If serum ALT and or AST increases up to 5X upper limit of normal (ULN) but with normal Bilirubin levels and without concomitant symptoms for overt liver disease (jaundice, weakness, nausea and vomiting) then ART can be continued with close monitoring of liver indices until clinical and biochemical remission is resumed.
- ART can be deferred where individual has ALT and or AST elevations is greater than 5XULN, with an increase in Total Bilirubin and or concomitant overt liver disease symptoms and referral for further expert consultation should be sought.

CHAPTER XI: SCREENING AND MANAGEMENT OF SEXUALLY TRANSMITTED AND REPRODUCTIVE TRACT INFECTIONS OTHER THAN HIV

11.1 Introduction

Sexually Transmitted and Reproductive Tract Infections (STI/RTIs) are a major public health concern globally, with a significant relationship to HIV transmission. Implementing a comprehensive control and prevention program for STIs/RTIs is vital to reduce the risk of acquiring and transmitting HIV.

11.2 Screening for STIs/RTIs

All RoC should be offered a screening service using the STIs/RTIs screening tool (*see Flow Charts Annex 12*)

11.3 Approaches for management of STIs/RTIs

STIs/RTIs can be managed through the following approaches:

Aetiological laboratory approach identifies causative agents through laboratory methods, followed by disease-specific treatment. An aetiology/laboratory approach is only undertaken in few health facilities that have well-equipped functional laboratories. It is the approach applied in STI referral facilities

Aetiological clinical approach targets disease treatment based on suspected causative agents diagnosed clinically. The clinical aetiological approach is not appropriate at any health facility because of its demands on the clinical acumen of the service provider and the danger of incorrect diagnosis and, hence, insufficient treatment.

Syndromic approach for managing STIs/RTIs involves identifying clinical syndromes through symptoms and signs, followed by targeted treatment for the causative agents. This approach is recommended by the Ministry of Health in Tanzania and has proven effective across various healthcare settings. Common signs and symptoms of STIs/RTIs include painful urination, abnormal discharge, genital ulcerations, itching, swollen lymph nodes, scrotal swelling, lower abdominal pain, and pain during sexual activity. Each syndrome can be a result of a number of different causative agents.

Healthcare workers should be cautious in distinguishing between RTIs and STIs. Prompt and accurate diagnosis and treatment of STIs are important, including treating sexual partners and providing periodic screening and presumptive treatment to sex workers as per national guidelines.

11.4 Indications and Opportunities for Screening

Screening opportunities include family planning, voluntary medical male circumcision (VMMC), speculum examinations, and testing all male partners of females with STI/RTIs, and vice versa. STI/RTI screening should be conducted early in pregnancy and repeated in the third trimester if possible, with testing at delivery for women who do not attend antenatal clinics. Screening for syphilis in pregnant women allows for early detection and treatment, although it

does not prevent congenital syphilis entirely. Women with a history of spontaneous abortion or stillbirth should also be screened for syphilis to address a significant cause of adverse pregnancy outcomes. Additionally, men and women presenting with STI symptoms other than genital ulcers should be screened for syphilis.

11.5 Overview of STI Syndromes

Although STIs are caused by many different organisms/agents, these organisms give rise to a limited number of syndromes. Table 11.2 below outlines the nine common STI syndromes and their etiologic agents.

Table 11.1: STI Syndromes and their Aetiological Agents

STI Syndrome	Sex	Common Etiologic Agent
Urethral Discharge Syndrome (UDS)	Males	*Chlamydia trachomatis* *Neisseria gonorrhoea*
Painful Scrotal Swelling (PSS) (acute epididymoorchitis)	Males	*Chlamydia trachomatis* *Neisseria gonorrhoea*
Vaginal Discharge Syndrome (VDS)[1]	Females	*Candida albicans Chlamydia trachomatis* *Gardnerella vaginali Neisseria genorrhoeae* *Trichomonas vaginalis*
Pelvic Inflammatory Disease (PID) (Lower Abdominal Pain)	Females	*Anaerobic bacteria* *Chlamydia trachomatis Neisseria gonorrhoea*
Genital Ulcer Disease (GUD)	Males Females	*Chlamydia trachomatis* *Haemophilus ducreyyi* *Herpes Simplex type 2* *Treponema pallidum* *Klebsiella granulomatis*
Inguinal Bubos	Males Females	*Chlamydia trachomatis* *Haemophilus ducreyi*
Anorectal Syndrome	Males Females	*Neisseria gonorrhoea Chlamydia Trachomatis* *Herpes simplex Treponema pallidum* *Human papilloma virus*
Neo-natal Conjunctivitis (Ophthalmic neonatorum)	New-borns Males and Females	*Neisseria gonorrhoea* *Chlamydia trachomatis*
Oropharyngeal infection	Males and Females	*Treponema pallidum Neisseria gonorrhoea* *Chlamydia trachomatis Klebsiella spp* *Human papilloma virus (HPV)*

Note: Cervical infections caused by Neisseria Gonorrhoea and Chlamydia trachomatis sometimes present with vaginal discharge.

For management of common syndromes, see Flow Charts for *Syndromic Management of STI's/RTI's in ANNEX 12* a-i.

CHAPTER XII: INTEGRATED MANAGEMENT OF NON-COMMUNICABLE DISEASES (NCDS) IN HIV

12.1 Introduction

With long-term antiretroviral therapy, RoC live longer and therefore HIV has become a chronic condition. The risk of developing non-communicable diseases due to HIV virus-related inflammatory and long-term medication effects increases. Integration of NCD screening and treatment with HIV care can can reduce hospital visits, costs, and improve efficiency of services. The service integration will, focus on screening, prevention, and control of common NCDs among people living with HIV. This chapter addresses the screening, prevention, and control of common NCDs (Hypertension, Diabetes, Cervical Cancer, and Kaposi's sarcoma) among PLHIV.

12.1.1 Screening, Diagnosis and Management of Hypertension

HIV infection and certain antiretroviral medications increase the risk of hypertension and cardiovascular disease in PLHIV. Regular screening for hypertension risk factors (smoking, obesity, physical inactivity, and unhealthy diet) is essential, along with measuring and recording blood pressure during clinic visits. A diagnosis of hypertension requires an average of three separate elevated readings on the same day, taken when the RoC is comfortable (e.g., on days 1, 3, and 5). Tables and an algorithm below provides guidance on diagnosing, and managing hypertension among PLHIV.

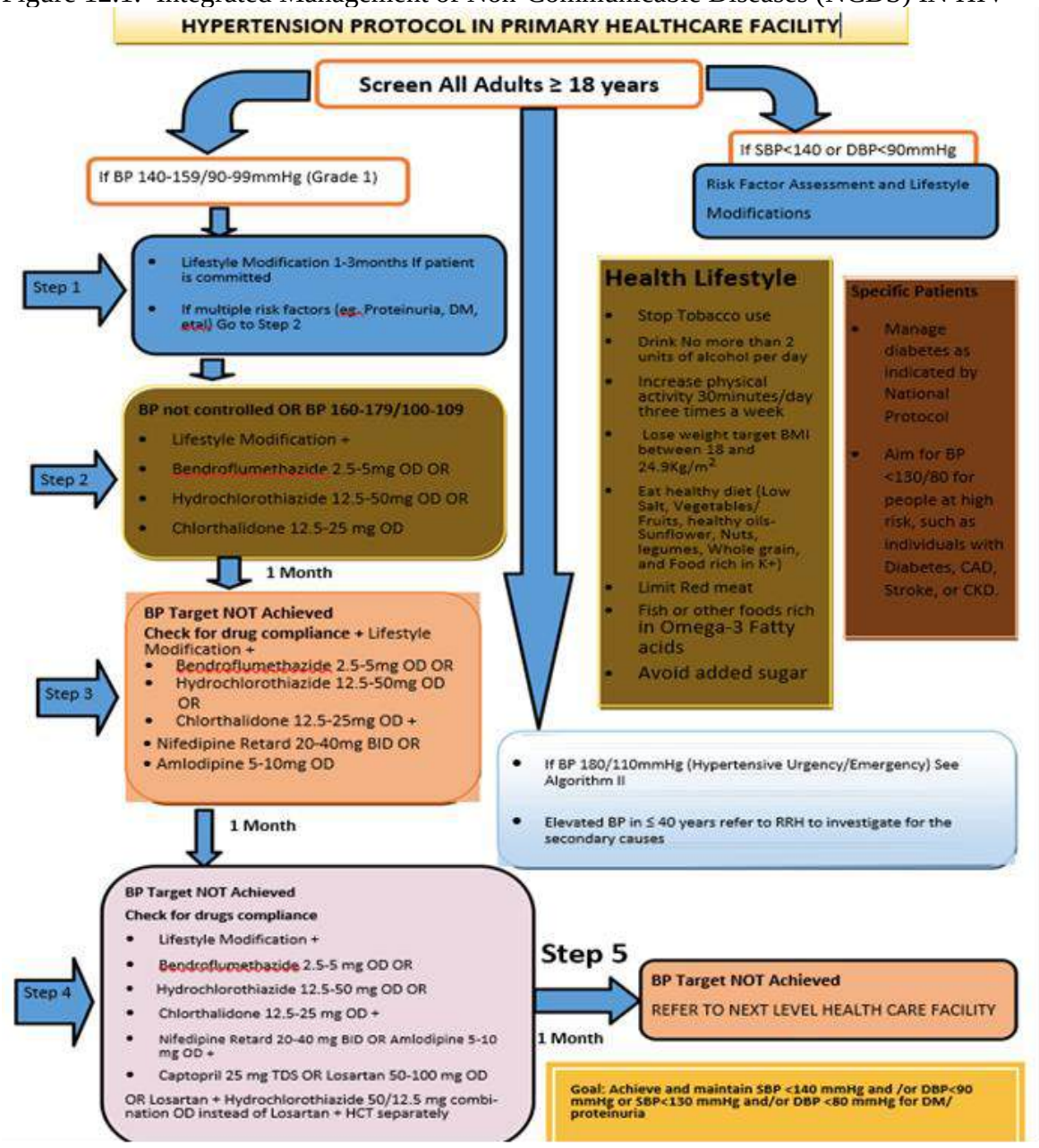
Table 12.1: Screening and diagnosis of Hypertension

Sn	Area of Intervention	Rationale for Intervention
1	Why screen for Hypertension	Uncontrolled hypertension is a preventable risk factor for stroke, heart attack, kidney disease and heart failure
2	Who to screen for Hypertension	All Persons living with HIV aged ≥ 15years
3	When to Screen for hypertension	At baseline and on every clinic visit
5	What are requirements for measuring hypertension	● Digital Blood Pressure machine ● A firm seat with back support ● A quiet room or area ● Recipient of care treatment card (CTC1) ● Recipient of care Monitoring tools
6	When to diagnose hypertension	1. RoC aged ≥ 15 years with: o An average systolic BP ≥ 140 and or diastolic BP ≥ 90mmHg on three separate readings on the same day. 2. A person on hypertension medicines even when the blood pressure is less than 140/90mmHg.

Table 12.2: Classification of Hypertension

Class of HTN	SBP mmHg	DBP mmHg	Confirm diagnosis
Grade 1	140-159	90-99	After 3 Month of lifestyle modification
Grade 2	160-179	100-109	Same visit
Grade 3	≥180	≥110	Same visit

Figure 12.1: Integrated Management of Non-Communicable Diseases (NCDS) IN HIV



12.1.2 Drug Interaction between Antihypertensive and ARVs

Thiazide diuretics and ACE inhibitors do not interact with ARVs. Calcium channel blockers and beta-blockers may have their drug levels affected by PIs and NNRTIs, requiring potential dose adjustments. However, calcium channel blockers and beta-blockers do not affect ARV drug levels, eliminating the need for dose adjustments.

Table 12.3: Drug interactions between antihypertensive and ARVs

Hypertension Drug	Interaction with ART	Action Required
Dihydropyridines (amlodipine and Nifedipine)	Efavirenz and Nevirapine could potentially decrease drug levels	No dose adjustments are required
	LPV/r, ATV/r and DRV/r increase drug levels	Use Nifedipine with caution
Losartan	Efavirenz may reduce formation of active form of losartan	No dose adjustments are required
	Protease inhibitors reduce elimination of losartan	Use with caution, in recipient of cares with hepatic impairment
Valsartan (and other ARBs except losartan and Ibesartan)	No clinically significant drug-drug interactions	None
All ACE inhibitors (including captopril)	No clinically significant drug-drug interactions	None
All diuretics (including Hydrochlorothiazide and Bendroflumethiazide)	No clinically significant drug-drug interactions	None

Note;
The goal is to achieve and maintain SBP <140mmHg and/or DBP <90mmHg

12.1.3 Screening, diagnosis and management of Diabetes Mellitus among PLHIV

Traditional risk factors like age, BMI, and genetic predisposition contribute to diabetes development in people living with HIV (PLHIV). Some ARVs like lopinavir (LPV) have shown to be diabetogenic (stronger associations with diabetes) compared to others like tenofovir (TDF), emtricitabine (FTC), lamivudine (3TC), darunavir (DRV), and atazanavir (ATZ). Integrase stand transfer inhibitors, INSTI e.g. dolutegravir have been shown to cause metabolic syndrome (central obesity, HTN, Insulin resistance) in some patients. HIV infection and co-infection with hepatitis C virus (HCV) can also increase the risk of diabetes. HIV infection and co-infection with hepatitis C virus (HCV) can also increase the risk of diabetes.

PLHIV should undergo regular blood glucose monitoring, with a baseline evaluation and subsequent assessments every 6 months. RoC experiencing symptoms like polyuria, polydipsia, polyphagia, having a family history of diabetes, or having a BMI>30kg/m^2 should be prioritized.

Table 12.4: Clinical Interpretation of Blood Sugar results

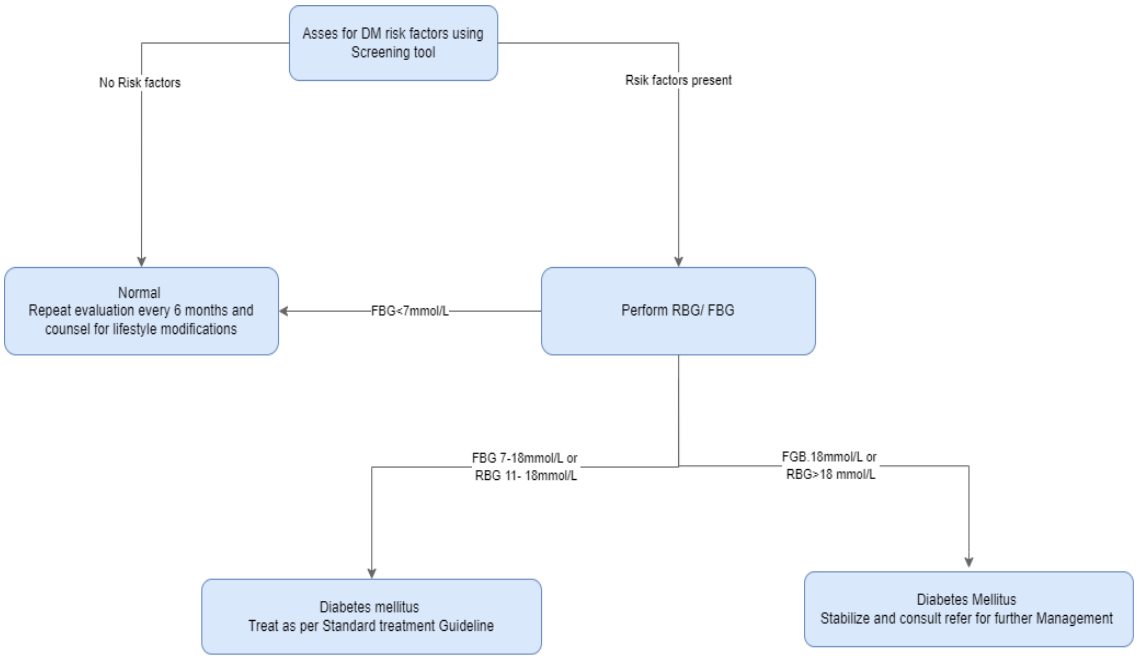
Test Category	Diagnosis		
	Normal	**Prediabetic**	**Diabetic**
Random Blood Sugar (RBG)	< 11mmol/L	7.8 – 11mmol/L	>11 mmol/L
Fasting Blood Sugar	< 6 mmol/L	6.1- 6.9mmol/L	>7 mmol/L

For further management of diabetes, including management of complications a RoC should be referred to high level facilities.

Table 12.5: Screening, diagnosis and management of Diabetes Mellitus among PLHIV

S/N	Area of Intervention	Rationale for Intervention
1.	Why screen for Diabetes	● Undiagnosed and/or Uncontrolled Diabetes leads to Stroke, kidney disease, Peripheral Neuropathy, Blindness, Diabetic foot and amputation
2.	Who to screen for Diabetes	● All RoC aged ≥15 years ● All RoC on DTG and/or LPV based regimen. ● All RoC before initiating ART
3.	When to Screen for Diabetes	● At baseline ● Present with signs and symptoms (Polyphagia, polydipsia, polyuria, polyneuropathy) ● Every 6 months
4.	How to diagnose diabetes?	● Two glucose tests, one week apart, are advised for individuals with elevated glucose levels but no hyperglycaemia symptoms. For RoCs experiencing symptoms of high glucose, a single glucose test is recommended.
5.	What are requirements for measuring blood glucose	● Screening tool for diabetes ● Glucometer (RBG Machine) with strips ● SOP for measuring blood glucose
6.	When to diagnose Diabetes	● Fasting blood glucose (8 hours without food or drink except water): Glucose reading >7.0mmol/l (126mg/dl). ● Random Blood Glucose (RBS) with classical symptoms of hyperglycaemia: Glucose reading >11.1mmol/l (200mg/dl). ● HBA1c: Glucose reading >6.5%.

Figure 12.2: Algorithm for Screening, Diagnosis & Management Diabetes Mellitus among PLHIV



- FBG – Fasting Blood Glucose(sugar)
- RBG – Random Blood Glucose (Sugar)

** Fasting: no food and only water for 8–14 hours before the test*

12.2 ART among PLHIV with Diabetes Mellitus

If a RoC develops diabetes while taking potentially diabetogenic ARVs, particularly thymidine based NRTIs (zidovudine), DTG and first-generation PIs (LPV, IDV), it is advisable to switch them to an alternative ART regimen if available. ARVs with a safer metabolic profile, such as TDF, ATZ, EFV and DRV, may be considered as part of the new regimen.

12.2.1 Drug Interactions of Diabetes Medicines with ARVs

Metformin and DTG**: a lower dose of metformin may be needed with closer monitoring of blood glucose.

*** Do not initiate or Transition RoC to DTG if known or confirmed to have diabetes*

12.2.2 Lifestyle Modification for prevention and control of complications of common NCDs

Conduct psychosocial education and counselling on the lifestyle modification for prevention and successful control of HTN based on the following guide.

Table 12.6: Lifestyle modification for prevention and control of complication of common NCDs

Risk Factor	Behaviour and Lifestyle Modification
Tobacco Smoking	Ceasing to smoke reduces the risk of, uncontrolled hypertension, diabetes, heart disease, stroke, and chronic lung diseases
Physical Inactivity	Persons should be advised to have physical exercises for at least 30 minutes a day, 5 days a week. Health care providers should help RoC find activities that they enjoy because this increases adherence
Unhealthy Diet	Eat a diet high in fruits and vegetables and low in fat
	Limit processed and fast foods e.g canned foods, Fried fast foods
	Reduce refined sugar intake e.g Soda, Processed juices
	Reduce Salt intake to <1.5 g/day (less than one teaspoon)
Overweight/Obesity	Maintain a normal body weight of a body mass index of 18 – 25kg/m^2 and or a waist circumference of < 82cm for females and < 102cm for males
Alcohol and Drug use	Promote responsible alcohol drinking
	Avoid use of psychoactive drugs

12.3 Screening and management of Dyslipidaemias among PLHIV

Baseline screening of fasting lipid profile (total cholesterol, LDL, and triglycerides) should be done for all PLHIV. Diagnosis of dyslipidaemia is made when fasting total cholesterol is >5.2mmol/L, LDL>3.4mmol/L or triglycerides > 2.2mmol/L.

Monitoring of lipid profile should be at 6 months after initiation of ART and then annually for normal test results.

PLHIV should be counselled on lifestyle modification both as a prevention and treatment option for dyslipidaemia. Recipient of Care on ARVs known to cause or exacerbate dyslipidaemia such as LPV/r should be switched to a more lipid-friendly drug such as ATV/r before adding a lipid-lowering drug. RoC with persistent dyslipidaemia despite the above interventions should be referred for further management.

12.4 Chronic Kidney Disease among PLHIV

CKD can develop as a complication of HIV, often due to certain ART therapies. Comorbid conditions such as Diabetes mellitus, Hypertension, Hepatitis B/C co infection and nephrotoxic drugs may lead to high-grade proteinuria, severely reduced eGFR increase the risk of progressing to Chronic Kidney Disease (CKD). However, initiating ART early has been shown to improve kidney function in individuals with HIV-related CKD. Screening PLHIV for kidney disease is crucial for timely diagnosis and management. Baseline serum creatinine and urinalysis for protein, as well as regular follow-up, are recommended. If abnormal results are found, dose adjustment or avoidance of nephrotoxic ARVs (TDF) should be considered. For RoC on a TDF-based regimen, switching to a non-TDF-based regimen (TAF/ABC) is advised once CKD is diagnosed.

12.5 Cervical cancer

Tanzania has a high burden of cervical cancer, with approximately 10,241 new cases annually and a mortality rate of 42.7 deaths per 100,000 women. It is the leading cause of morbidity and mortality among women in the country. HIV-positive women face an increased risk and an earlier onset (10 years earlier) of cervical cancer compared to HIV-negative women, due to higher rates of persistent HPV co-infection. To address this, cervical cancer screening should be integrated into the routine care of HIV-positive women.

Figure 12.3: Screening and Treatment Approach for Cervical Cancer

- **Screen-and-Treat Approach (SVA-Single Visit Approach).:** Treatment is provided based on a positive primary screening test alone, without triage (i.e., no second screening test and no histopathological diagnosis) and treatment is offered on the same day.
- When the patient is eligible for treatment of small and moderate size pre cancer lesions, can use either Cryotherapy or Thermocoagulation (*Ablative Treatment*).
- Women who are not eligible for ablation can use Loop Electrosurgical Excision Procedure (LEEP). If LEEP is not available on-site, women should be referred.
- **Screen, Triage and Treat Approach**: The triage test is done if the primary screening test is positive, and the decision to treat is made when both the primary test and the triage test are positive with or without histologically confirmed diagnosis. Recommended primary screening test could be HPV DNA test and the triage test can be VIA.

Figure 12.4: Flow diagram for cervical cancer screening with VIA

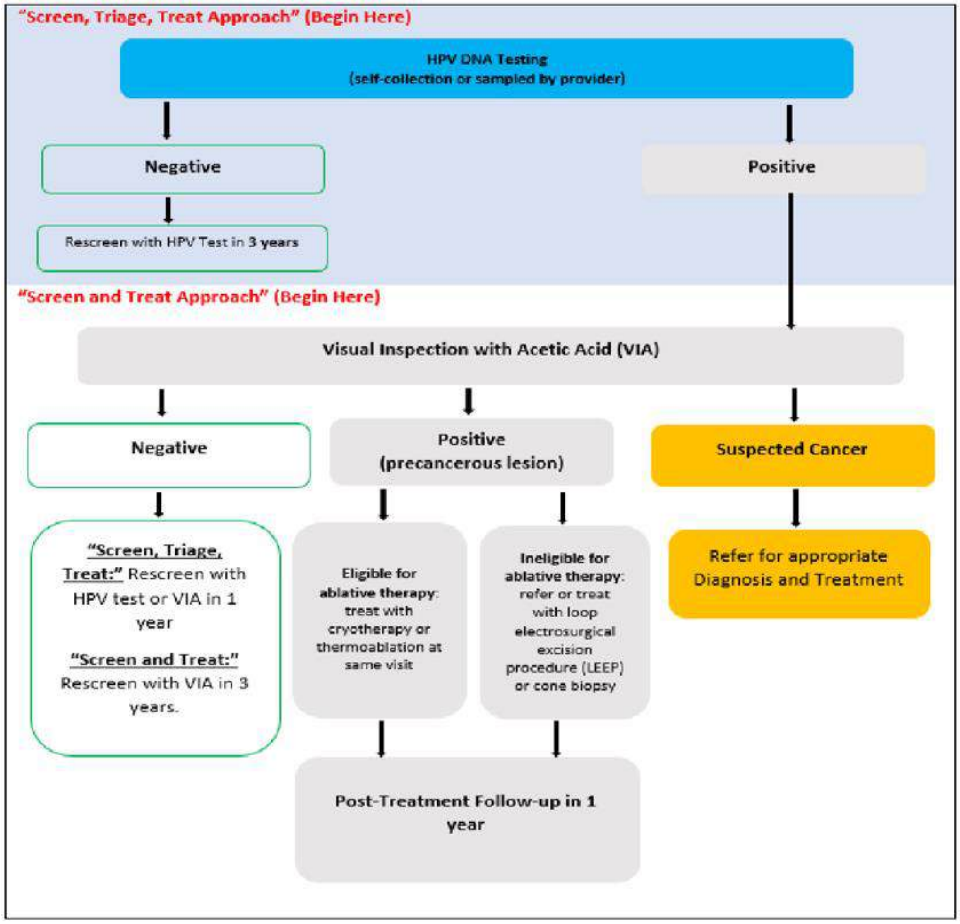


Table 12.7: Programmatic intervention to prevent and/or Control cervical cancer

Primary prevention	● Focuses on Girls 9- 14 years** ● HPV vaccination for Girls RoC should also be offered, according to IVD guidelines. ● Health information and education. ● Sex education tailored to age and culture. ● Condom promotion and provision for those engaged in sexual activity ● Male circumcision
Secondary Prevention	● Focuses on women living with HIV ≥ 25 years of age (Screen every 3 years) ● HPV DNA screening is recommended for women aged 25-60 years. ● Screening with VIA for positive HPV DNA test, followed by immediate treatment as quickly as possible after identification of precancerous lesions. ● Perform Pap smear test for women who are 60Years and above.
Tertiary Prevention	● All WLHIV as needed. ● Treatment of invasive cancer at any age (Surgery, Radiotherapy, Chemotherapy, Palliative care)

**Girls 9-14 years living with HIV are given three HPV vaccine doses at month zero, two and six.

(Refer to the "*Tanzania Service Delivery Guidelines for Cervical Cancer Prevention and Control (2023)*" for detailed information and guidance).

12.6Kaposi's sarcoma (KS)

Kaposi's sarcoma is a malignant tumour of angio–proliferative cells usually starting from the skin but occasionally involving many other organs of the body caused by the Kaposi's sarcoma Herpes Virus (KSHV). Kaposi sarcoma can be primarily categorized into four types: epidemic of AIDS–related Kaposi's sarcoma, classic, or sporadic, endemic (African) and Iatrogenic (immunosuppression related KS). In Tanzania, AIDS related (epidemic) KS is the most common. ART has led to the decline of prevalence of KS among PLHIV, however the emergence of drug resistance may cause rise in AIDS related KS.

Table 12.8: Clinical presentation, diagnosis, treatment and follow up

Clinical presentation	Lesions may involve skin, oral mucosa, lymph nodes, visceral organs, and mucous membrane (palate, gingiva, conjunctiva) May present as macular, papular, nodular, or plaque like appearances. Presence of B symptoms (fever, sweating and weight loss) is commonly associated with epidemic type.
Diagnosis	*Biopsy and Histology of KS lesions to confirm diagnosis
Treatment	Antiretroviral therapy together with Systemic chemotherapy* and/or Radiation Therapy*
Follow up	Follow up Physical examination, CXR, Abdominal Pelvic USS every 3 months for 2 year, every 4 months in third year, every 6 months in fourth and fifth years, then annually.

**A referral to higher level facility should be issued if service are not available. Refer to the Tanzania Service Delivery Guidelines for Cervical Cancer Prevention and Control (2023) for detailed information and guidance.*

CHAPTER XIII: INTEGRATION OF MENTAL HEALTH SERVICES IN HIV AND AIDS CARE

13.1 Introduction

Mental health conditions are common in HIV infected individuals. In some instances, this is due to; preexisting mental health conditions prior to HIV infection, mental health condition as a psychological consequence of chronic HIV infection and the effect of HIV in the brain. It is important to be aware that HIV infected individuals have an increased risk of developing mental health conditions i.e cognitive, mood and anxiety disorders due to social difficulties, stigma and discrimination. HCWs should assess and manage mental health conditions as part of routine care for PLHIV at every visit.

Mental health conditions common among people living with HIV can be grouped into the following categories.

- Mood Disorders (i.e. Depression and Mania)
- Anxiety Disorders (i.e. adjustment disorders, panic disorders, generalized anxiety disorders, post-traumatic stress disorders, HIV and AIDS related phobia)
- Psychotic Disorders (i.e. schizophrenia, schizoaffective disorders)
- Organic Disorders (Delirium and Dementia)
- Alcohol and other substance use disorder (i.e. cannabis, heroin and cocaine)

13.1.1 Mood disorders among PLHIV

The most common mood disorders among PLHIV include Depression and Manic disorders

13.1.2 Depression

PLHIV are at high risk of developing depression, it is estimated that in Africa 36% of PLHIV have depressive condition which affects ART adherence leading to poor treatment outcomes. It is particularly important to screen for depression during the following situations:

- When newly diagnosed with HIV or at disclosure of HIV status to family and friends.
- Occurrence of any physical illness, recognition of new symptoms/progression of disease or hospitalization or diagnosis of AIDS.
- Initiation of medication.
- Persistence of high viral load
- Return to care after a lost to follow up
- Post GBV
- Death of a significant others.
- Major life changes, e.g., childbirth, pregnancy, loss of a job, end of a relationship

Screening and Management.

- HCWs should use Patient Health Questionnaire No.2 (PHQ2, Annexes 13B) as first approach to screen for symptoms of depression. For patients with mild symptoms PHQ2 score of 3-4 provide counselling using Mental Health and psychosocial support (MHPSS), For patients with PHQ2 score above 4 refer to psychiatric evaluation.

Management:
Psychosocial
Use MHPSS counselling tool for depression.

Note;

- PLHIV receiving antidepressant drugs HCWs should take note of ART/Antidepressants interactions as highlighted in Table 13.1 below.

Table 12.9: Antidepressant dosage and possible ART interaction

Drug groups of antidepressants	Specific drugs registered in Tanzania	Dose range (mg)	Interactions with ARVs
1. Tricyclic Antidepressant	Amitriptyline Imipramine	25mg to 75mg per day	Lopinavir/r & ritonavir increase antidepressant levels in serum
2. Selective Serotonin re-uptake inhibitors) Recommended in RoC on ART	Fluoxetine Citalopram	10mg to 20mg per day 10mg to 40mg per day	Nevirapine decreases level; AD increases levels of Amprenavir, Delavirdine, Efavirenz, Indinavir, LPV/r, Ritonavir, Saquinavir

13.1.3 HIV-Related Mania

Definition and Characteristic Features: AIDS related mania is secondary to HIV CNS involvement. It is characterized by loss of the ability to control mood, and it presents with elated or irritable moods, increased activity and energy regardless of the physical status, decreased need for sleep and an exaggerated sense of self-importance. The condition occurs with more advanced immunosuppression.

Management:

- Continue with ART treatment because it relieves the symptoms of AIDS related mania and refer for further psychiatric evaluation.

Possible drug interactions.

- Carbamazepine induces liver enzymes and increases metabolism of ART drugs. If possible, avoid in RoC on ART.

13.2.1 Anxiety disorders

RoC with HIV infection may have any of the anxiety disorders, but generalized anxiety, post-traumatic stress, and obsessive-compulsive disorders are particularly common. Symptoms of anxiety disorders are both psychological and physical.

The physical manifestations include: shortness of breath, chest pain, increase of heart beats, dizziness and gastrointestinal disturbances. These symptoms may overlap with symptoms of other common medical disorders. In addition, the RoC present with fear, worry, insomnia,

impaired concentration and memory, diminished appetite, compulsive rituals and avoidance of situations that make them anxious.

Screening and Management.
HCWs should use Generalized Anxiety Disorder 2 (GAD 2 annexes 13A) as first approach to screen for symptoms of Anxiety. For patients with mild anxiety symptoms GAD2 score of 3-4 provide counselling using Mental Health and psychosocial support (MHPSS), For patients with GAD2 score above 4 refer for further psychiatric evaluation

Management:
Psychosocial
Use Mental Health and Psychosocial Support (MHPSS) counselling tool for anxiety.

13.3.1 Psychotic Disorders
RoC with psychotic conditions may have any of schizophrenias and schizoaffective disorders. Common symptoms of schizophrenia include; Hallucinations, Delusions and other thought disorders.

Screening and Management.
HCWs should use modified psychosis screening questionnaire (PSQ- Annexes 13E) to screen for psychotic conditions among RoC, for patients with a score of Yes at any of the symptoms in PSQ refer for further psychiatric evaluation

13.4 Organic Disorders
RoC with organic disorders may present with any of Delirium and HIV associated Dementia.

13.4.1 Delirium
This condition may present with an acute onset of impaired consciousness and memory loss.

Management;
Upon diagnosis of Delirium provide supportive Airway, ensure breathing and stabilize circulation. Refer immediately to emergency department for further assessment and treatment.

13.4.2 HIV Associated Dementia (HAD)
Condition mainly presenting with memory loss and psychomotor retardation.

Screening and Management;
Screening for HAD uses the International HIV Dementia Scale see Annex 13F

13.4.3 Alcohol and drug use
Alcohol and drug use disorders occur when a person uses either one or both substances (Alcohol and drugs) leading to health and psychosocial impairments. RoC who use and abuse alcohol and other drugs are at risk of poor adherence to HIV care and treatment, they are at risk for both drug-drug interactions and substance related toxicities. Using alcohol and substance of abuse increases risk-taking behaviours i.e promiscuity. The most used and abused substances among PLHIV are alcohol, benzodiazepines, cannabis, opioids and Cocaine.
Health care providers should screen for and provide management of substance use disorders in PLHIV at every visit.

Screening and Management;
HCWs should use modified AUDIT-3 or ASSIST to screen for alcohol and other substance use disorders among RoC, Annexes 13D

Management of Alcohol and other substance abuse

Figure 13.1: Algorithm for Assessment of Substance Use

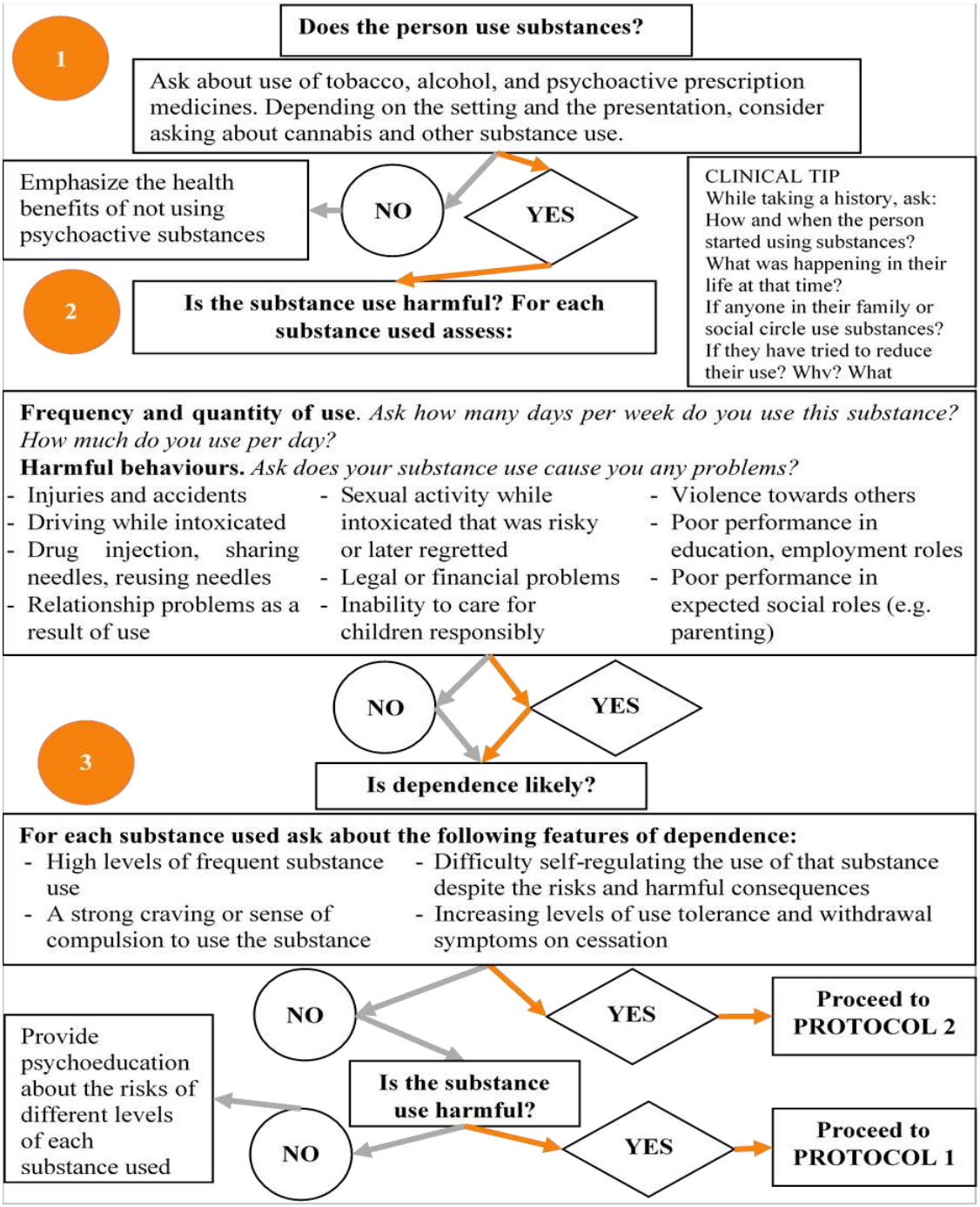


Table 13.1: Management of PLHIV with Substance Use Disorder, Protocol 1 and 2.

Protocol 1: Harmful Use

- Provide psychoeducation and emphasize that the level of substance use is causing harm to health
- Explore the person's motivations for substance use. Conduct motivational interviewing.
- Advice stopping the substance completely or consuming it at a non-harmful level, if one exists. Verbalize your intention to support the person to do this. Ask them if they are ready to make this change.
- Explore strategies for reducing or stopping use and strategies for reducing harm.
- Address food, housing, and employment needs
- If the person is an adolescent or a woman of child-bearing age, pregnant, or breastfeeding, see special population

Protocol 2: Dependence

If The Person Is Dependent on Opioids:

- Assess severity of dependence and, if appropriate, REFER the person for opioid agonist maintenance treatment, also known as opioid substitution therapy (OST) such as Medical Assisted Treatment (MAT)

If The Person Is Dependent On Benzodiazepines:

- Sudden cessation can lead to seizures and delirium. Consider gradually reducing the dose of benzodiazepine with supervised dispensing or a more rapid reduction in an inpatient setting, refer RoC or consult mental health specialist addiction professional.

If The Person Is Dependent On Alcohol:

- Sudden alcohol cessation can lead to seizures and delirium; however, if the person is willing to stop using alcohol, facilitate this. Determine the appropriate setting to cease alcohol use, and arrange inpatient detoxification, REFER RoC, or consult mental health specialist.
- Provide thiamine at a dose of 100 mg/day p.o.
- Consider pharmacologic intervention to prevent relapse in alcohol dependence; medications include acamprosate, naltrexone and disulfiram.

For All Substances:

- Advise stopping the substance completely and verbalise potential health effects on ART adherence.
- Explore strategies for reducing or stopping use and strategies for reducing harm.
- Consider referral to peer help groups or rehabilitation/residential therapeutic communities.
- Address food, housing, and employment needs
- Assess and treat any physical or mental health co-morbidity, ideally after 2-3 weeks of abstinence.

In all cases:

- Provide psychoeducation.
- Arrange for detoxification services.
- Treat withdrawal symptoms as needed.
- Provide a brief intervention using motivational interviewing to encourage the person to engage in treatment of their substance dependence.
- Provide psychosocial treatment for persons with ongoing problems related to their substance use, if they do not respond to the initial brief interventions.

CHAPTER XIV: PHARMACEUTICAL AND LABORATORY SERVICES
PART 1: SUPPLY CHAIN MANAGEMENT AND RATIONAL USE OF HIV AND AIDS COMMODITIES

14.1 Introduction

A comprehensive HIV and AIDS Programme requires a wide range of commodities supporting a range of interventions that encompass prevention, care, and treatment. Supply chain management of HIV and AIDS commodities is critical to support the national policy and to ensure adequate and continuous availability of quality and affordable essential medicines, diagnostics, and other consumables at service delivery sites in the right quantities, at lowest possible cost and in a timely manner. These commodities are relatively expensive and therefore they require proper handling to ensure effective use.

Since all people living with HIV will be initiated on ART, resources and strong Procurement and Supply Management (PSM) should be available at all levels of the health system. Procurement team and ART Programme managers need to work together to ensure that the national supply system is functioning properly i.e., forecasting, procuring, and distributing the quantities of HIV and AIDS commodities required to meet the national demand and the 95–95– 95 targets.

The key components of procurement and supply management include: (i) product selection (ii) forecasting and supply planning (iii) procurement (iv) storage and distribution (v) Logistics Management Information System (LMIS) (vi) Use or serving customers (vii) Quality monitoring, and (viii) Policy. Management support is integral to each component. It includes a variety of activities at all levels of the healthcare delivery system from the national level down to where medicines are dispensed, and diagnostics are used. The main activities include managing the information system (LMIS), ensuring timely information flow between stakeholders at different levels and securing financial and other resources for procurement, storage and distribution of medicines and diagnostics needed for the Programme.

14.2 Rational Use of Medicines (RUM)

Rational use of medicines requires providers to prescribe and dispense appropriate medications to the RoC' clinical needs, doses meet their own individual requirements, and medications are given for an adequate period of time and at the lowest cost to the RoC and his or her community.

ART is a complex undertaking that involves a large variety and quantity of drugs. It is a lifelong treatment that is in constant development. It is therefore very important to use medicines rationally since irrational medicine use (especially in the context of ART) may have unwanted consequences at both the individual and the population levels. These may include:

- Treatment failure
- Rapid development of drug resistance
- Increase risk of toxicity
- Increase cost for treatment due to the need to use expensive medication after failure of first line regimen.
- Spread of new HIV and Hepatitis infection.

Figure 13.2: Medicine Use Process

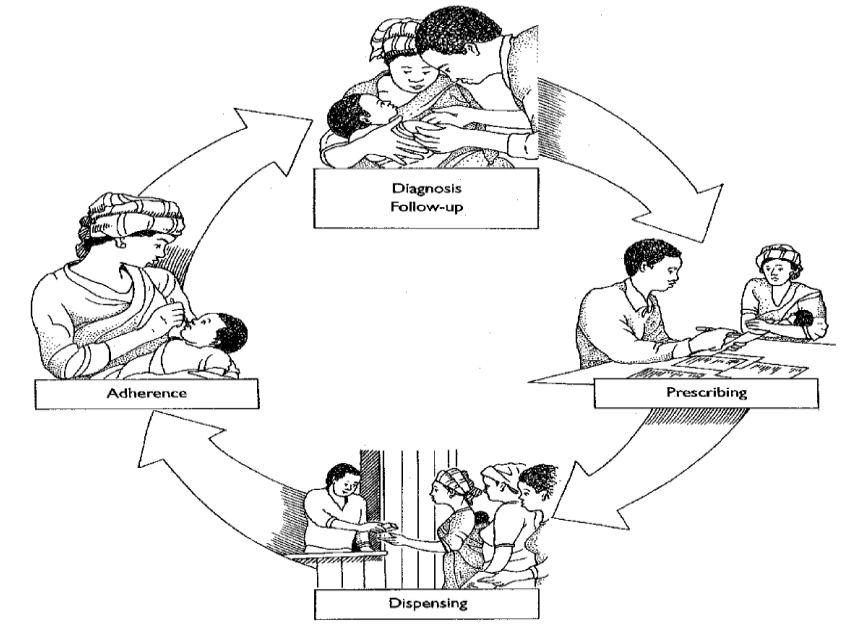


Table 14.1: Aspects HCPs should observe to Avoid Irratinal use of Medicine.

Diagnosis	● Inadequate examination of a RoC ● Incomplete communication between a RoC and the doctor ● Lack of documented medical history ● Inadequate laboratory Resources.
Prescribing: Irrational prescribing is observed when there is:	● Incorrect prescribing ● Diagnosis is inadequate Inappropriate medicines are prescribed ● Under prescribing ● Needed medications are not prescribed ● Dosage is inadequate ● Inadequate duration of treatment ● Overprescribing ● Prescribing inappropriate length of course ● Prescribing very high dose ● Extravagant prescribing ● Prescribing a more expensive branded medicines when there is a less expensive generic medicines ● Treating symptoms instead of treating the disease ● Multiple prescribing ● Two or more medications are prescribed when fewer would achieve the same effect.
Dispensing: Incorrect interpretation of the prescription	● The dispenser does not pick up errors or the dispenser sees the error but does nothing about it ● Incorrect calculation of dosage ● Retrieval of wrong medicines ● Inaccurate counting ● Inadequate labelling ● Unsanitary procedures

	● Inability to effectively communicate with RoC on how to use the prescribed medicines and adherence to dose schedules.
RoC aspects of irrational Use of Medicines This occurs when	● The RoC demands a prescription of more medicines than required ● Not following the given instructions ● Sharing medicines with others ● Medicine misinformation ● Lack of RoC readiness ● There is stigma ● The conflict between cultural values and therapy ● Misleading beliefs about HIV and AIDS ● RoCs' misunderstandings about the medicines and their uses ● RoC concerns about side effects and ADRs.

14.2.1 Prescriptions

Only trained and authorized prescribers in certified healthcare facilities are allowed to prescribe ARVs. The prescription for ARVs should clearly indicate the name/RoC ID No., age, sex of the RoC, body weight, medicines, dosage, and should include the name, signature, and prescriber's code.

14.2.2 Dispensing

ARVs are prescription-only medicines. They should only be dispensed to treatment-ready RoCs with clear instructions and advice. The dispenser should ensure that the prescription is appropriately written and signed by an authorized prescriber before dispensing. ARVs should only be given to the named RoC or appointed adherence assistant. Adequate time should be scheduled for antiretroviral dispensing and counselling.

The pharmacist/dispenser should ensure RoC understands the dosage and drug intake schedule as well as instructions regarding the storage and food requirements. The pharmacist/dispenser should also caution RoC about possible side effects and drug-drug interactions and respond to specific questions and problems related to ARV treatment encountered by RoC. It is also imperative for the dispenser to advise RoC on measures to be taken to reduce the side effects, including immediate return to the clinic when they experience unwanted effects.

14.2.3 Recipient of Care Identification Cards

Recipient of Cares (o*r appointed adherence assistants where recipient of cares cannot collect the medication themselves*) must present the cards to the dispenser every time they collect medicines and all medications received must be recorded on the card.

***Note**: ARVs dispensed at the community level should only be prescribed by authorized certified prescribers and dispensed by certified experts.*

14.3 Supply Chain Management

14.3.1 Selection of Pharmaceuticals and Diagnostics

The selection of antiretroviral (ARV) drugs and regimens is based on recommendations from the World Health Organization (WHO) and the specific context of each country's efforts to scale up antiretroviral therapy (ART). The treatment guidelines for a public health approach provide guidance for countries to ensure universal access, standardization, and simplification

of ARV regimens, while minimizing the risk of drug resistance. Consideration of procurement, forecasting, and distribution issues is important when selecting ARV drugs, regimens, formulations, and diagnostics. The guidelines also provide criteria for different treatment lines, management of treatment failure or toxicity, and specific subgroups such as RoC with tuberculosis, pregnant women, children, and healthcare workers in need of pre-exposure and post-exposure prophylaxis.

14.3.2 Forecasting and Supply planning (Quantification)

Program coordinators play a crucial role in preparing medium-term forecasts to ensure a continuous supply of HIV and AIDS commodities in Tanzania. These forecasts, typically covering a one-year period, rely on morbidity data, national strategies, and input from stakeholders. Quantification is informed by data collected at service delivery points using a bottom-up approach. Health facilities utilize consumption data from the electronic Logistics Management Information System (e-LMIS) to determine their HIV and AIDS requirements. The forecasts and procurement plans are subject to regular revisions every six months to align with evolving ART acceptability, tolerability, and efficacy, as well as changing demands and supply chain data. This allows for effective coordination of funding, procurement, and supply planning to meet the needs of RoC and maintain uninterrupted access to ARVs.

14.3.3 Procurement

A uniform and harmonized procurement system is essential for efficiently acquiring quality-assured and affordable health commodities, including ARV drugs and diagnostic products. The procurement process should be guided by the selection of appropriate products and forecasted needs, taking into account consumption patterns, service expansion, formulation changes, and WHO recommendations. The responsibility for procurement, storage, and distribution lies with the Medical Stores Department, which should adopt transparent procedures to ensure the best-value procurement and implement a quality assurance system. The procurement system should prioritize the acquisition of effective, heat-stable, fixed-dose ARV formulations and diagnostic commodities in the right quantities, at the lowest possible cost, and within the required timeframe. Collaboration with partners supporting the national HIV program and exploring options for pooling demands under a common tender system can enhance efficiency. Access to information about prices through a publicly accessible database and adherence to the United Nations interagency guidelines for donated drugs are also important principles to follow in the procurement process.

14.3.4 Inventory Management

a) Ordering and Receiving HIV and AIDS commodities

ARVs and other HIV commodities should be reported & ordered to MSD on bi-monthly (R&R) and reported on monthly basis through electronic Logistics Management Information System (eLMIS) under re-designed Integrated Logistics System (ILS) and re-designed Laboratory supplies logistics system. Upon receiving at facilities, custodians record them in store ledger and issue them to the dispensing area as per logistics SOP.

Report & Request form prepared by.

- Obtaining stock on hand data from actual quantities of available commodities after conducting physical inventory at the end of the reporting month
- Obtaining consumption and usage data from dispensing register/CTC2 database (Pharmacy module), laboratory information system (LIS) and national rapid test register.
- Preparing order by filling bi-monthly report and request forms (R&R) for ARVs, Lab commodities and related supplies and submitting to Council by 5th and get approved and reach MSD by 10th day of the ordering month (primary health facilities, dispensaries, and health centres).
- Preparing order by filling bi-monthly report and request forms (R&R) for ARVs, Lab commodities and related supplies and submitting to get approved and reach MSD by 10th day of the ordering month (Hospitals).
- Electronic reports and orders should be submitted electronically to MSD after being endorsed and approved by the authorities of Health Care facilities.
- Ordering of other commodities (RTK's, Laboratory supplies, etc.) will follow the same system (ILS). MSD will review orders, process, and deliver the medicines and related supplies directly (DD) to the health facility by 30th of the same month.

Health Facilities with CTC and PMTCT services:

- PMTCT will report & order ARVs and RTK's from CTC and Lab, respectively.
- Stand-alone PMTCT sites will follow ILS to order PMTCT commodities along with essential medicines from MSD.

Upon receiving of ARVs and other health commodities at the facility, the receiving officer will ensure that the following particulars of commodities and related supplies on the delivery note and invoice match with the delivered items in the following areas:

- Strength and dosage form
- Pack size(s)
- Batch numbers
- Expiry dates (remaining shelf life should at least above 3 months)
- Specifications
- Quantities delivered.
- Condition of the commodities (not damaged).

After ensuring that all the areas are satisfactory, the receiving officer should sign, stamp and date the Invoice and Delivery Note. If not satisfied with any of the above, the officer should not receive or accept the item(s) that are in dispute; but sign against each disputed item(s) on the Delivery Note and write "*item not accepted*" and immediately record all discrepancies on the *verification and Claims form (Form 7)*. The completed form number 7 should be submitted accordingly i.e. to the supplier and copied to the facility for records.

b) Storage and Distribution

Facilities should have adequate storage space with conducive storage conditions, trained personnel, and the logistics tools (store's ledger and Bin cards for usable commodities and

unserviceable ledger for expired items) to manage supplies effectively. Stock must be kept in a high security storage area with single pharmaceutical personnel / Laboratory personnel (at any one time) and any other authorized personnel responsible for receipts and issues. Arrange Commodities to facilitate the first-to-expire first-out (FEFO) and First-in-First-Out (FIFO) procedure of stock management. Accurate inventory records should be maintained, and a system created to track products that enter and leave the supply system along with a running balance and ledgers maintained for each item.

At the end of each month, physical inventory shall be conducted, and the available stock shall be checked against the stock records. The information from the physical inventory report must be entered into the store Ledger/bin cards. Stocks that have short shelf life that cannot be used before their expiry dates shall be redistributed accordingly to facilities in need using a redistribution form and issue voucher.

Damaged and expired commodities should be immediately separated from usable ones in the inventory and recorded in suspensory ledger. Disposal of expired and damaged products should follow government procedures.

c) Assessing Stock status.

Adequate stock levels of Max-Min of 4/2 Months of stock for each item for all required commodities shall be always maintained. If the stock level for a particular item is falling below the emergency order point (1 month of stock), an emergency order shall be made to bring the stock to maximum level.

Facility should determine monthly; the number of months (Months of Stock) HIV commodities will last based on present consumption/usage rate. The formula below should be used to determine Months of Stocks (MoS).

Months of Stocks (MoS) = Stock on Hand (SoH) ÷ Average Monthly Consumption (AMC).

The result of this calculation (Months of Stock-MoS) will guide providers to make decisions based on the standardized national stock levels as mentioned above to place emergency orders or conduct redistribution to avoid stock out and expiry.

d) Record keeping

To facilitate efficient administration and management of HIV commodities, all information regarding ARVs, and OI medicine dispensed should be recorded in a dedicated dispensing register/ or in the CTC2 database (pharmacy module) and ART RoC card (CTC1). All information regarding usage of RTK's and other Laboratory diagnostics should be recorded in the rapid test register and Laboratory register, respectively. At the store, all HIV commodity transactions should be recorded in the store ledger and/or in the CTC2 database (pharmacy module).

Close monitoring of the consumption/usage data and stock levels of HIV and AIDS commodities is important for supplying the correct quantity and quality medicines, for

responding to changes in demand, for managing increased volumes of commodities, and for minimizing pilferage and misuse.

14.4 Logistics Management Information System (LMIS)

Logistics management information system (LMIS) collects processes and reports the supply chain information. A well-functioning LMIS provides decision makers throughout a supply chain with accurate, timely, and appropriate logistics data. The LMIS can be manual (paper based), or electronic (pharmacy database). There are three essential LMIS data which are:(**Stock on Hand, Losses and adjustment and Consumption data)** this must be documented and reported.

14.4.1 Logistics management tools used in HIV and AIDS commodities Logistics system

The tools are used for recording information about supplies in storage, reporting & requesting (R & R) commodities, issuing, and receiving commodities. These tools include:

- Store's Ledger (and suspensory ledger for expired commodities)
- Form A1: ARV Daily Dispensing register/Pharmacy module
- Rapid test registers
- Laboratory register
- Requisition and issue voucher
- Form 4: MSD sales invoice
- Form 6: Goods Received Note
- Form 7: Claim and Verification for Redistribution form.

Health facilities should ensure these tools are available and properly completed in a timely manner.

14.4.2 Supply Chain Monitoring

Monitoring and evaluation is a cross-cutting function that is needed for all programmes and functions to ensure commodity security. National programmes and their constituent functions must be capable of measuring progress and outcomes if they are to ensure that targets are being met and to determine the corrective actions to be taken.

Monitoring of supply chain management will also be done through the effective use of early warning indicators for monitoring and evaluations of procurement and supply management systems to prevent stock-outs and overstocks leading to expiry as stipulated in Supply Chain Key performance indicators such as:

- Stock availability
- Stock status (% of overstock, % of Understock, % of adequately stocked, % of stock out and % of unknown), Stocked according to plan.
- Expiry rate
- Reporting rate and timeliness

14.4.3 Supply chain data quality monitoring

Effective and efficient supply chains mostly rely on accurate and timely data for decision making. Quality data guarantee accurate forecasts and eventually ensure constant availability of commodities at SDPs. This can be addressed through DQA and data quality improvement

through involving and strengthening implementation of Information Mobilized for Performance Analysis and Continuous Transformation (IMPACT) approach by scaling up to all primary health facilities. Teams will have following roles like; meeting regularly, review performance against targets, identify challenges and setting priorities of the identified challenges, conduct root causes and come up with improvement plans, develop performance plans, develop, and implement team action plans to solve identified supply chain problems.

14.5 Pharmacovigilance

Monitoring and reporting of adverse drug events should be done according to the Tanzania medical device and Drug Authority (TMDA) guidelines. Adverse drug reactions reporting forms (yellow forms) will be distributed to facilities that have been certified to deliver ART. It is important for the health facilities to record the adverse drug reactions and report the information to TMDA. Reporting will be done through yellow forms/ or electronic reporting system by using smartphones or ADR Report Tool), through USSD (*152*00#), Toll free number (0800110084) and electronic system (email: info@tmda.go.tz)).

Facilities are advised to utilize the available information to monitor RoC and make appropriate regimen switches when needed. For instance, RoC experiencing drug-induced nephrotoxicity should be switched to regimens based on ABC, while those experiencing severe hepatotoxicity induced by DTG should be switched to PIs. Healthcare providers should document such information during follow-up using the TMDA yellow form and adhere to the surveillance protocol.

Table 14.2: Types of toxicities associated with First, Second and Third-line ARV drugs.

ARV	Major types of toxicity	Risk factors	Suggested management
TDF	Tubular renal dysfunction, Fanconi syndrome	● Underlying renal disease ● Older age ● BMI<18.5 (or body weight <50kg) ● Untreated diabetes mellitus ● Untreated hypertension ● Concomitant use of nephrotoxic drugs or a boosted PI	● If TDF is being used in first-line ART, substitute it with ABC or TAF in special circumstances (see the section on using TAF in first line ART) ● Do not initiate TDF at an estimated glomerular filtration rate of <50mL/min, uncontrolled hypertension, untreated diabetes or kidney failure ● If TDF is being used in second-line ART, substitute it with
	Decreases in bone mineral density	● History of osteomalacia and pathological fracture ● Risk factors for osteoporosis or bone loss	
	Lactic acidosis or severe hepatomegaly with steatosis	● Prolonged exposure to nucleoside analogues ● Obesity ● Liver disease	

ARV	Major types of toxicity	Risk factors	Suggested management
			AZT or ABC.
	Exacerbation of hepatitis B (hepatic flares)	Discontinuation of TDF due to toxicity	No available alternative drug in the country for treatment of hepatitis B e.g. Entecavir
ABC	Hypersensitivity reaction	Genetic predisposition (HLA-B 5701 gene)	If ABC is being used in first or second-line ART, substitute with TDF or AZT
TAF	Dyslipidaemia Body weight gain	Female sex Concomitant use of DTG	Monitor body weight and promote anti-obesity measures (such as diet, physical exercise). If significant increase despite measures, consider substituting EFV or boosted PI
AZT	Anaemia, neutropaenia,	● Baseline anaemia or Neutropaenia ● CD4 cell count ≤200 cells/mm^3	If AZT is being substute with TDF or ABC consider consider using low dose AZT
	Lactic acidosis or severe hepatomegaly with steatosis Lipoatrophy, lipodystrophy Myopathy	● BMI >25 (or bodyweight >75 kg) ● Prolonged exposure to nucleoside analogues	Substitute TDF or ABC
EFV	Persistent central nervous system toxicity (such as dizziness, insomnia and abnormal dreams) or mental symptoms (anxiety, depression and mental confusion)	● Depression or other mental disorder (previous or at baseline) ● Daytime dosing	For central nervous system symptoms, dosing at bedtime. Consider using EFV at a lower dose (400 mg/day or an integrase inhibitor (DTG) if EFV 400 mg is not effective in reducing symptoms.
	Convulsions	History of seizure	

ARV	Major types of toxicity	Risk factors	Suggested management
	Hepatotoxicity	● Underlying epatic disease ● Coinfection with hepatitis B or C ● Concomitant use of hepatotoxic drugs	For severe hepatotoxicity on hypersensitivity reactions, substitute with another therapeutic class (integrase inhibitors or boosted PIs).
	Severe skin and hypersensitivity reactions	Risk factors unknown	
	Gynaecomastia	Risk factors unknown	Substitute with another therapeutic class (integrase inhibitors or boosted PIs).
NVP	● Hepatotoxicity ● Severe skin rash and Hypersensitivity reaction, including Stevens-Johnson syndrome	● Underlying hepatic disease ● Coinfection with hepatitis B or C ● Concomitant use of hepatotoxic drugs ● High baseline CD4 cell count (CD4 count >250 cells/mm3 for women or >400 cells/mm3 for men)	● If hepatotoxicity is mild, consider substituting with EFV, including for children three years and older. ● For severe hepatotoxicity and hypersensitivity, and for children younger than three years, substitute with another therapeutic class (integrase inhibitors or boosted PIs).
LPV/r	Hepatotoxicity	● Underlying hepatic disease ● HBV and HCVco- infection ● Concomitant use of hepatotoxic drugs	Replace it with ATV/r
	Pancreatitis	Advanced HIV disease	
	Electrocardiographic abnormalities (PR and QRS interval prolongation, torsades de pointes	People with pre-existing conduction system disease Concomitant use of other drugs that may prolong the PR or QRS intervals Congenital long QT syndrome Hypokalaemia	Use with caution for people with pre-existing conduction disease or taking concomitant drugs that may prolong the PR or QRS intervals

ARV	Major types of toxicity	Risk factors	Suggested management
	Lipoatrophy or metabolic syndrome dyslipidaemia	Cardiovascular risk factors such as obesity and diabetes	Substitute another therapeutic class (INSTIs)
	severe diarrhoea and risk of prematurity	Risk factor is unknown	Substitute atazanavir/r, darunavir/r or INSTIs
ATV/r	Indirect hyperbilirubinaemia (clinical jaundice)	● Underlying hepatic disease ● HBV and HCVco- infection ● Concomitant use of hepatotoxic drugs ● presence of ● UDPglucuronoglysyltransferase 1-1 (UGT1A1) enzyme (UGT1A1*28 gene)	Indirect hyperbilirubinemia is usually transient and ATV/r can be continued, however, if severe jaundice develops and is associated with significantly raised transaminases, then ATV/r should be replaced with LPV/r This phenomenon is clinically benign but potentially stigmatizing. Substitute only if adherence is compromised.
	Nephrolithiasis and risk of prematurity	History of Nephrolithiasis	Replace it with LPV/r or DR/r. If boosted PIs are contraindicated and NNRTIs have failed in firstline ART, consider substituting INSTIs
	Electrocardiographic abnormalities (PR and QRS interval prolongation	People with pre-existing conduction system disease Concomitant use of other drugs that may prolong the PR or QRS intervals Congenital long QT syndrome	Use with caution for people with pre-existing conduction disease or who are taking concomitant drugs that may prolong the PR or QRS intervals
DTG	Increase in cholesterol levels; mild elevated liver enzymes; significant rises in creatinine levels; and headache may also be experienced	History of dyslipidaemia, diabetes, hypertension	● Monitor cholesterol levels; monitor Liver function especially in HBV and HCV. ● Provide symptomatic treatment
	Insomnia Body	Older than 60 years Low CD4 or	● Consider morning

ARV	Major types of toxicity	Risk factors	Suggested management
	weight gain or obesity	high viral load Female African ethnicity Concomitant use of TAF	dose or substitute EFV, boosted PI or RAL Monitor body weight and promote anti-obesity measures (such as diet and physical exercise). If significant increase despite measures, consider substituting EFV or boosted PI
	Hepatotoxicity Hypersensitivity reaction	Coinfection with hepatitis B or C Liver disease	● Substitute another therapeutic class: EFV or boosted PIs
ETR	Common: Skin rash, allergic reactions, Nausea, increased low density Lipids, Gastrointestinal disorders and Fatigue Rare: Severe skin rash, Peripheral neuropathy and renal failure	No known risk factors	● Monitor severity and occurrence of fever and other symptoms. ● Provide symptomatic treatment
RAL	Increased Cholesterol levels, Glucose, Aspartate Amino Transferase (AST), Bilirubin. Rash, Cough, Fatigue, dizziness and insomnia	History of dyslipidemia, diabetes, hypertension	In case of severe adverse effects, switch to DTG if RoC is >12 years old
	Rhabdomyolysis, myopathy and myalgia	Concomitant use of other drugs that increase the risk of myopathy and rhabdomyolysis, including statin	Stop ART. When symptoms are resolved, substitute another therapeutic class (NNRTIs, boosted PIs)
	Hepatitis and hepatic failure Severe skin rash and hypersensitivity reaction	Risk factor(s) unknown	

ARV	Major types of toxicity	Risk factors	Suggested management
DRV/r	Increased Cholesterol levels, triglycerides; Diarrhoea, Headache, Rash, Abdominal pain and Nausea	History of dyslipidaemia	● Monitor severity and occurrence of fever and other symptoms. ● Provide symptomatic treatment
	Hepatotoxicity	Underlying hepatic disease Coinfection with hepatitis B or C Concomitant use of hepatotoxic drug	● Substitute with ATV/r or LPV/r. When it is used in third-line ART, limited options are available For hypersensitivity reactions, substitute another therapeutic clas
	Severe skin and hypersensitivity reactions	Sulfonamide allergy	

14.6 Collaborating with Clinical Staff

Close collaboration between pharmaceutical and laboratory personnel and clinical staff is crucial for ensuring accurate diagnosis, appropriate prescription, and selection of ARV regimens. The pharmaceutical and laboratory personnel, as well as other healthcare workers involved in supply chain management, should keep the clinical staff informed about the stock levels of ARVs and diagnostic commodities, particularly items at risk of stock-out or expiration. In case of nationwide supply shortages, communication between supply chain personnel and clinical staff is essential for determining the best course of action. Additionally, pharmacists should stay updated on new information and changes in ARV regimens, serving as a resource for clinicians and providing guidance on drug-related side effects, formulation changes, available options, and drug combinations.

14.7 Secure supply for program flexibility and avoiding expiry of health commodities.

Risk of stock-outs and expiry of health commodities must be minimized by addressing the following.

- Programme managers and clinicians should agree on the speed at which new people will initiate treatment, how the treatment outcomes will be measured, how new-born babies will be screened and how people with advanced HIV disease will be assessed to ensure that the required commodities are available.
- The supply chain implications of any recent or proposed changes in the service delivery model, such as multi-month dispensing or community distribution of ARV drugs, should be clearly understood.
- Ensure that the ARV and diagnostics supply chain distribution should be allocated by facility – reflects the geography of the epidemic.
- New recipients should initiate the preferred first-line regimen, unless clinically contraindicated.

- Quantification and ordering should include a rotating safety buffer to compensate for errors in forecasting and potential delivery delays.
- Orders are placed at least 12 months ahead of the required date of delivery since this will allow adequate time for production and – where volumes allow delivery by sea freight – reduce the cost of shipping.
- Deliveries are staged rather than arriving as a large shipment for six months or more of stock.

14.8 HIV AND AIDS LABORATORY SERVICES

Medical laboratories play an essential role in determining clinical decisions and providing clinicians with information that assists in preventing, diagnosing, treating, and managing diseases. This has been made possible by the MoH implementing Laboratory Management Systems (LMS) to strengthen Laboratory Information Systems (LIS), Planned Preventive Maintenance (PPM), Quality Management Systems (QMS) and Sample transportation systems. In line with the broader concept of Diagnostic Network Optimization (DNO) a network analytics approach will continue to be used to improve and implement a RoC-centre and cost-efficient diagnostic system that offers equitable diagnostic services to all.

Under HIV program laboratory service is very important starting from identification, care, and treatment. Program support and these guidelines insist on proper laboratory testing as per given a logarithm/SOP, baseline and monitoring testing of **CD4**, **Creatinine, ALAT/ASAT, HB, CrAg**, recording & reporting all used reagents for continue availability.

Note:

Other detail information is well elaborated in:

- *Redesign Logistics system manual 2019*
- *HVL and HEID testing guidelines.*
- *Sample referral system guidelines*
- *HTS guidelines*

CHAPTER XV: NUTRITION IN HIV AND AIDS

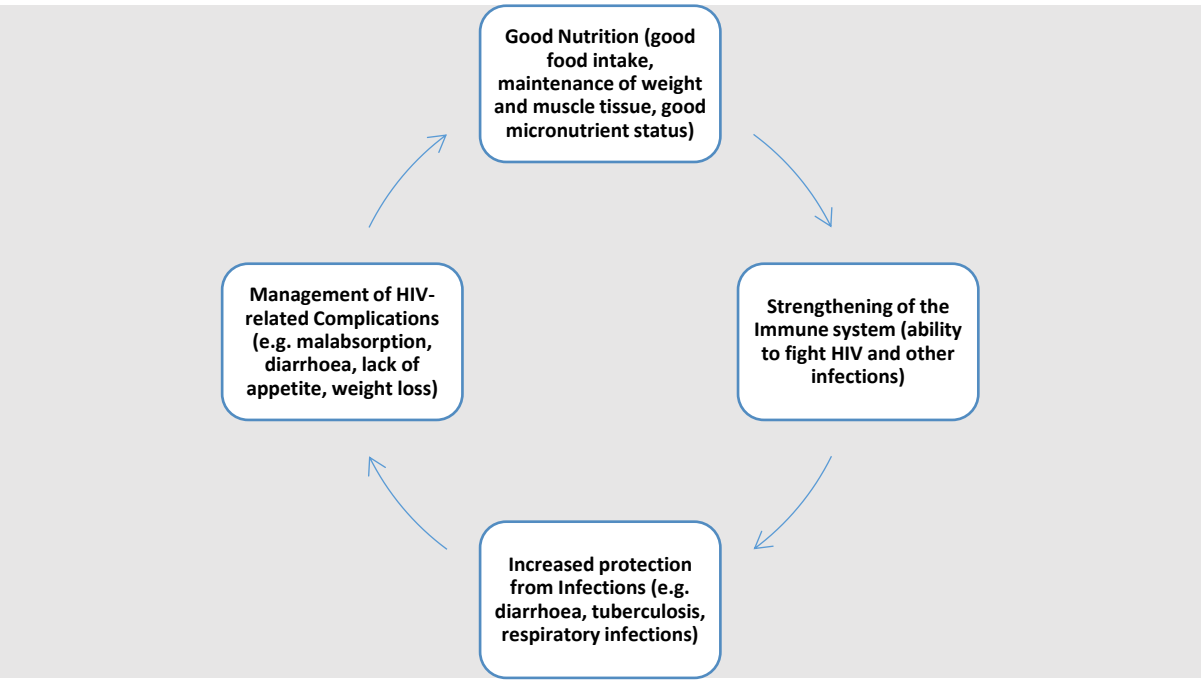
15.1 Introduction

Malnutrition is common among people with HIV, worsening their health and leading to varying response to treatment. Malnutrition can lead to treatment failure and higher infection risks. Children are the most affected group. Addressing malnutrition is vital, especially with universal HIV testing and treatment.

15.1.1 Relationship between nutrition and HIV/AIDS

Malnutrition and HIV fuel each other in vicious cycle. HIV can cause malnutrition, and malnutrition worsens HIV's impact. HIV weakens immunity, inviting infections deplete nutrients, while malnutrition weakens immunity. Malnourished people with HIV progress rapidly to AIDS, unlike well-nourished counterparts. HIV/AIDS reduce food intake, nutrient absorption, and food security. This cycle leads to illness and death, with nutrient deficiencies also affecting immune function and HIV progression on the other hand, good health and nutrition can help delay the progression from HIV to AIDS, strengthens the body's ability to fight OIs and improves the effectiveness of ART hence improving quality of life (Figure 15.1).

Figure 15.1: The Cycle of Nutrition and protection from infections in Context of HIV



15.2 Healthy eating for People Living with HIV

Health care provider should encourage PLHIV to include different food groups at each meal as directed in the National Food Based Dietary Guidelines of 2022 (FBDGs)

- *Variety*-Recommend choosing different types of food within each food group whenever possible.
- *Balance*- Recommend choosing foods from all food groups according to the recommended amounts.
- *Moderation*– Recommend controlling portion size so that balance and variety are possible. This is essential to avoid over-nutrition or under-nutrition.
- Although water is not part of the food groups it is recommended that a person should drink at least eight glasses (1.5 litres) of water a day.

Health Care Providers should use the following tips during nutrition counselling, education sessions and monitoring as in table 15.1;

Table 15.1: Diet, lifestyle and monitoring

Diet and Lifestyle Tips	Monitoring Nutrition Status	Key Actions
• Eat variety of foods together to aids absorption of nutrients. • Use high nutrient-dense foods such as grounded nuts, milk, fats and oils, honey, coconut milk and eggs to enrich the meals especially starchy foods • Eat snacks of fruits, cooked or roasted groundnuts or porridge at least twice a day to increase energy and nutrient intake. • Be physically active to stimulate the appetite, reduce nausea, improves functioning of the digestive system • Avoid alcohol, which interferes with food intake, digestion and absorption and decreases the effectiveness of ARVs. • Avoid consuming "empty calories" such as sodas and other artificial drinks. • Use spices for appetite and absorption: ginger, garlic, cardamom, lemon • Eat germinated and fermented foods such as *togwa* or yoghurt to improve taste and prevent the growth of diarrhoea-causing germs and enhance digestion and absorption in larger quantities. • Mash or grind food, facilitate swallowing, digestion and absorption of nutrients. • Eat fortified foods such as fortified wheat and maize, edible Oil with vitamin A and iodized salt to improve micronutrient intake. • Eat biofortified foods such as orange fleshed sweet potatoes (OFSP), iron and zinc rich beans (Jesca), Mung beans etc to increase micronutrients intake • Drink plenty of fluids, including boiled or treated water, natural fruit juice etc. to avoid dehydration and clear toxins from the body. • Observe food safety, improve cooking methods and hygiene principles. • Limit/ reduce sugar and salt intake • Eat adequate amount of fruits and vegetables daily	• **Clinical assessment** - History taking (intake, weight changes and growth, GI symptoms, and functional capacity) • **Physical examination** ▪ Anthropometric measurements for growth monitoring in children - Height, Weight, BMI for age and Sex MUAC • **Bodyweight changes in adults** ▪ (BMI in kg/m 2) - underweight ≤ 18.5 - normal = 18.5 – 24.9 - overweight = 25 – 29.9 - obese ≥ 29.9 • **Waist** -Hip Ratio • **Biochemical measurements** of metabolic parameters, serum proteins, and micronutrients • **Dietary assessment** ▪ Use 24-hour dietary recall and food frequency questionnaire. ▪ Probe information about the types, quality and amount of meals taken, appetite, food habits and eating behaviours. ▪ Identify food availability, traditional food taboos and economic factors that affect food intake. ▪ Ask about medications and alternative therapies that the RoC is taking. ▪ Review food preparation methods to determine the amount of salt, sugar and oil/fat which when taken in excess is harmful to health as may increase risk of Non-Communicable Diseases.	• Monitor nutritional status. • Counsel to consume healthy diet • Promote physical activity to stay healthy and prevent excessive weight gain that might lead to overweight and obesity. • Promote good hygiene and sanitation, water and food safety to prevent food and water born-diseases. • Provide micronutrient supplementations when necessary. • Discourage use alcohol, tobacco, traditional herbs and others (charcoal, soil). • Provide therapeutic and supplementary foods to malnourished clients according to the national protocol. (Food by prescription) • Encourage use of ARVs and other drugs prescribed by medical personnel as per regimen. • Encourage use of iodized salt throughout pregnancy and lactating period to prevent iodine deficiency. • Encourage pregnant and lactating women to meet their additional energy requirements by eating at other home-prepared nutritious foods • Promote exclusive breastfeeding for the first 6 months of life; complementary foods for children aged 6 - 24 months with continued breastfeeding to prevent malnutrition. • Educate on 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

Note: *There is no single food that contains all the nutrients that the body needs, except breast milk for infants up to six months of age. For a balanced meal use at least one type of food from each food group.*

Table 15.2: Daily Protein and Energy requirements for PLHIV

Energy and protein requirement	Energy (calories per day)	Protein (grams per day)	Micronutrients
2−3 years	1,000 - 1,400	25	Same to general population
4−8 years	1,400 - 1,600	35	
9−13 years	1,600 - 2,000 (girls)	62 (girls)	
	1,800 - 2,200 (boys)	65 (boys)	
14−18 years	2,000 (girls)	64 (girls)	
	2,400 (boys)	84 (boys)	
Adults	2,000−2,580	50–80	
Pregnant/ lactating women	2,460−2,570	55−68	
HIV+ adults (symptomatic)	10% extra (asymptomatic) 20%–30% extra (symptomatic)	50–80	
HIV+ children	10% extra (asymptomatic) 20%–30% extra (symptomatic) 50%–100% extra (losing weight)	Same as for uninfected children	

15.1.2 Nutritional consideration at different stages of HIV infection

Different HIV infection stages presents with different conditions such as mouth sores, sore throats, and diarrhoea. Infections increase energy requirements, potentially causing nutrient deficiencies and further stressing the already weakened immune system. Table 15.1 below describes Nutrition, Care, and Support Priorities categorized by stages.

Table 15.3: Nutritional, care and support priorities by WHO HIV stages

HIV stage	Features	Nutritional Advice
Early Stage (stage 1 & 2 of WHO clinical staging)	Asymptomatic or mild symptoms weight loss under 10% of presumed or measurable body weight	● Assess nutritional status regularly including anthropometric, biochemical, clinical and dietary history ● Counsel on healthy diet and healthy lifestyle ● Consider critical nutrition actions during counselling
Middle Stage (stage 3 of WHO clinical staging)	● Weight loss over 10% of presumed or measurable body weight ● Opportunistic infections	● Assess nutritional status regularly including anthropometric, biochemical, clinical and dietary history ● Consider critical nutrition actions during counselling ● Provide therapeutic food when severely malnourished
Late stage (stage 4 of WHO clinical	Weight loss Symptomatic	● Assess nutritional status regularly including anthropometric, biochemical, clinical and dietary

HIV stage	Features	Nutritional Advice
staging)		history ● Advise on treating opportunistic infections. ● Counsel to modify diet according to symptoms. ● Consider critical nutrition actions during counselling. ● Provide therapeutic food when severely malnourished

15.3.6: Key actions to ensure good lifestyle behaviour to PLHIV

Note: HIV infected individuals are encouraged to include a variety of foods in the diet to prevent deficiency. There is evidence that some micronutrient supplements such as vitamin A, zinc and iron at higher doses may produce adverse outcomes in HIV infected persons.
Do not give high dose of Vitamin A if the Recipient of Care (RoC) with SAM are already receiving F75, F100 or RUTF which already have sufficient Vitamin A. (only give to those who are not provided F75, F100 or RUTF according to the protocol).

15.4: Nutrition care and support for PLHIV

People living with HIV need adequate care and support to improve their nutritional status at all stages of HIV infection.
Therefore, recommend nutrition care and support for People Living with HIV to;

- Ensure adequate nutrient intake by improving eating habits to build stores of essential nutrients needed for the immune system to function effectively.
- Prevent nutritional deficiencies and excessive weight gain.
- Prevent loss of weight and muscle mass.
- Improve uptake and adherence to ART.
- Manage HIV-related symptoms and medication side effects that affect food intake.
- Promote a sense of well-being, self-esteem and a positive attitude, which improve the quality of life

To achieve these goals, health service providers should consider including nutrition assessment, counselling and support (NACS) services, as part of a clinical package of HIV care and treatment services and it should have strong links to community-based services. All PLHIV should receive nutritional assessment, counselling, and support tailored to the individual needs of the patients, including:

i. Nutrition assessment, classification and care plans
ii. Nutrition education and counselling
iii. Nutrition support including provision of therapeutic and/or supplementary feeding for malnourished HIV infected patients.
iv. Referral to follow-up care and other needed services such as food security, Livelihood and social safety net programmes (e.g. food support and cash transfers)

15.4.2: Interpretation of Z-scores, BMI and MUAC

Health service provider should consider measuring nutritional status of PLHIV , interprets the results and take specific actions for each age group as described in Table YY below;

Table 15.4: Interpretation of Z-scores in 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			

Table 15.5: Interpretation of BMI Results for Adults

BMI Level	Classification	Action to be taken
< 16	Severe malnutrition	Recommend for health 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	Conduct Nutritional counselling and supplementary feeding. Screen for TB
18.5–25.0	Normal/ recommended	Recommend nutritional counselling, consistent exercise to build muscles
25.1–30	Overweight	Recommend nutritional counselling to reduce energy intake; aerobic physical activity to reduce weight
>30	Obesity	Recommend counselling to change lifestyle and reduce energy intake; aerobic physical activity to reduce weight. Recommend screening for NCDs for early management and treatment Counselling based on healthy eating tips including limiting sugar, salt and oil intake

Table 15.6: Interpretation of MUAC results for children, adolescents and PBFW

Interpretation of MUAC results for children, adolescents				
6-9 months	**5-9 years**	**10-18 years**	**Classification**	**Action to take**
< 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	Supplementary feeding is recommended
12.6–13.5			Mild acute malnutrition	Nutritional education and counselling recommended
> 13.5			Normal	Education and counselling of caregivers recommended
Interpretation of MUAC results for Pregnant and Breastfeeding Women				
≤ 23			Malnourished	Provide nutritional support
> 23			Normal	Provide nutrition education and counseling

15.4.2: Nutrition Education and Counselling

Nutrition education and counselling can improve eating behaviours and nutritional status. Correct and relevant nutrition information helps people with HIV make rational nutrition choices and changing lifestyles behaviours. Nutrition education provides information to groups of people on topics of common interest. Topics should be based on the identified needs and characteristics (location, age, culture, socioeconomic status) of the intended audience. Possible topics for nutrition education for PLHIV include;

The relationship between nutrition and HIV

- Nutritional requirements for PLHIV
- Promotion of Healthy lifestyles behaviour for PLHIV
- Food and water safety and hygiene
- Dietary management of HIV-related symptoms and medication side effects

Nutrition counselling: Nutrition counselling for PLHIV depends on individual nutritional status, stage of HIV infection, ARV use, conditions or complications and socio-economic situation of the individual. This can be done in a health facility or during home visits. It can help PLHIV and TB individuals to manage food-medication interactions, medication side effects and improve medication efficacy, tolerance and adherence. Below are the Critical Nutrition Actions for people living with HIV of counselling messages to be used when providing nutrition counselling to PLHIV.

- Get weighed regularly and have weight recorded.
- Eat a variety of foods and increase your intake of nutritious foods.
- Drink plenty of boiled or treated water.

- Maintain food hygiene and water safety.
- Avoid habits that can lead to poor nutrition and health
- Get exercise as often as possible. Regular exercise such as walking and light housework builds and strengthens muscle, improves appetite, manages stress and improves health and alertness.
- Prevent and seek early treatment of infections and manage symptoms through diet.
- Manage medication and food interactions and side effects through diet.
- Take all medications as advised by your health care provider.
- Avoid stress and seek psychosocial support. Psychological support is an important component of nutritional care and support because depression, stress and stigma can affect appetite.

15.4.3: Nutrition Support to PLHIV

Consider providing Nutrition supports to PLHIV or Tb individuals to reduce the risk of non-adherence of drugs among food- insecure and acute malnourished individuals. Nutritional support may include therapeutic food products, micronutrient supplementation and enteral or parenteral feeding.

(i) Therapeutic food products

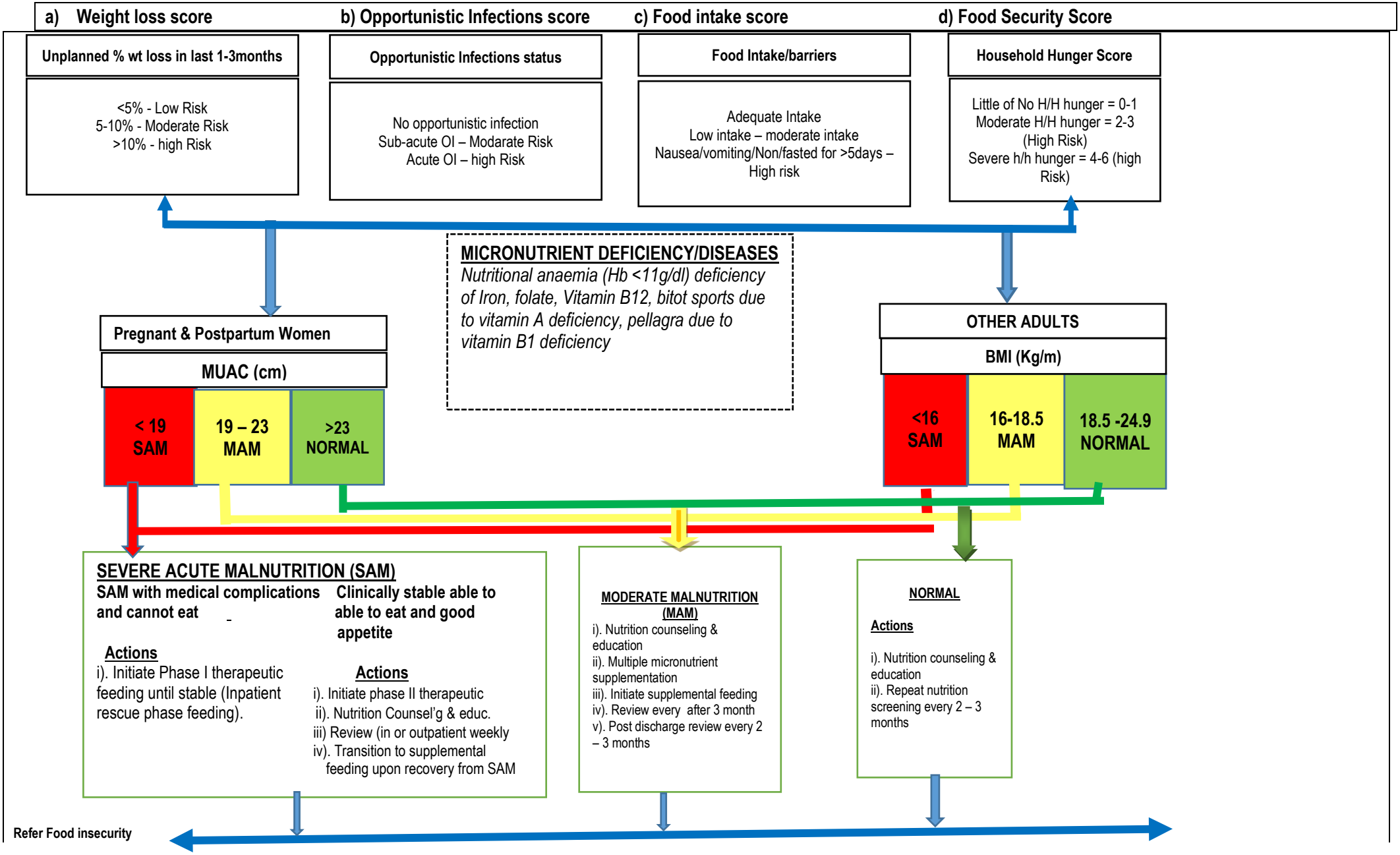
These are specifically designed to treat acute malnutrition and they are prescribed to severely malnourished individuals according to eligibility criteria to improve health and nutritional status. Health service providers should provide therapeutic food to PLHIV who are severely malnourished to stabilize their health and nutritional status and enhance treatment regimes.
The recommended therapeutic food products include:

1. Therapeutic milks
    - F-100 and F-75; for inpatient treatment of SAM

2. Ready-to-Use Therapeutic Food (RUTF)
    - RUTF is an energy-dense, mineral- and vitamin-enriched food that requires no preparation and is specifically designed to treat severe acute malnutrition (SAM) both inpatient and outpatient.

(a) Therapeutic foods for management of Acute Malnutrition

After the assessment of nutritional status in PLHIV, children below five years of age who are severely malnourished, and have no medical complications (i.e. no other disease), should be given nutrition education and Ready to Use Therapeutic Food (RUTF) e.g. Plump nuts. Those with medical complications should not be given RUTF; instead, should be referred for in-patient care and treatment. Management of Acute Malnutrition should be done based on the existing guidelines as per conceptual framework below and the descriptions under Annexes 14.


a) Weight loss score
b) Opportunistic Infections score
c) Food intake score
d) Food Security Score
Unplanned % wt loss in last 1-3months
<5% - Low Risk
5-10% - Moderate Risk
>10% - high Risk
Opportunistic Infections status
No opportunistic infection
Sub-acute OI – Modarate Risk
Acute OI – high Risk
Food Intake/barriers
Adequate Intake
Low intake – moderate intake
Nausea/vomiting/Non/fasted for >5days – High risk
Household Hunger Score
Little of No H/H hunger = 0-1
Moderate H/H hunger = 2-3 (High Risk)
Severe h/h hunger = 4-6 (high Risk)
MICRONUTRIENT DEFICIENCY/DISEASES
Nutritional anaemia (Hb <11g/dl) deficiency of Iron, folate, Vitamin B12, bitot sports due to vitamin A deficiency, pellagra due to vitamin B1 deficiency
Pregnant & Postpartum Women
MUAC (cm)
< 19 SAM
19 – 23 MAM
>23 NORMAL
OTHER ADULTS
BMI (Kg/m)
<16 SAM
16-18.5 MAM
18.5 -24.9 NORMAL
SEVERE ACUTE MALNUTRITION (SAM)
SAM with medical complications and cannot eat
Actions
i). Initiate Phase I therapeutic feeding until stable (Inpatient rescue phase feeding).
Clinically stable able to able to eat and good appetite
Actions
i). Initiate phase II therapeutic
ii). Nutrition Counsel'g & educ.
iii) Review (in or outpatient weekly
iv). Transition to supplemental feeding upon recovery from SAM
MODERATE MALNUTRITION (MAM)
i). Nutrition counseling & education
ii). Multiple micronutrient supplementation
iii). Initiate supplemental feeding
iv). Review every after 3 month
v). Post discharge review every 2 – 3 months
NORMAL
Actions
i). Nutrition counseling & education
ii). Repeat nutrition screening every 2 – 3 months
Refer Food insecurity

Clients for livelihood • **Refers to h/h food security assessment tool** • **For overweight and obesity, refer for counseling** • **Implement local clinical policy and protocol**	**Refer non respondents for further clinical assessment and management**

Note:

- *BMI is not used to assess nutritional status of pregnant women and women within the period of six months after delivery.*
- *Visual assessment is not recommended as the primary method for screening or nutritional assessment.*
- *MUAC is recommended as the primary method for screening or nutritional assessment for pregnant women.*

15.5: Medication-Food Interactions

ARVs can negatively change the way the body consume fat, protein and energy. Some ARVs affect nutrient availability, absorption and utilisation. Consequently, some foods might reduce the effectiveness of certain ARVs and other medications by interfering with their absorption, metabolism, distribution and excretion. In addition, ARV side effects can reduce food intake, absorption of nutrients and adherence to the medications. People infected with HIV may take several medications, including antibiotics, ARVs, anti-malarial, anti-helminths, anti-fungal, etc. Foods and medications can interact in 4 major ways as shown in Table 15.2 below:

Table 15.7: Relationship between foods and medications

1. FOOD	(Affects)	MEDICATION ABSORPTION, METABOLISM, DISTRIBUTION, EXCRETION
2. MEDICATION	(Affects)	NUTRIENT ABSORPTION, METABOLISM, DISTRIBUTION, EXCRETION
3. MEDICATION SIDE EFFECTS	(Affects)	FOOD CONSUMPTION, NUTRIENT ABSORPTION
4. MEDICATION + CERTAIN FOODS	(Creates)	SIDE EFFECTS

Further, Health service provider should guide on medication-food interactions and approaches to be taken to mitigate such interactions and side effects. Annexes 15, describe the common ARVs and other medications used to manage opportunistic infections in Tanzania along with guidance on how to take them and possible side effects:

CHAPTER XVI: MONITORING AND EVALUATION

16.1 Introduction

A comprehensive Monitoring and Evaluation (M&E) system is needed to assess the response to HIV, viral hepatitis and STIs interventions among RoC receiving these services. It is critical that these systems are practical, not overly complicated, and that they collect information that is current, useful and readily used while adhering to human rights principals.

M&E system involves tracking of RoC in each stage of service (monitoring), determining whether the programme is attaining its planned targets, describes the implementation of the programme (Performance Evaluation) as well as determining whether there are changes happened which can be attributed to the programme (Impact Evaluation).

Monitoring therefore refers to continuous process of systematic collecting and analysing information about HIV/AIDS, Viral Hepatitis and STIs programmed, and comparing results against set targets\to judge how well the interventions are being implemented. It uses the data generated by the programme itself (characteristics of individual participants, enrolment and attendance, end of programme situation of beneficiaries and costs of the programme) and it makes comparisons across individuals, types of interventions and geographical locations. The existence of a reliable monitoring system is essential for evaluation compilation and analysis of data on RoC over time and across service delivery points, using information taken from RoC records (either paper-based or electronic). The primary purpose of RoC monitoring is to enable clinical staff to record and use individual RoC data to guide the clinical management of a RoC over time and ensure continuity of care between health facilities. RoC monitoring focuses on care. Also monthly aggregated data are reported through DHIS2 to provide snapshot progress on selected performance indicators to guide implementation.

Evaluation refers to a process that systematically and objectively assesses all the elements of a programme (e.g. design, implementation and results achieved) to determine its overall worth or significance. The objective is to provide credible information for decision-makers to identify ways to achieve more of the desired results. Broadly speaking, there are two main types of evaluation:

Process/Performance evaluations focus on the quality-of-service delivery and the outcomes (results) achieved by a programme. They typically cover short-term and medium-term outcomes (e.g., TPT achievement levels by age, sex, location etc., or the number of RoC who moved to 3 and 6 MMD). They are carried out on the basis of information regularly collected through the programme monitoring system. Performance evaluation is broader than monitoring.

Impact evaluation looks for changes in outcomes that can be directly attributed to the programme being evaluated. They estimate what would have occurred had beneficiaries not participated in the programme. The determination of causality between the programme and a specific outcome is the key feature that distinguishes impact evaluation from any other type of assessment.

Countries including Tanzania have adopted UNAIDS targets of ending HIV epidemics by 2030 of 95-95-95 and WHO Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030. In the process of achieving these targets, innovative and integrated interventions need to be implemented in order to reach the last miles.

There is need for transformation in data collection from paper-based to electronic-based (electronic Medical Records-eMR). Digitization will improve the quality of data collection as well as improving data access and use for programme improvement. There is also increasing attention to have RoC-centered services monitoring; a shift from measuring services provided to monitoring RoC receiving services. To achieve this, M&E system now focuses on longitudinal individual monitoring, Case-Based Surveillance (CBS) from HIV diagnosis (new HIV case) and subsequent sentinel events in HIV care and treatment, Viral Hepatitis, STIs, Reproductive and Child services, laboratory, pharmacy and any other health services provided to the client. Longitudinal CBS, on the other hand, requires the presence to unique identifiers to uniquely identify RoC in all service points. There are different electronic databases from different service delivery points. An interoperability platform is therefore necessary to receive electronic data from different electronic data sources; to be able to ensure that variables submitted are in the same format.

One of the advantages of digitalization of Health Information (HI) is to make data readily available to inform HIV/AIDS, Viral Hepatitis and STI programming. However, digitalization also calls for appropriate security measures and governance in data management to preserve client's privacy and confidentiality and ensure data security.

16.2 Key Components of HIV/AIDS, Viral Hepatitis and STI Monitoring and Evaluation

16.2.1 Data Recording

Collection of data on HIV/AIDS, Viral Hepatitis and STI interventions is done by HSPs and community health workers at the HF and community levels using standardized tools either paper base or electronic (Biometrics finger print and Unified Community System) and coordinated by DACCs and RACCs. Reporting is done on monthly and for some data basis from the community and HF levels to the council level where it is entered in to the DHIS2. From the DHIS2, data can be accessed by different authorities without necessarily contacting the national level.

At the National level, through the NACP data from HFs are compiled to generate National reports which are utilized by different stakeholders within and outside the country to inform programming

Tools for Recording: Recording of the data for the HIV/AIDS, Viral Hepatis and STI services uses the following tools:

a) **RoC Identification Card (CTC1):** This is a card with a unique RoC identification number. It is issued at the registration section of the HF during the first visit of the client to the care and treatment clinic. It is then kept and used by the client for identification purposes when he/ she visit at the CTC.

b) **RoC encounters' Record Form (CTC2):** This is a form initiated when an HIV positive person attends for the first visit at the CTC. It is used for recording the management and monitoring of client's clinical outcomes. The form has a client's unique ID number, as in the RoC Identification Card. It is kept in the client's file and retained at the HF registry or dedicated HIV and AIDS care and treatment cabinet.

c) **Registers:** There are five types of registers used at the CTC for easy follow up of the RoC:

Appointment register: A standardized register that has been designed to help monitor clinic attendances for all RoC who are enrolled into HIV care and treatment clinic,

regardless of their being on ART or not.

Tracking register: A register that is used mostly by the community based HSPs to track back to care those Recipients of Care who have missed their appointments and those who are confirmed as lost to follow up. It records the number of RoC who have been tracked and returned to CTC, transferred out, or stopped using services

Pre ART-Register: This register records all RoC who are attending to the CTC and are not yet started on ART. The ART Register

ART Register: A register used for recording all RoCs who are attending at the CTC clinic and have already initiated on ART.

Cohort Analysis register: This register uses information from the ART register to compile reports for specific RoC' cohorts at 6, 12, 24, 36, 48, 60 and 72 months.

Note: *For high volume facilities with CTC2 database, ART Register and Cohort Analysis registers are generated automatically from the system and HCP do not have to fill the paper-based registers.*

d) **RoC Referral Form**: This is a form that is used when a client is transferred from one CTC to another to enable him/ her carry to the next HF the relevant information about care and/ or treatment given.

Data Storage: Data collected from RoC receiving HIV/ AIDS, Viral Hepatis and STIs care and treatment services are stored either electronically through the CTC2, pharmacy module and the CTC3 macro database or on hard copies of the tools used for data collecting purposes. The electronic means of data storage must be secured by passwords while hard copies must be kept in rooms where confidentiality are ensured.

Data Analysis: Analysis of data on HIV/AIDS, Viral Hepatis and STI services is done from the HF to the national level. In high volume HFs data are entered into the CTC2 (HF based) database, which aggregates automatically and links them directly to CTC3 macro and then to DHIS2. Small volume HFs aggregate data manually and send reports to the office of the DMO for entering in to DHIS2. Two forms of data analyses are done; indicator based and cascade analyses.

Data Reporting: Reporting of data for HIV/AIDS, Viral Hepatis and STI services is done on monthly for HFs that use electronic system, its reports are generated automatically and thereafter directly exported to DHIS 2. For HFs that use paper base system, they aggregate data and submit to the office of the DMO by the 7th day of the following month. Data are reported from HFs to the council, region and finally to the national level.

Facilities with CTC2 database submit data to the CTC3 Macro Database on weekly basis. The CTC3 database is a national client level database with information from all RoC receiving care and treatment services.

Data Presentation: Depending on the needs of the intended audience, presentation of the analysed outputs is done in the form of notes, tables, graphs, maps or chats. Data should be presented in simple, interpretable and actionable form to facilitate

understanding and utilization.

Data Dissemination: After the data are presented in the different forms as shown above, they need to be disseminated so as to reach a greater number of the audience for them to use the data. Dissemination of the data is done by posting them on the notice boards that are placed in public places as well as through conferences.

Data use: It is expected that data will be reported and presented/ disseminated on monthly and or quarterly basis. Data will be used at different levels by stakeholders for the purposes of planning and improvement of the delivery of HIV/AIDS, Viral Hepatis and STI services.

Data Quality: Quality is a key component while monitoring and evaluating a project. Quality data are data that are reliably and accurately representing the measure it was intended to present. It also refers to the totality of features and characteristics of data that bears on its ability to satisfy a purpose for which the data was collected for. Data are considered to be of high quality when they are complete, accurate, consistent, relevant and timely reported. HSPs should strive to produce data of high quality. For HFs to produce high quality data, Data Quality Assessments (DQAs) should routinely be conducted at all levels by using DQA tools that are approved by the MoH

Roles and Responsibilities of Each Level in Relation to M&E

Activities for Monitoring and Evaluation of HIV/AIDS, Viral Hepatis and STI services are carried out at HFs, council, region and national levels. Each level has its roles and responsibilities as follows:

National Level (NACP)

i. Prepares and coordinates implementation of M&E framework for HIV/AIDS, Viral Hepatis and STI services including preparation of M&E guidelines and SOPs for C&T
ii. Guides in the preparation, revision, printing and distribution of recording and reporting tools for HIV/AIDS, Viral Hepatis and STI care and treatment services
iii. Coordinates supportive supervision, mentoring and data quality assessment activities for C&T services
iv. Manages a national database in line with health sector data management guidance Advocates for use of electronic database at HFs that provide services
v. Coordinates capacity building to HSPs in electronic data management Coordinates and guides dissemination of HIV/AIDS, Viral Hepatis and STI output data at all levels
vi. Guides sub-national levels on data management especially on analysis and dissemination; and advocate for data use
vii. Provides feedback on the quality of reports generated by the lower levels

Regional and District Levels

i. Building capacity of the council and primary HFs on the management of the data
ii. Support the HFs in the region and the council on the recording and reporting of HIV/AIDS, Viral Hepatis and STI services
iii. Coordinate capacity building of the HSPs at the HFs on the M&E system of the HIV/AIDS, Viral Hepatis and STI services

iv. Mobilize resources for strengthening M& E system of the HIV/AIDS, Viral Hepatis and STI services, Coordinate the quarterly meetings on review of data
v. Disseminate HIV/AIDS, Viral Hepatis and STI data at region and council levels
vi. Strengthen communication with national level on all HIV/AIDS, Viral Hepatis and STI M&E matters at regional and council levels
vii. Provide feedback on the quality of reports generated by the lower levels. Health Facility Level
viii. Ensures availability and effective use of the recording and reporting tools for HIV/AIDS, Viral Hepatis and STI care and treatment services
ix. Ensures timely submission of the care and treatment reports to the council's office Reports to the DMO on all challenges faced by the HF on all HIV/AIDS, Viral Hepatis and STI M&E system conducts on quarterly basis an internal data quality assessment and data review.

HIV and AIDS Implementing Partners

- Comply with the national M&E system for HIV/AIDS, Viral Hepatis and STI care and treatment services Support regions and councils to implement the HIV/AIDS, Viral Hepatis and STI care and treatment M&E system
- Support regions and councils on analysis, dissemination and use of quality data reviews.

Supportive Supervision and Mentoring of the HIV/AIDS, Viral Hepatis and STI Services

A Manual on Comprehensive supportive supervision and mentoring of the HIV/AIDS, Viral Hepatis and STI services describes 'supportive supervision' as a "process of helping HSPs to improve their work performance continuously." It is carried out in a respectful and non-authoritarian way to promote quality outcomes through strengthening communication, identifying and solving problems, facilitating teamwork, and providing leadership and support.

Mentorship is described as a process of practical training and consultation that fosters on-going professional development to yield sustainable high-quality health outcomes.

It is crucial that all levels of health service delivery adhere to the implementation of the supportive supervision and mentoring of HIV/AIDS, Viral Hepatis and STI services as stipulated in the Manual of the Comprehensive Supportive Supervision and Mentoring of the HIV and AIDS Services (2017 Edition).

Annexes

Annexes I: WHO Clinical Staging

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

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

Annexes II: Health Facility Assessment Tool

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

ASSESSMENT TOOL FOR HEALTH FACILITY TO PROVIDE HIV CARE AND TREATMENT SERVICES

Minimum Criteria for a Health Centre and Dispensary

Name of health facility:	
Type of Facility:	
Village/Street:	
Ward:	
District:	
Region:	
Date of Assessment:	

☐ **Baseline visit** ☐ **re-assessment visit**

Instruction

1. The answers to the minimum criteria should be derived from the health center and Dispensary assessment tool (version 4, October 2021).
2. The numbers in brackets refer to the question numbers in the Health center and Dispensary Assessment tool.
3. Circle the appropriate response (yes/no) as recorded in the assessment tools
4. If the response is yes, circle the appropriate score
5. Sum all circled yes score to make a total of minimum score
6. Cut of point
    a. If the facility scored 60% and above with a consultation room, at least three staff (Clinician, nur,se and other health worker) the facility qualify for initiation.
    b. If the facility scored below 60% action plan for improvement should be in place before 2nd assessment.

1 Organization of HIV and AIDS care services within facility			
1.a One or more confidential consultation rooms			**Score**
One clinical consultation rooms available (4.2.1)	yes	no	
Consultation rooms with visual privacy (4.2.4)	yes	no	
Consultation rooms with Auditory privacy (4.2.5)	yes	no	
1.b Space/room and register for registration of HIV and AIDS patients *(1.8.1 and 1.8.2 = yes, seen)*	yes	no	
2 Human resource capacity and training			
2.a At least one clinician (ACO, CO, AMO, MO) *(2.3.1)*	yes	no	
2.b At least one nurse (NO,ANO,Nurse) *(2.3.3)*	yes	no	
2.c At least one other health worker *(2.3.4, 2.3.5, 2.3.6 or 2.3.7)*	yes	no	
2.d At least two staff (Clinicians and Nurse) trained on National Curriculum on ART (CTC/PMTCT) *(2.2)*	yes	no	
3 HIV Testing Services			
3.a One confidential room for testing and counseling *3.2.1 and 3.2.2* + *3.2.3 = yes, observed)*			Score
One confidential room for testing and Counseling (3.2.1)	yes	no	
Testing & Counselling rooms with visual privacy (3.2.2)	yes	no	
Testing & Counselling rooms with Auditory privacy (3.2.3)	yes	no	
3.b At least one HTS provider (CITC/PITC) *(3.3.3 & 3.4.4)*	yes	no	
4 Care and Treatment Services			
4.a Availability of PMTCT services (4.8.1)	yes	no	

5 Patient records and Administration			
5.a An established and working medical record system *(5.1.1-5.1.5,=yes)*	yes	no	
5.b Locked area for medical records with limited access *(5.2.1=yes)*	yes	no	
6 Continuum of Care			
6.a Availability of CBHS (*at least one = 6.2.1 & 6.2.2)*	yes	no	
6.b Functional system for patients tracking *(5.5.2)*	yes	no	
7 Laboratory services			
7.a Adequate laboratory space *(7.2.1= yes, 7.2.3 = yes),* at least one room	yes	no	
7.b HIV testing (rapid) *(7.4.1)*	yes	no	
7.c Basic blood tests (haematology/biochemistry) *(7.5 and 7.6)*	yes	no	
7.d Malaria blood test *(7.4.14)*	yes	no	
7.e TB sputum smears (ZN stain) + (STI screening) *(7.4.13) & (7.4.4)*	yes	no	
7.f Routine testing of stool and urine *(7.4.12)*	yes	no	
7.g Pregnancy Test *(7.4.10)*	yes	no	
8 Pharmacy services			
8.a Secure storage space large enough for 6 months supply of ARVs *(8.6.1= yes, seen)*	yes	no	
8.b Refrigerator in pharmacy *(8.6.2)*	yes	no	

Annexes III: Pediatric Dosing Chart 1 - 3

Chart 1

DRUG NAME	ABC /3TC Adult	ABC /3TC Baby	AZT/ 3TC Adult	AZT/ 3TC Baby	TDF/3TC/ EFV(TLE) Tabs	TDF/ FTC Tabs	TDF/3 TC/DT G (TLD) Tabs	Pediatric Dolutegravir (pDTG) Tabs	Dolutegravir(DTG) Tabs
DOSE	**ONCE daily**	**ONCE daily**	**TWICE daily**	**TWICE daily**	**ONCE daily**	**ONCE daily**	**ONCE daily**	**ONCE Daily**	**ONCE Daily**
STRENGTH	**600 mg ABC / 300 mg 3TC tablet**	**120 mg ABC / 60 mg 3TC tablet**	**300 mg AZT/ 150 mg 3TC tablet**	**60 mg AZT/ 30 mg 3TC tablet**	**300mg TDF/ 300mg 3TC/ 400mg or 600mg EFV**	**300 mg TDF/ 200 mg FTC**	**300mg TDF / 300mg 3TC / 50mg DTG**	**pDTG 10mg**	**50mg DTG**
Weight range (kg)									
3-4.9		1 tab OD		1 tab BD				0.5 tab OD	
5-5.9		1 tab OD		1 tab BD				0.5 tab OD	
6-6.9		1.5 tab OD		1.5 tab BD				1.5 tab OD	
7-7.9		1.5 tab OD		1.5 tab BD				1.5 tab OD	
8-8.9		1.5 tab OD		1.5 tab BD				1.5 tab OD	
9-9.9		1.5 tab OD		1.5 tab BD				1.5 tab OD	
10-10.9		2 tab OD		2 tab BD				2 tab OD	
11-11.9		2 tab OD		2 tab BD				2 tab OD	
12-13.9		2 tab OD		2 tab BD				2 tab OD	
14-16.9		2.5 tab OD		2.5 tab BD				2.5 tab OD	
17-19.9		2.5 tab OD		2.5 tab BD				2.5 tab OD	
20-24.9	0.5 tab	3 tab OD	0.5 tab	3 tab BD					1 tab OD

	OD		BD						
25-29.9	1 tab OD		1 tab BD						1 tab OD
30-34.9	1 tab OD		1 tab BD		1 tab OD	1 tab OD	1tab OD		1tab OD
≥35	1 tab OD		1 tab BD		1 tab OD	1 tab OD	1tab OD		1tab OD

NOTE
DTG 10mg is not recommended for children less than one month of age regardless of weight.
TDF is only approved for children above 12 years with weight ≥ 30 kg because of TDF-associated reduction in bone density.
DTG 50mg is recommended for children with weight ≥ 20 kg
Chart 2.

DRUG NAME	**Lopinavir/ritonavir (LPV/r) Tabs**					**Atazanavir/ ritonavir (ATV/r)**
DOSE	**TWICE daily**					**ONCE daily**
STRENGTH	**SYRUP 80 mg LPV/20 mg ritonavir/ml**		**GRANULES sachet 40 mg LPV/ 10 mg ritonavir/sachet**	**PEDIATRIC 100 mg LPV/ 25 mg ritonavir tabs**	**ADULT TABLETS 200 mg LPV/ 50 mg ritonavir tabs**	**ADULT Tablets 300mg ATV/ 100mg ritonavir**
Weight range (kg)	**< 4 Weeks**	**≥ 4 Weeks**				
2-2.9	**0.6ml BD**					
3-3.9	**0.8ml BD**	**1 ml BD**	**2 Sachets BD**			
4-4.9	**1ml BD**	**1 ml BD**	**2 Sachets BD**			
5-5.9		**1 ml BD**	**2 Sachets BD**			
6-6.9		**1.5 ml BD**	**3 Sachets BD**			
7-7.9		**1.5 ml BD**	**3 Sachets BD**			
8-8.9		**1.5 ml BD**	**3 Sachets BD**			
9-9.9		**1.5 ml BD**	**3 Sachets BD**			
10-10.9		**2 ml BD**	**4 Sachets BD**	**2 tabs AM, 1tabs PM**		
11-11.9		**2 ml BD**	**4 Sachets BD**	**2 tabs AM, 1tabs PM**		
12-13.9		**2 ml BD**	**4 Sachets BD**	**2 tabs AM ,1tabs PM**		

14-16.9		**2.5 ml BD**	**5 Sachets BD**	**2 tabs BD**	**1 tab BD**	
17-19.9		**2.5 ml BD**	**5 Sachets BD**	**2 tabs BD**	**1 tab BD**	
20-24.9		**3 ml BD**	**6 Sachets BD**	**2 tabs BD**	**1 tab BD**	
25-29.9				**3 tabs BD**	**2 tabs AM 1 tab PM**	**1tab OD**
30-34.9				**3 tabs BD**	**2 tabs AM 1 tab PM**	**1 tab OD**
≥35					**2 tabs BD**	**1 tab OD**

NOTE

Do not use LPV/r solution in infants aged < 2 weeks of age.

Consider giving LPV/r tablets for children weighing ≥ 10kg to reduce giving large numbers of granules. LPV/r tablet must be swallowed whole and should not be split, chewed, dissolved, or crushed as it loses effectiveness.

ATV/r 300mg tabs can be used in children with body weight ≥ 25kgs.

LPV / r Oral Granules 40 mg / 10 mg must be taken after meals twice daily. LPV / r Oral Granules 40 mg / 10 mg should be sprinkled/mixed with soft food such as porridge or mixed with a liquid such as water. LPV / r Oral Granules 40 mg / 10 mg should not be chewed or crushed.

Chart 3.

DRUG NAME	**Darunavir + ritonavir (DRV+ r)**	
DOSE		
STRENGTH	**Adult Tablets Darunavir 600mg**	**Adult ritonavir 100mg**
Weight range (kg)		
14-14.9	**300mg BD**	**50mg BD**
15-29.9	**375mg BD**	**50mg BD**
30-39.9	**450mg BD**	**100mg BD**
≥40	**600mg BD**	**100mg BD**

Annexes IV: ART Readiness Assessment Form

ART Readiness Assessment Form	YES	No
A. Psychosocial/Knowledge Criteria (applies to RoC and caregivers)		
1. Understands the nature of HIV infection and benefits of ART?		
2. Has screened negative for alcohol or other drug use disorder, (see Chapter XIII)		
3. Has screened negative for depression or other psychiatric illness, (see Chapter XII)		
4. Is willing to disclose/has disclosed HIV status, ideally to a family member or close friend?		
5. A demonstration of how to take/administer ART and other prescribed medications has been conducted for the RoC?		
6. Has received information on probable side effects of ART and understands what steps to take in case of these side effects?		
7. For ROCrecipient of care dependent on a caregiver: caregiver is committed to long-term support of the recipient of care, 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. RoCRecipient of care/caregiver has provided accurate locator information and contact details?		
10. RoCRecipient of carecaregiver feels ready to start ART today?		
B. Support Systems Criteria (applies to recipient of cares 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 the next counselling session?		
3. RoC is aware of support group meeting time/s?		
4. If the facility has an SMS reminder system: Has enrolled into the SMS reminder system?		
5. Other support systems are in place or planned (e.g. setting phone alarm, pill box)?		
C. Medical Criteria (applies to recipient of cares)		
1. Newly diagnosed with TB: delay ART initiation until RoC can tolerates anti-TB medication; initiate ART as soon as possible preferably within 2 weeks; for TB meningitis consider delaying ART for up to 8 weeks); monitor closely for IRIS		

ART Readiness Assessment Form	YES	No
2. Newly diagnosed cryptococcal meningitis (CM), or symptoms consistent with CM (progressive headache, fever, malaise, neck pain, confusion): delay ART until completed 5 weeks of CM treatment and symptoms resolved, or until CM has been ruled out as the cause of symptoms; monitor closely for IRIS		
3. TB screen conducted to rule out TB, If eligible initiate TPT		
***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**		

Annexes V: Check list for assessment of elevated viral Load –(PROBE assessment)

Probe for adherence issues	Probe for factors that may be barriers to adherence; ● Cost of clinic visits to RoC, e.g. transport, loss of income, cost of social responsibilities ● Medication side-effects ● Unpalatable medications ● Depression or other mental health conditions ● Alcohol or substance abuse ● Poor social support and/or GBV ● Non-disclosure Pregnant women may experience nausea/vomiting, heartburn, and constipation. Assess the need for symptomatic treatment with an anti-emetic, anti-diarrhoea agent, or fibre supplement. Adherence difficulties in young children are often linked to poor tolerability of unpalatable formulations. It is important to ask the caregiver about how the child tolerates the medication e.g. does the child refuse to swallow, does the child vomit the medication	Tips Ask open ended questions "What makes it difficult for you to take your treatment?", and "How many doses have you missed this week?" Statements like "we all miss a dose now and then" can encourage a client to be more open. Create a safe and non-judgmental space for your client to discuss challenges.
Rule out infection	Check for symptoms and signs of infection. Do a TB and STI screen.	Remember that immune compromised, malnourished, and pregnant recipient of care may not exhibit overt symptoms of TB. If in doubt, do a TB GXP
On correct dose	Is the client on the correct dose for their weight? This is especially applicable to growing children, or RoC with deteriorating renal function or previous renal impairment	
Be aware of Drug-Drug interaction	Review ● Prescribed treatment e.g. rifampicin, anti-epilepsy drugs and pregnancy supplements (iron, calcium) ● Over the counter treatment e.g., antacids, multivitamins ● Other supplements and traditional medications	See also "Drug Interactions with DTG and Rifampicin-containing TB Treatment
Evaluate Resistance	After ruling out other causes of virological failure consider HIV drug resistance if the	Refer to the algorithm Management of

	RoC adherence is objectively good	Virological Failure
Barrier of adherence	Interventions	EAC indicated?
Difficulty getting to facility to collect treatment	Reduce unnecessary visits through enrolling client to multi-month dispensing (MMD)	No need for EAC
Drug side effects or unpalatability impacting adherence?	Change to more palatable regimen	No need for EAC
Challenges with taking/remembering to take treatment	Provide EAC	

Reference, Adopted and modified from South African guideline

Annexes VI: EAC Form for Children, Adolescent and Adult with Low and High level Viremia

(For Enhanced Adherence Counselling and Second/Third line Consideration)

RoC Information

RoC Name :_____RoC ID: _____

Date of Birth:_____ Sex: M/F_____ Facility Name :_____

ARV Information

ARV Regimen: Date of Initiation

_____/_____/_____

_____/_____/_____

_____/_____/_____

Reason for ARV regimen change(Substitution/Switching)

- ☐ Treatment failure
- ☐ Side effects
- ☐ Change of guideline
- ☐ Drug interaction
- ☐ Any other specify:

Viral Load before EAC :_____cp/ml

Date :____/____/___

Previous HVL (if *any*):

_____cp/ml Date: ____/____/___

_____cp/ml Date: ___/____/___

_____cp/ml Date ____/____/__

Enhanced Adherence Counselling (To be filled by the counsellor)

Your Impression about RoC adherence before EAC

☐ Likely to be good ☐ Likely to be NOT good *(relevant barriers identified*) ☐ Clearly poor (defaulter *)*

For each session, assess major barriers for possible poor adherence

Date of 1st Session: _____/_____

☐ Behavioural:

_____

☐ Cognitive:

_____

☐ Emotional:

_____

☐ Socio economic:

_____

ARV-Intake demonstration by RoC/caretaker done? Y/N Pill Count done? Y/N Pill Intake: _____%

Planned Interventions:

_____

_____

_____

Summary: _____

Date of Next Session:

_____

Date of 2nd Session: _____/_____

☐ Behavioral:

_____

☐ Cognitive:

_____

☐ Emotional:

_____

☐ Socio economic:

_____

ARV-Intake demonstration by RoC /caretaker done? Y/N Pill Count done? Y/N Pill Intake: _____%

Planned Interventions:

_____

_____

Summary:_____

Date of Next Session:

_____

Date of 3rd Session: _____/_____

☐ Behavioural:

_____

☐ Cognitive:

_____

☐ Emotional:

_____

☐ Socio economic:

_____

ARV-Intake demonstration by RoC /caretaker done? Y/N Pill Count done? Y/N Pill Intake: _____%

Planned Interventions:

_____

_____

_____

_____

Summary: _____

Date of Next Session:

_____

Date of Extra Session: _____/_____

☐ Behavioural:

_____

☐ Cognitive:

_____

☐ Emotional:

_____

☐ Socio economic:

_____

ARV-Intake demonstration by RoC /caretaker done? Y/N Pill Count done? Y/N Pill Intake:

_____%

Planned Interventions:

_____

_____

_____

_____

Summary: _____

Did the RoC attend all the appointments? Y/N If No, any reason?

_____

_____

_____

_____

ASSESSMENT SECTION

Your Impression about RoC adherence during and after EAC

☐ Likely to be good ☐ kely to be NOT good *(relevant barriers identified and not cleared)* ☐ rly poor (*defaulter)**

(*) If RoC is defaulting repeat viral load should be deferred and EAC extended Share decision with the team

Major remaining barriers identified after EAC sessions:

☐ Behavioural Y/N if yes:

_____

☐ Cognitive Y/N if yes:

_____

☐ Emotional Y/N if yes:

_____

☐ Socio economic Y/N if yes:

_____

Date of collection of repeat Viral load

_____/_____/_____

Counsellor name:_____ Date of assessment

_____/_____/_____

Repeat Viral load result: _____cp/ml Date

_____/_____/_____

Was it a significant drop in the viral load (good response to EAC?) Y/N (Log drop _____)

Is RoC presenting with OIs' or signs of immunosuppression? Y/N if yes, describe

_____

OUTCOME

Regarding the ARV Regimen, what is the plan? C[ ]ue current regimen

[ ]er to Facility MDT for discussion

Name of Assessor : _____ Date of Assessment

_____/_____/_____

Outcome for ROCs with persistent high viral load : *To be filled by the treatment failure Review Team (FMDT)*

What is the plan for this RoC? ☐ Remain on current regimen

☐ Switch to 2nd Line

☐ Refer RoC for GART

☐ State any other action

Comment_____

_____

Review Team Lead Name:_____ Date : _____/_____/_____

Annexes VII: MORSIKY Adherence Form

ASSESSMENT OF MOTIVATION AND KNOWLEDGE TOWARD MEDICATION-TAKING BEHAVIOUR

CLIENT NAME……

SNO	QUESTION	PATIENT RESPONSE	
		MOTIVATION	KNOWLEDGE
1	Do you sometimes forget to take your medications? IF YES How often do you have difficulty remembering to take all your Medications? 1. never/rarely-4 2. once in a while -3 3. sometime- 2 4. usually-1 5. all the time-0	NO(1)	
2	People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medications?	NO(1)	
3	Have you ever cut back or stopped taking your medications without telling your doctor, because you felt worse when you took it?		NO (1)
4	When you travel or leave home, do you sometimes forget to bring along your medications?		NO(1)
5	When you feel like your health condition is under control, do you Sometimes stop taking you medications?		NO(1)
6	Taking medications every day is a real inconvenience for some People. Do you ever feel hassled about sticking to your treatment Plan?		NO(1)
	TOTAL SCORE	0-1=LOW MOTIVATION >1=HIGH MOTIVATION	0-1=LOW KNOWLEDGE 2-4HIGH KNOWLEDGE

EXAMPLE 4 POINTS HIGH KNOWLEDGE AND 2 MOTIVATION POINTS HAS GOOD ADHERENCE

Annexes VIII: Weight and Age Based Dosing Charts

i) **3HR based regimen recommended dosing chart for the treatment of tuberculosis infection in children and adolescents less than 15 years.**

Strength: 3HR 75mg/50mg Dispersible FDC		**Strength: 3HR 150mg/75mg FDC**	
Weight Bands	3HR Tablets	Weight bands	3HR Tablets
4-7 kgs	1	25-37 kgs	2
8-11 kgs	2		
12-15 kgs	3	38-54 kgs	3
16-24 kgs	4		
≥25 kgs	Use Adult Formulations	≥55 kgs	4

ii) **3HP dosing Chart for adults above 15years**

Medicine	**Formulation**	**Weight Bands**				
		30–35 kg	**36–45 kg**	**46–55 kg**	**56–70 kg**	**>70 kg**
Isoniazid	300 mg	3	3	3	3	3
Rifapentine	150 mg	6	6	6	6	6
Isoniazid + Rifapentine (FDC)	300m/300 mg	3	3	3	3	3

iii) **INH Dosing Chart**

Weight Ranges (Kgs)	**Dose Given (mgs)**	**Tablets of INH (of 100mg) per Dose**
<5 kgs	50 mg	½ tab
5.1 - 9.9 Kg	100 mg	1 tab
10 - 13.9 Kg	150 mg	1 ½ tab (or ½ adult tab)
14 - 19.9 Kg	200 mg	2 tabs
20 - 24.9 Kg	250 mg	2 ½ tabs
≥25 Kg	300 mg	1 adult tablet

Annexes IX: Drug-Drug Interactions between Rifamycin Based TPT and Available Art Regimens in Tanzania

ARV Regimen	Type of interaction	Recommended action
1st Line regimen (Paediatric)		
ABC+3TC +pDTG/DTG AZT + 3TC + DTG	Reduced concentration of DTG	If <20Kg, double* the dose of pDTG If above 20Kg double* the dose of DTG 50mg **One dose in the morning and one dose in the evening*
TDF+3TC+DTG	Reduced concentration of DTG	Double the dose to 50mg bid
ABC/3TC+LPV/r AZT/3TC+LPV/r	Reduced concentration of LPV/r	Double the dose of LPV/r
2nd Line regimen (Paediatric)		
AZT/3TC+LPV/r ABC+3TC+LPV/r	Reduced concentration of LPV/r	Double the dose of LPV/r
TDF+3TC+DTG AZT+3TC+DTG	Reduced concentration of DTG	If <20Kg, double* the dose of pDTG if above 20Kg double* the dose of DTG 50mg **One dose in the morning and one dose in the evening*
3rd Line regimen (Paediatric)		
pDTG+DRV+RTV+AZT+3TC DTG+DRV+RTV+AZT+3TC	No studies	Don't use
1st Line regimen (Adolescents and Adults)		
TDF +3TC +DTG (TLD) ABC + 3TC+ DTG AZT + 3TC + DTG	Reduced concentration of DTG	Increase the dose of DTG by 50mg
TDF + 3TC +EFV (TLE400)	Reduced concentration	No dose adjustment
2nd Line regimen (Adolescents and Adults)		
AZT/3TC+ATV/r TDF/FTC+ATV/r	Reduced concentration of ATV/r	Don't use
AZT/3TC+LPV/r	Reduced concentration of LPV/r	Double the dose to 800mg/200mg
3rd Line regimen (Adolescents and Adults)		
DTG + DRV/r + AZT/3TC	No studies	Don't use
DTG (BD) + LPV/r + (AZT/3TC or TDF/FTC)	Reduced concentration of DTG Reduced concentration of LPV/r	Double the dose to 800mg/200mg
DTG+ATV/r+ AZT/3TC	Reduced concentration of ATV/r	Don't use

Annexes X: Co-trimoxazole formulations and dosage for infants and children living with HIV or exposed to HIV

Recommended daily dosage	Suspension (5 Ml of syrup 200 mg/ 40 mg)	Child tablet (100 mg/ 20 mg)	Single strength adult tablet (400 mg/ 80 mg)	Double strength Adult tablet (800 mg/ 160 mg)
<6 months (<5 kg) 100 mg Sulfamethoxazole/ 20 mg trimethoprim	2.5 ml	One tablet	¼ tablet, Possibly Mixed with feeding[a]	-
6 months- 5 years (5-15 kg) 200 mg Sulfamethoxazole/ 40 mg trimethoprim	5ml[b]	Two tablets	½ tablet	-
6 - 14 years(15- 30 kg) 400 mg Sulfamethoxazole/ 80 mg trimethoprim	10 ml[b]	Four tables	One tablet	½ tablet
>14 years (>30 kg) 800 mg Sulfamethoxazole/ 160 mg trimethoprim	-	-	Two tablest	One tablet
Frequency- once a day				

[a] Splitting tablets into quarters is not considered best practice. This should be done only if syrup is not available.

[b] Children of these ages (6 months–14 years) may swallow crushed tablets

Annexes XI: Fomu ya Kusaidia Utambuzi wa Uwezekano wa Kuwepo kwa Magonjwa ya Ngono na via vya Uzazi

Jina la mteja:……..

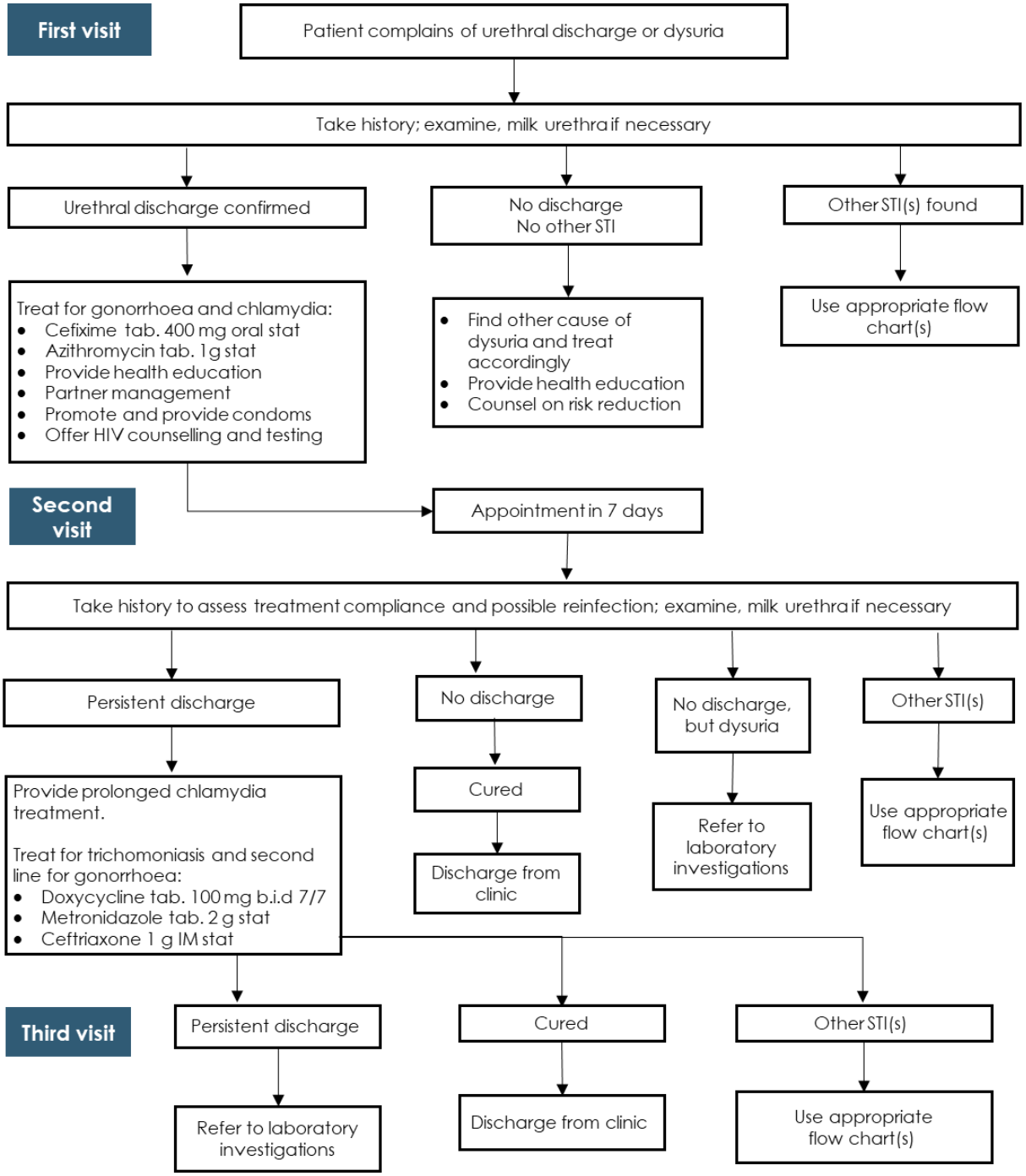
Namba ya usajili**:** …… **Umri:** …… **Jinsi:** Me/Ke

Tarehe ya hudhurio

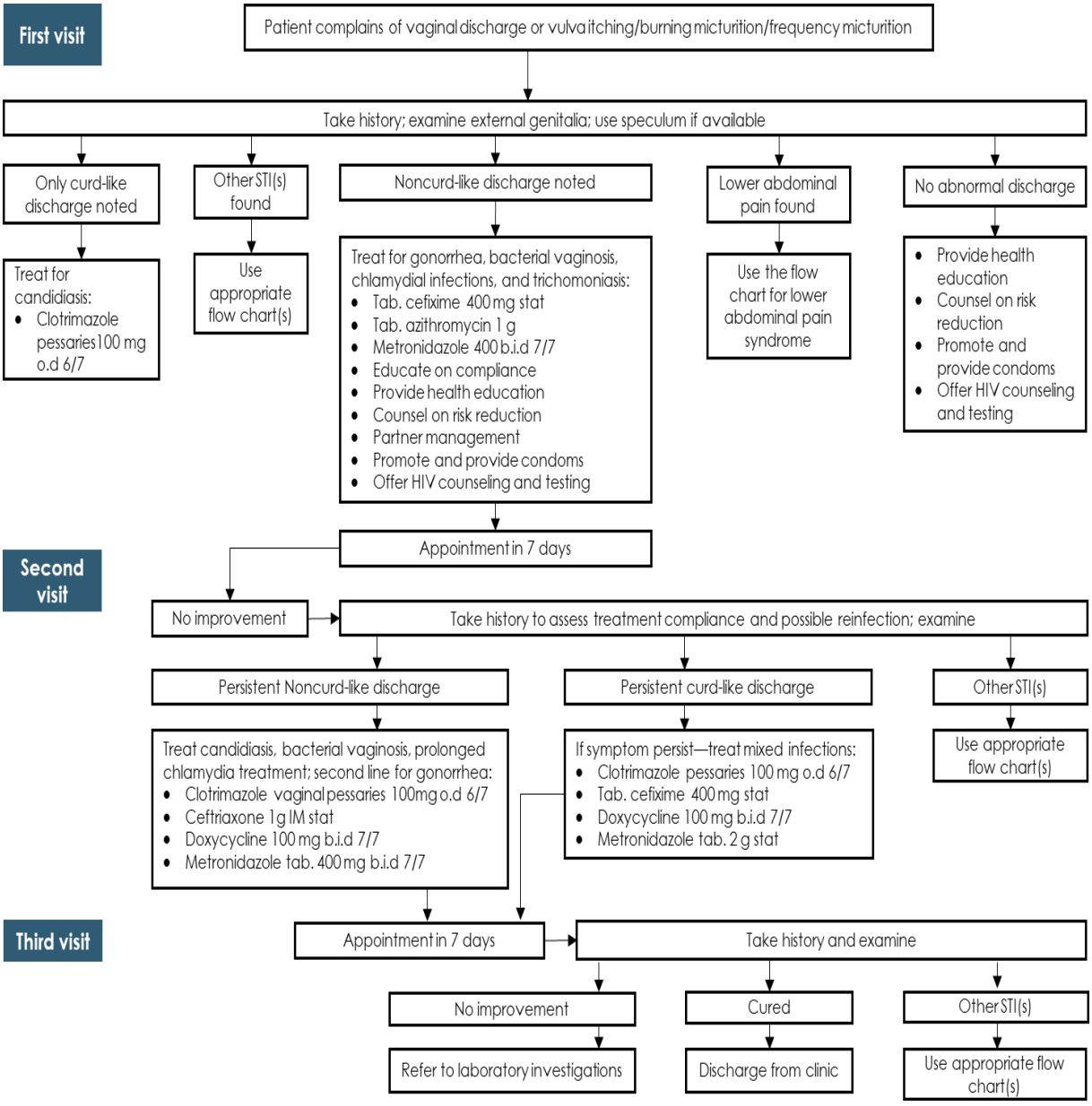
Weka alama ya vema panapohusika	**N**	**H**	**N**	**H**
Je, Unatokwa na usaha/majimaji yasiyo ya kawaida ukeni /Uumeni?				
Je, Unapata maumivu wakati wa kujisaidia haja ndogo?				
Je, Una kidonda/kipele kwenye uume au uke?				
Je, Unapata maumivu chini ya kitovu au wakati wa kujamiiana? (Kwa wanawake)				
Je, Una viotea au kuwashwa sehemu za ukeni/ uumeni?				
Je,Unapata maumivu au kutokwa na majimaji katika njia ya haja kubwa ?				
Je, Unahisi maumivu wakati wa kumeza au koo kukauka?				

Flow Chart 1: Syndromic Management of STI's/RTI's

a) **Management of Urethral Discharge Syndrome (UDS)**

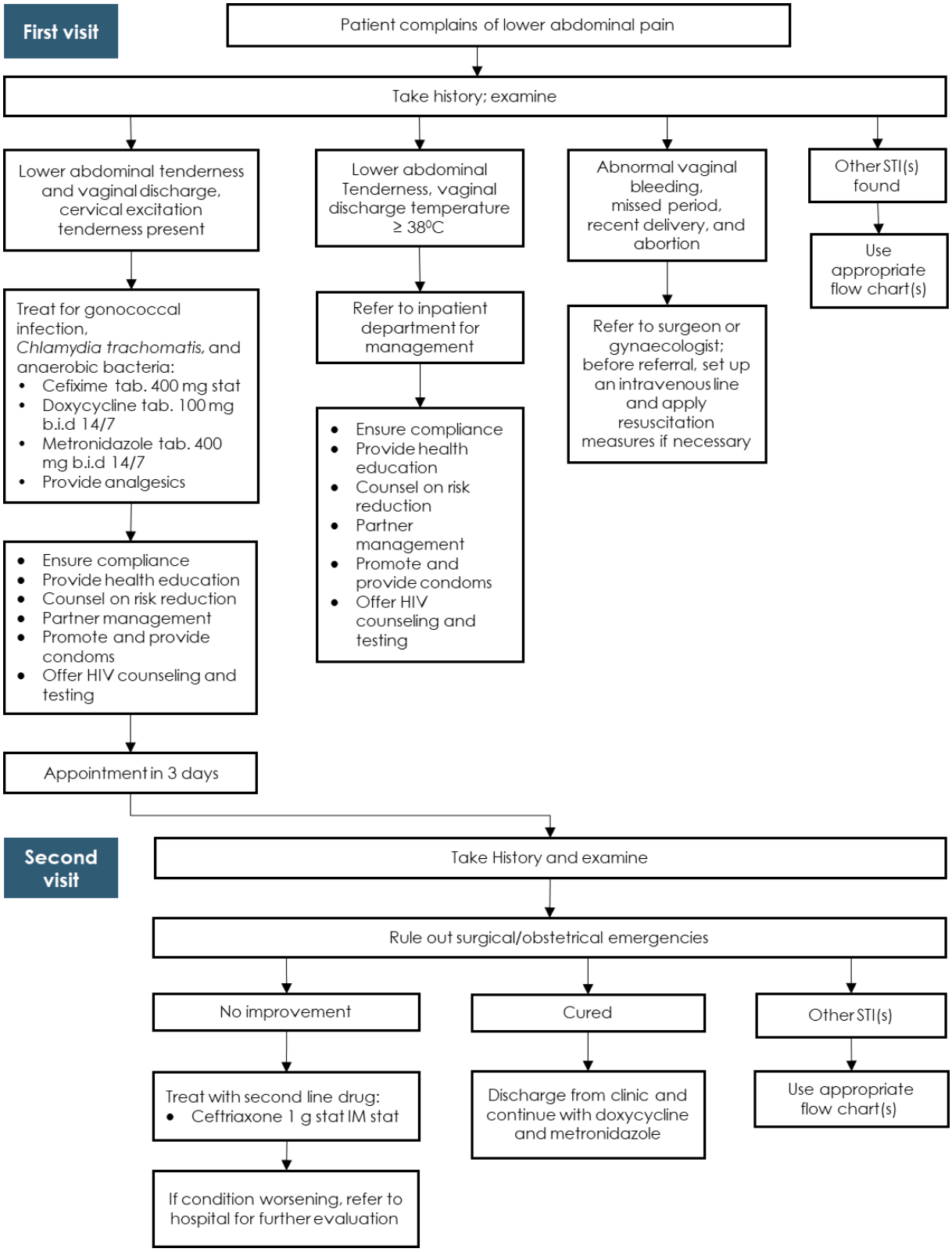


b) Management of Vaginal Discharge Syndrome (VDS)

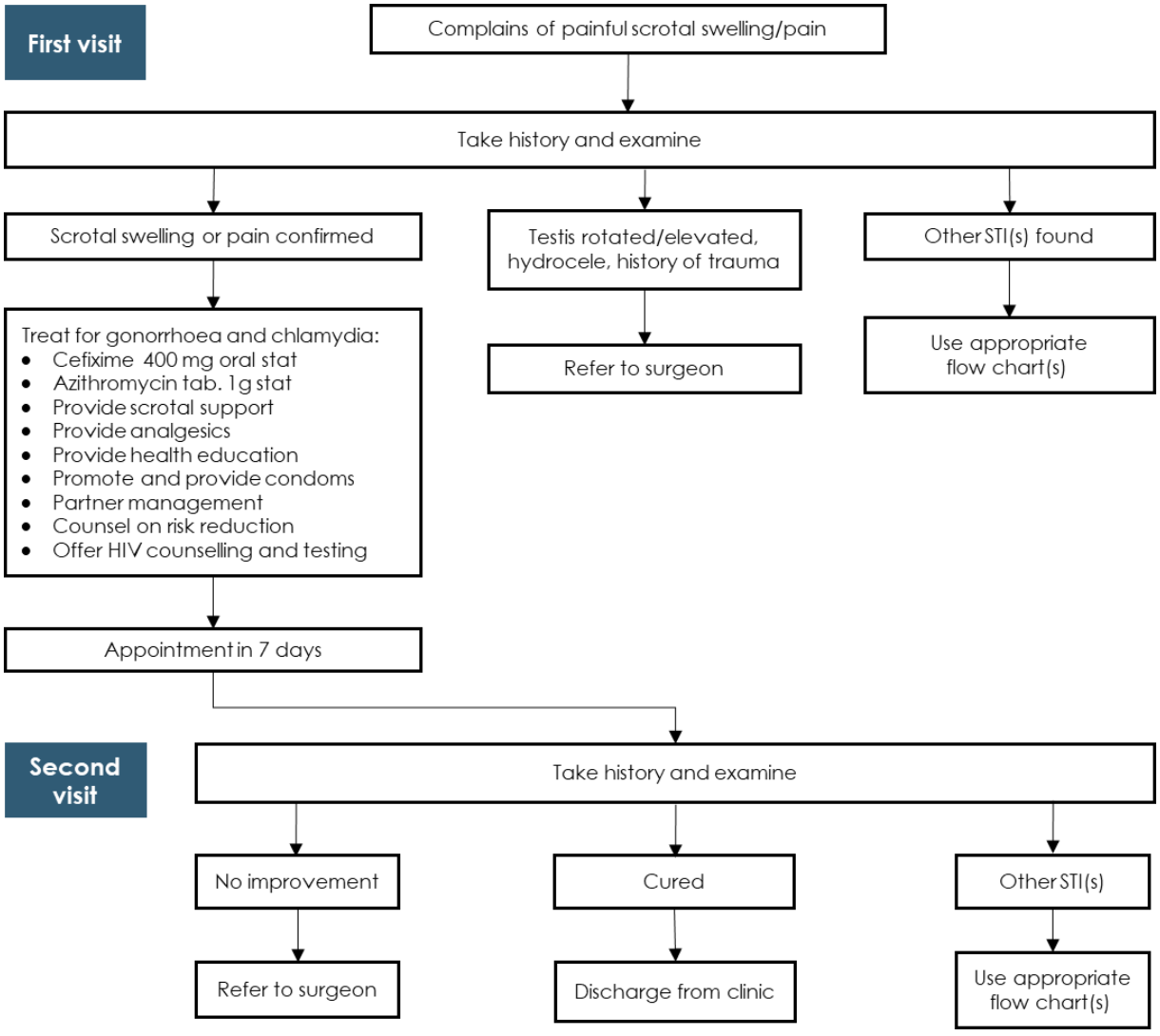


- Do not give Metronidazole in 1st trimester of pregnancy:
- Do not give Doxycycline in pregnancy or to lactating mother: substitute with Erythromycin 500 mg t.i.d 7/7 and Ceftriaxone 250 mg i.m. stat.

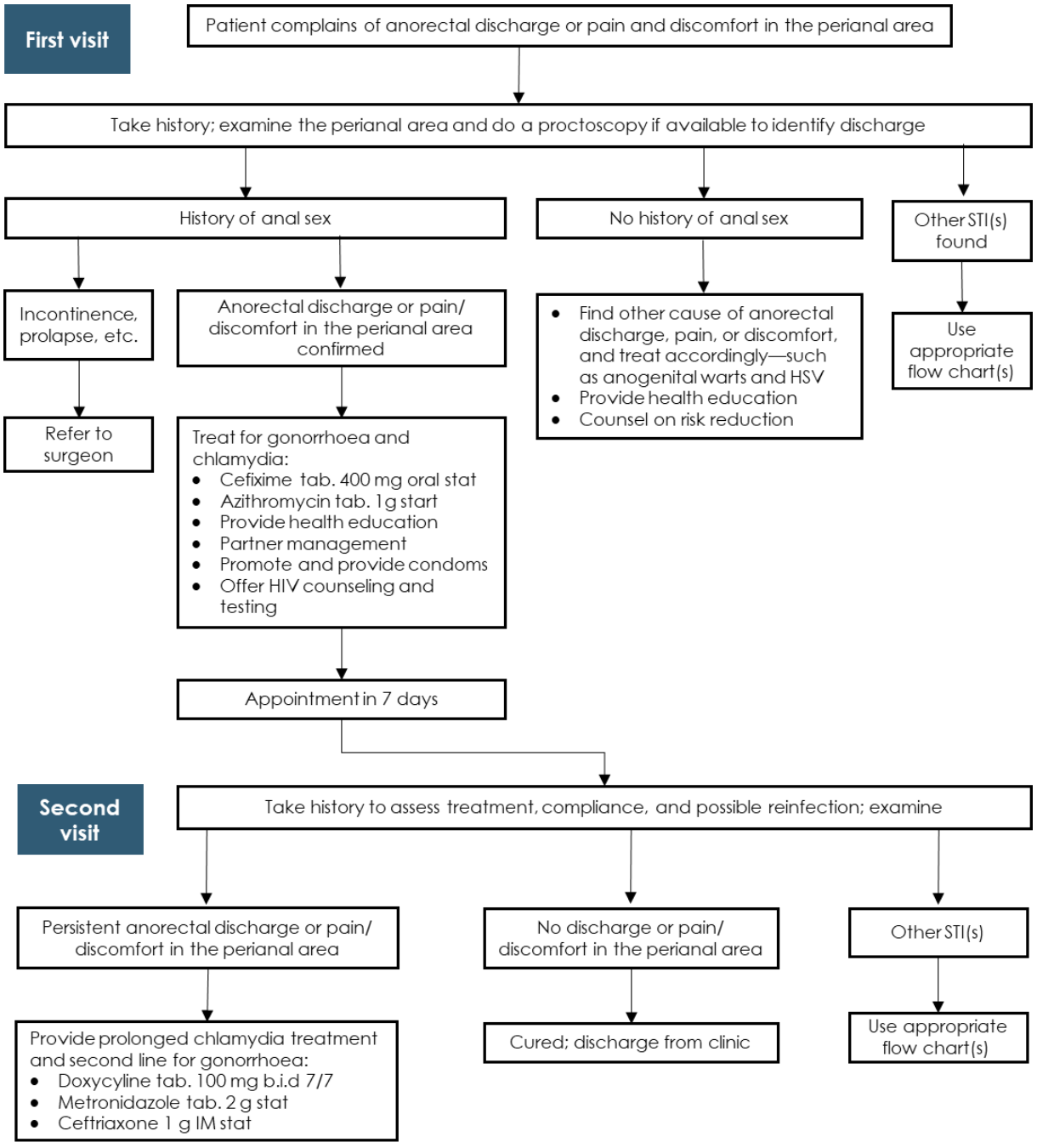
c) Management of Lower Abdominal Pain Syndrome (PID)



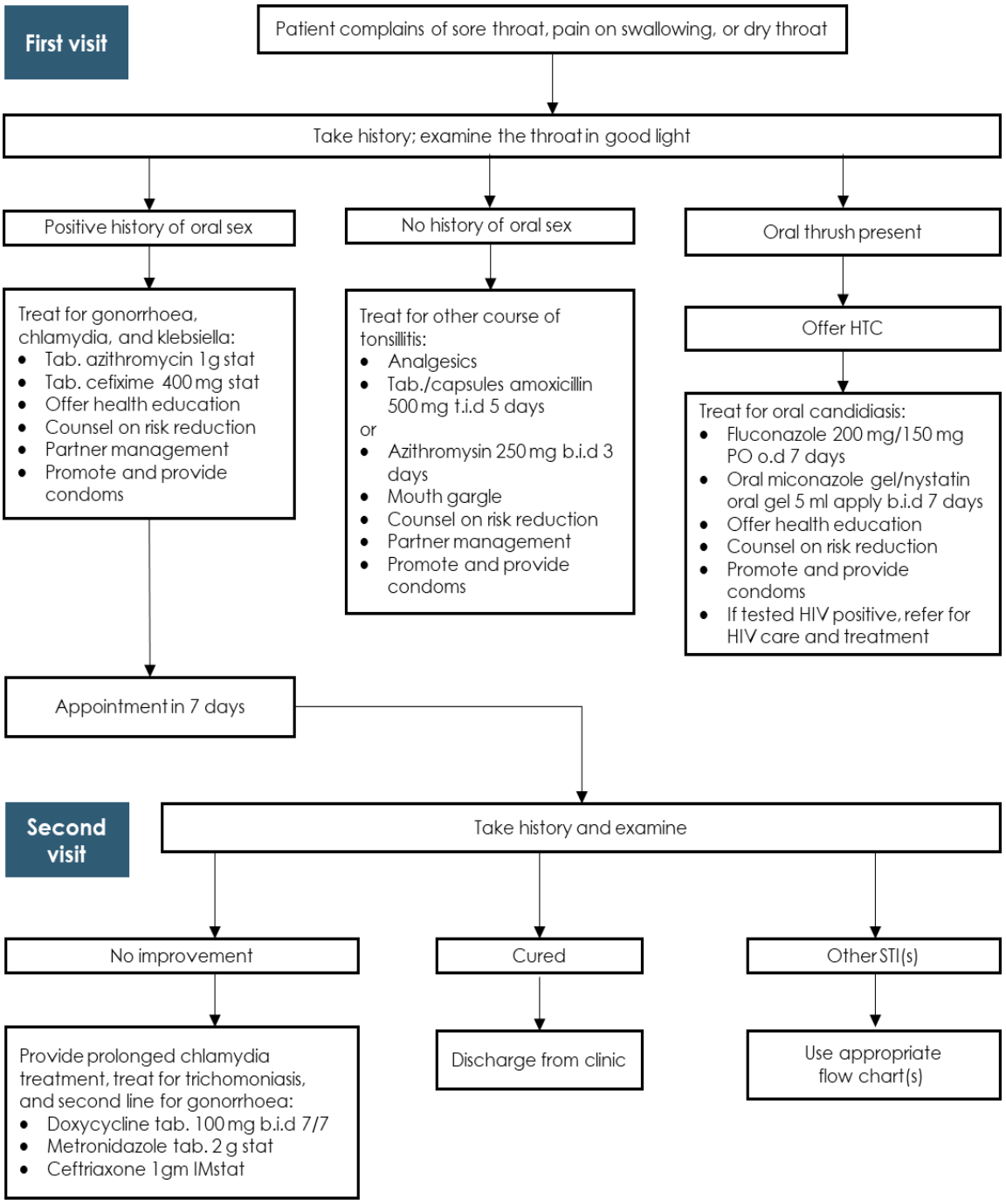
Flow Chart 2: Management of Painful Scrotal Swelling (PSS)



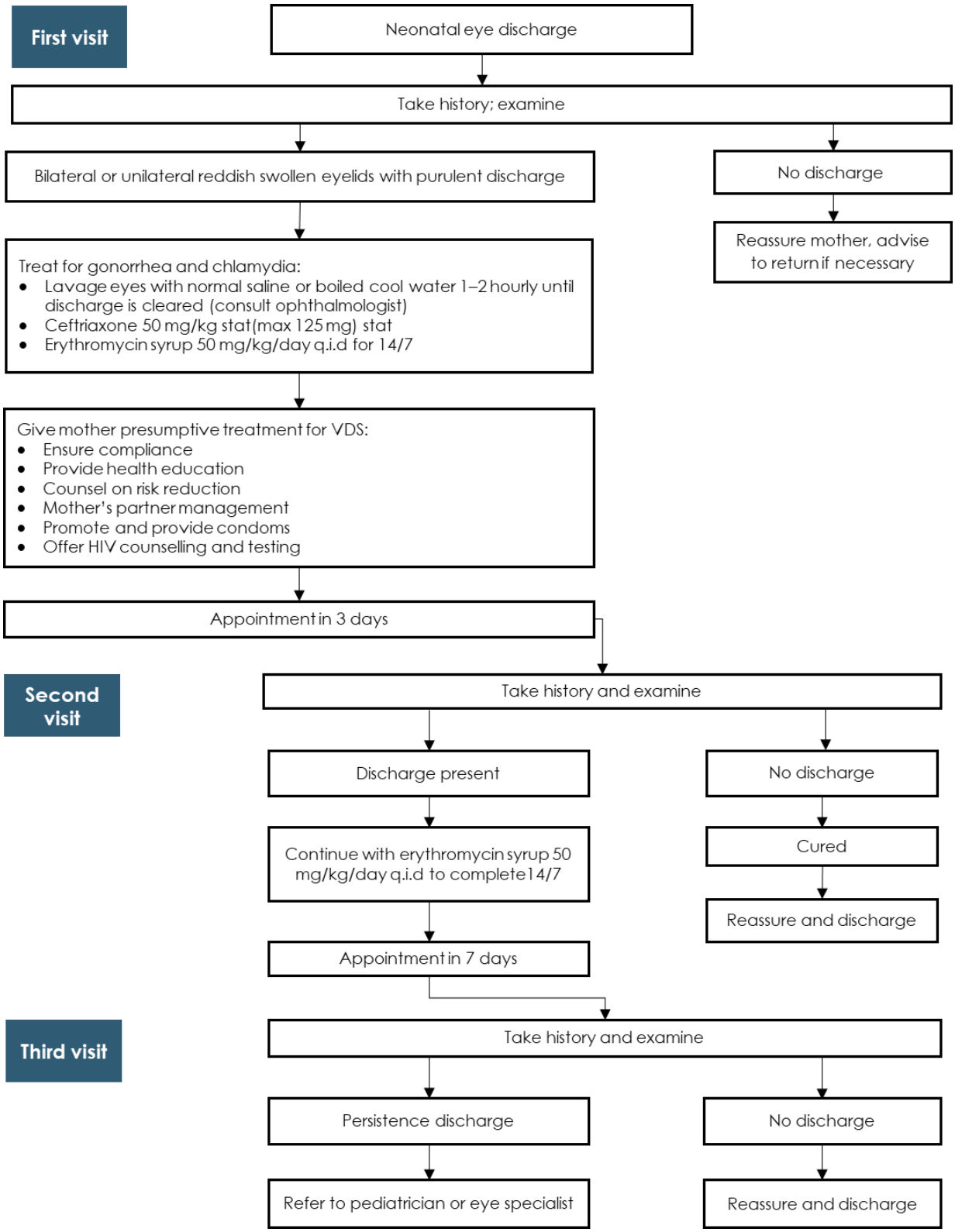
d) Management of Anorectal Syndrome (ARS



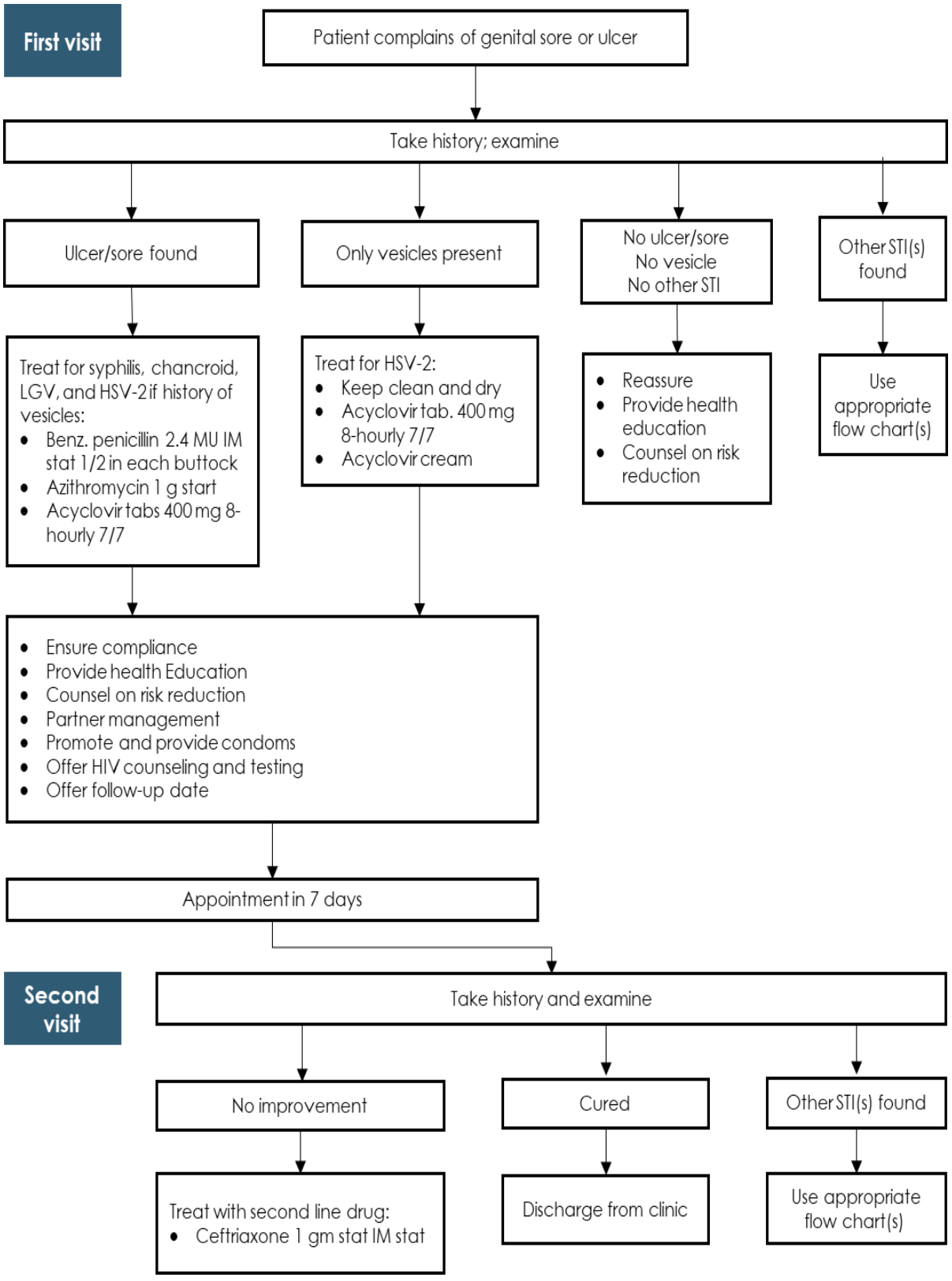
e) : Management of Oropharyngeal Syndrome



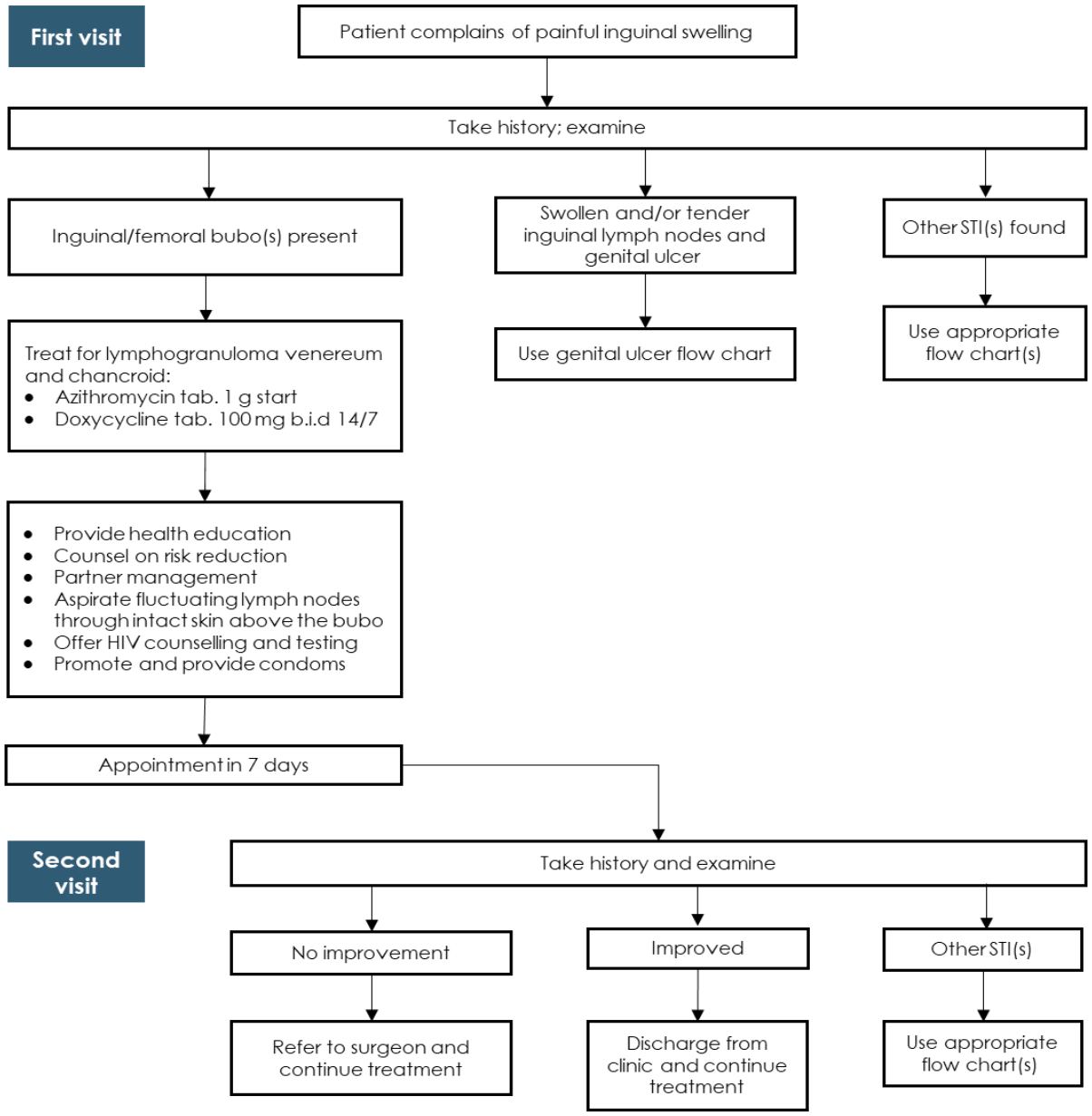
f) Management of Neonatal Conjunctivitis



g) Management of Genital Ulcer Syndrome



h) Management of Inguinal Bubos (IB)



Annexes XII: Fomu ya Uchunguzi wa Afya ya Akili - CTC

Namba ya CTC ……..….Umri…..... Jinsia ..... Kazi …… ART anazotumia sasa .....

A. Generalized Anxiety Disorder (GAD – 2) Ugonjwa wa Wasiwasi uliopitiliza.

	Katika wiki 2 zilizopita, ni mara ngapi umesumbuliwa na matatizo yafuatayo?	**0 - Sivyo kabisa 1 - Siku kadhaa 2 - Zaidi ya nusu ya siku 3 - Karibu kila siku**	Date	Date	Date	Date	Date	Date
1.	Kuhisi wasiwasi au hofu	0 1 2 3						
2.	Kutokuwa na uwezo wa kuacha kuhisi wasiwasi.	0 1 2 3						
	Jumla ya Alama							

GAD – 2; Alama inapatikana kwa kujumlisha pointi kwa kila swali (jumla ya pointi). Alama ya pointi 3 na zaidi ndiyo inaashiria ugonjwa.

B. Depression (PHQ – 2) - Ugonjwa wa Sonona.

	Katika wiki 2 zilizopita, ni mara ngapi umesumbuliwa na matatizo yafuatayo?	**0 - Sivyo kabisa 1 - Siku kadhaa 2 - Zaidi ya nusu ya siku 3 - Karibu kila siku**	Date	Date	Date	Date	Date	Date
1.	Nia ndogo au kukosa raha katika kufanya mambo. Kutojisikia raha kama vile wakati wa kula, kugusa, au ngono	0 1 2 3						
2.	Hisia ya chini, huzuni au kutokuwa na tumaini. Kujisikia ya huzuni	0 1 2 3						
	Jumla ya alama							

PHQ – 2; Alama inapatikana kwa kujumlisha pointi kwa kila swali (jumla ya pointi).
Alama ya pointi 3 na zaidi ndiyo inaashiria ugonjwa.

C. **Post-Traumatic Stress Disorders (PC PTSD – 5) - Mfadhaiko wa Baada ya Kiwewe.**

	Wakati mwingine matukio hutokea kwa watu ambayo si ya kawaida au ya kiwewe kwa mfano ajali mbaya au moto.							
Je, umewahi kushuhudia matukio haya katika kipindi cha mwezi uliopita? (ndio endelea na swali namba 1, Hapana funga dodoso)								
	Andika N – Ndio, au H - Hapana		N au H	N au H	N au H	N au H	N au H	N au H
1	Je ulishawahi kufikiria kuhusu matukio haya yaliyotokea wakati hukutaka kuyafikiria?							
2	Je ulishawahi kujizuiya kufikiria matukio haya?							
3.	Je unahisi umekuwa mwangalifu sana siku hizi?							
4	Je ulishawahi kujitenga na wenzako?							

5.	Je ulishawahi kujilaumu kuhusu matukio yaliyotokea?							
	Jumla ya NDIYO							

PC PTSD – 5; Ikiwa mgonjwa atajibu NDIYO kwa maswali yoyote 3 au zaidi inachukuliwa kuwa matokeo "chanya

D. Drug Use AUDIT-3 - Matumizi ya Pombe.

			Date	Date	Date	Date	Date	Date
		0. Sivyo kabisa **1.** kila mwezi au chini						
1	Ni mara ngapi unakunywa kinywaji kilicho na pombe?	**2.** Mara 2-4 kwa mwezi **3.** Mara 2-3 kwa wiki **4.** 4 au zaidi kwa wiki						
2	Unakunywa vinywaji vingapi vyenye pombe kwa siku?	**0.** 1 au 2 **1.** 3 hadi 4 **2.** 5 hadi 6 **3.** 7 hadi 9 **4.** 10 au zaidi						
3	Ni mara ngapi unakunywa vinywaji sita au Zaidi kwa tukio moja	**0.** Kila siku au karibu kila siku **1.** Kila wiki, **2**. Kila mwezi, **3**. Chini ya kila mwezi, **4.** Kamwe						

AUDIT-C imewekwa kwa alama 0-12 (alama za 0 zinaonyesha kutotumia pombe). Kwa wanaume, alama ya 4 au zaidi inachukuliwa kuwa chanya; kwa wanawake, alama 3 au zaidi inachukuliwa kuwa chanya. Kwa ujumla, kadri alama ya AUDIT-C inavyokuwa juu, ndivyo uwezekano wa unywaji wa mgonjwa kuathiri afya na usalama wake.

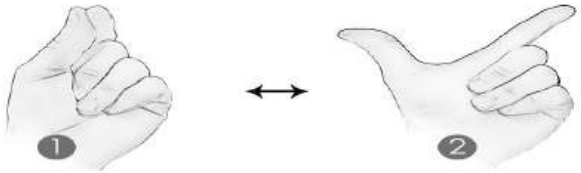
E. Modified Psychosis Screening Questionnaire (PSQ) - Ugonjwa wa kuchangantikiwa

		Date	Date	Date	Date	Date	Date
	Swali la uchunguzi (Ndiyo au Hapana)	N au H	N au H	N au H	N au H	N au H	N au H
1	Katika mwaka uliopita, kumekuwa na nyakati ambapo ulijisikia furaha sana bila mapumziko kwa siku kumi mfululizo?						
	a) Je, jamaa/marafiki zako walifikiri ni jambo geni au kulalamika?						
2	Katika mwaka uliopita umeshawahi kuwa na hisia kwamba mawazo fulani ambayo unayo si mawazo yako mwenyewe? **Kama ndiyo,**						
	a) Ulifikiri ni mawazo ya nani?						
3	Katika mwaka uliopita, kumekuwa na nyakati ambapo ulihisi kwamba uko karibu kudhuriwa au kudhulumiwa na wengine kwa njia fulani?						
4	Katika mwaka uliopita, kumekuwa na nyakati ambapo ulihisi kwamba jambo lisilo la kawaida lilikuwa likiendelea? **Kama ndiyo,**						
	a) Je, ni jambo gani lisilo la kawaida uliwahi kuhisi?						

5	Katika mwaka uliopita, kuna nyakati ambapo ulisikia au kuona kitu ambacho hakipo? Mambo ambayo watu wengine hawakuweza kuyasikia au kuona?						

Kumbuka; Kama mteja ana alama ya NDIYO katika mojawapo ya dalili zilizo hapo juu rejelea kwa uchunguzi zaidi.

F. International HIV Dementia Scale (IHDS) - Dementia itokanayo na VVU.

1.	Usajili wa kumbukumbu	1. Toa maneno manne ya kukumbuka (mbwa, kofia, maharagwe, nyekundu) – sekunde 1 kusema kila moja. 2. Kisha muulize mgonjwa maneno yote manne baada ya kusema. 3. Rudia maneno ikiwa mgonjwa hatayakumbuka yote mara moja. 4. Mwambie mgonjwa baadaye utauliza maneno hayo tena. Alama ……
2.	Kasi ya neva. 0-4 pointi	 1. Mwambie mgonjwa aguse vidole viwili vya kwanza vya mkono usio na nguvu kwa upana na haraka iwezekanavyo. Angalia picha hapo juu 2. Hesabu idadi ya miguso iliyotekelezwa kwa sekunde 5: 3. Recodi namba ya migusano ndani ya sekunde 5 **Scoring:** ≥ 15 taps = **4 points** 11-14 taps = **3 points** 7-10 taps = **2 points** 3-6 taps = **1 points** 0-2 taps = **0 points** **Score/Alama ……..**
3.	Kasi ya uelewa na utendaji.	Mruhusu mgonjwa kufanya harakati kwa mkono usio na nguvu haraka iwezekanavyo;  **1. Nyosha mkono kwa ngumi kwenye uso tambarare.** **2. Weka mkono juu ya meza na kiganja kikitizama chini.** **3. Weka mkono sambamba na meza** **Score/Alama…….** Onyesha na umruhusu mgonjwa afanye mazoezi mara 2 kwa vitendo. Hesabu idadi ya mifuatano iliyofanywa kwa sekunde 10

		Scoring: ≥ 4 mifuatano = **4 points** 3 mifuatano = **3 points** 2 mifuatano = **2 points** 1 mifuatano = **1 point** **Score/ Alama……**
4.	Upimaji wa Kumbukumbu.	Uliza mgonjwa kukumbuka maneno manne kwenye usajili wa kumbukumbu. Kwa maneno ambayo hayajakumbukwa, uliza kwa kidokezo cha kisemantiki kama ifuatavyo. Mnyama (Mbwa), kipande cha nguo (Kofia), mboga (Maharagwe), Rangi (Nyekundu). Toa alama 1 kwa kila neno lililokumbukwa kwa hiari, toa alama 0.5 kwa jibu sahihi baada ya kidokezo. Jumla ya alama 4.

Alama ya juu = 12. Alama <10 inapaswa kutathminiwa zaidi kwa uwezekano wa shida ya Dementia.

Maoni:

……

Rufaa kwenda ……..…….....

Psychiatric Unit……

Aliyetoa rufaa …… Tarehe ……

Annexes XIII: Management of Malnutrition for PLHIV using Therapeutic Food Products

Age Group	Entry criteria	Product	Transition/exit criteria
Children 6 - 59 month	**SAM** • MUAC: <11.5cm W/H < -3 SD	**0– less than 6** **Inpatient** Stabilisation: • If no oedema, 130 ml of F-100-Diluted/kg of body weight/day. • If oedema, F-75 according to SAM protocol Transition and rehabilitation: • F-100-Diluted according to SAM protocol (F-100-Diluted if < 6 months of age) **6 months–14 years** Inpatient Stabilisation: • 130 ml of F-75/kg of body weight/day (100 ml if severe oedema) Transition: • Days 1 and 2: Same amount of F-100; Day 3: Increase each feed by 10 ml until child reaches rehabilitation phase	• 6–59 months: No bilateral pitting oedema for two consecutive visits, MUAC ≥ 11.5 cm, WHZ ≥ – 2 OR 15% weight gain on two consecutive visits AND appetite AND medical problems stabilised or subsiding AND continued weight gain of more than 5 g/kg of body weight/day
	MAM • MUAC: 11.5cm - <12.5cm • W/H -3 SD to <-2 SD W/H -3 Z-scores to <-2	• If the child was treated for SAM, 1 packet of RUTF per day PLUS 100 g of FBF/day • for children 6 months to 9 years of age • 200 g of FBF/day • for children 10–14 years of age for 1 month • If the child was NOT treated for SAM, only FBF as above (no RUTF)	• 6–59 months: MUAC ≥ 12.5 cm OR WHZ OR BMI-for-age ≥ −2 for two consecutive visits 5–9 years: MUAC ≥ 14.5 cm 10–14 years: MUAC ≥ 18.5 cm
Children aged 6 to 14 years	**SAM** • Bilateral pitting oedema OR • severe visible wasting OR • MUAC 5–9 years: < 13.5 cm 10–14 years: < 16.0 cm OR WHZ OR • BMI-for-age < −3	**Inpatient** Stabilization: • If no oedema, 130 ml of F-100-Diluted/kg of body weight/ day. • If oedema, F-75 according to SAM protocol Transition and rehabilitation: • F- 100-Diluted according to SAM protocol (F-100-	• 15% weight gain on two consecutive visits AND appetite AND medical problems stabilized or subsiding AND continued

		Diluted if < 6 months of age) **10–14 years** **Inpatient** Stabilization: • 130 ml of F-75/kg of body weight/day (100 ml if severe oedema) Transition: • Days 1 and 2: Same amount of F-100; • Day 3: Increase each feed by 10 ml until child reaches rehabilitation phase	weight gain of more than 5 g/kg of body weight/day (Need to be confirmed if correct
	(MAM) • Confirmed weight loss of more than 5% since last visit OR • MUAC 5–9 years: ≥ 13.5 to < 14.5 cm 10–14 years: ≥ 16.0 to < 18.5 cm OR WHZ OR • BMI-for-age −3 to <–2	**Children 6 months to 9 years of age** • If the child was treated for SAM, 1 packet of RUTF per day PLUS 100 g of FBF/day for 200 g of FBF/day **for children 10–14 years of age** • for 1 month If the child was NOT treated for SAM, only FBF as above (no RUTF)	• **5–9 years:** MUAC ≥ 14.5 cm • **10–14 years:** MUAC ≥ 18.5 cm
Adolescents 15– 17 year	**SAM** • Confirmed unintentional weight loss of more than 10% since the last visit • Bilateral pitting oedema OR • MUAC less than 18.5 cm OR BMI less than 16.0	**Inpatient** Stabilization: • 50 kcal of F- 75/ kg of body weight/day • Transition: • 50 kcal of F100/kg of body weight/day Rehabilitation: • 3 packets of RUTF/day PLUS 300 g of FBF/day **Outpatient** • 3 packets of RUTF/day PLUS 300 g of FBF/day	• MUAC ≥ 18.5 cm
	MAM • Confirmed unintentional weight loss of more than 5% since last visit • MUAC 18.5 to less than 22.0 cm OR BMI 16.0 to less than 18.5	• 300 g of FBF/day	• MUAC ≥ 22.0 cm
Adults (non - pregnant/≤ 6 months post-partum)	**SAM** • Bilateral pitting oedema OR • MUAC less than 18.5	**Inpatient** Stabilization: 53 ml of F- 75 OR 40 kcal of F-75/ kg of body weight/day	• MUAC ≥ 19.0 cm OR BMI ≥ 16.0 and < 18.5 OR sustained

	cm OR BMI less than 16.0	Transition: • 50 ml of F-100 OR 40 kcal of F-75/kg of body weight/day • Rehabilitation: 3 packets of RUTF/day PLUS 300 g of FBF/day **Outpatient** • 3 packets of RUTF/day PLUS 300 g of FBF/day	weight gain
	MAM • MUAC 18.5 to less than 22.0 cm OR • BMI 16.0 to less than 18.5	• 300 g of FBF/day	• MUAC 22.0 cm or greater OR BMI 18.5 or greater for two consecutive visits
Pregnant women and women ≤ 6 months postpartum	**SAM** • Bilateral pitting oedema OR • MUAC less than 19.0 cm	**Inpatient** Stabilization: • 53 ml of F- 75 OR 50 kcal of F-75/kg body weight/day Transition: • 40 kcal of F- 100/kg body weight/day Rehabilitation: • packets of RUTF/day PLUS 300 g of FBF/day **Outpatient** • 3 packets of RUTF/day PLUS 300 g of FBF/da	• MUAC 19.0 cm or greater
	MAM • Poor weight gain OR • MUAC 19.0 to less than 23.0 cm	• 300 g of FBF/day	• MUAC 23.0 cm or greater OR • over 6 months post-partum

Annexes XIV: Nutrition guidance for multiple medications including ARV

Antiretroviral medications (ARVs)		
Nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs)		
Medication	**Possible side effects**	**Nutrition guidance**
Abacavir (ABC)	Nausea, vomiting, fever, allergic reaction, anorexia, abdominal pain, diarrhoea, anaemia, rash, hypotension, pancreatitis, dyspnea, weakness and insomnia, cough, headache	Can be taken with or without food, though taking with food reduces side effects. Avoid alcohol.
Emtricitabine (FTC)		Can be taken with or without food Avoid alcohol
Lamivudine (3TC)	Nausea, vomiting, headache, dizziness, diarrhoea, abdominal pain, nasal symptoms, cough, fatigue, pancreatitis, anaemia, insomnia, muscle pain, and rash	Can be taken with or without food. Avoid alcohol.
Tenofovir (TDF)	Headache, diarrhoea, nausea, vomiting, abdominal pain, rash, headache, flatulence, anorexia, dizziness, insomnia, depression, sweating, renal function impairment	Can be taken with or without food. Avoid alcohol
Zidovudine (ZDV, AZT)	Anorexia, anaemia, nausea, vomiting, bone marrow suppression, headache, fatigue, constipation, fever, dizziness, dyspnea, insomnia, muscle pain, rash	Can be taken with or without food. But avoid a meal with high-fat. Avoid alcohol.
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)		
Medication	**Possible side effects**	**Nutrition guidance**
Efavirenz (EFZ)	Elevated blood cholesterol levels, elevated triglycerides, rash, dizziness, anorexia, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence	Can be taken with or without food, but avoid a meal with high-fat. Should be taken just before bedtime. Avoid alcohol.
Nevirapine (NVP)	Nausea, vomiting, rash, fever, headache, skin reactions, fatigue, stomatitis, abdominal pain, drowsiness, paresthaesia, high hepatoxicity	Take with or without food. Avoid using St. John's wort plant.
Protease inhibitors (PIs)		
Medication	**Nutrition guidance**	**Possible side effects**
Atazanavir (IDV)	Gastrointestinal complaints, renal toxicity (especially when renal function is already reduced)	Should bo taken only with food.
Lopinavir/ Ritonavir (LPV/r)	Nausea, vomiting, weakness, diarrhoea, headache, dizziness, abdominal pain, fever, diabetes, anorexia, hepatitis, jaundice	Take with or without food. Avoid the use of St. John´s wort plant.
Ritonavir (RTV)	Nausea, vomiting, diarrhoea, hepatitis, jaundice, weakness, anorexia, abdominal pain, fever, diabetes, headache, dizziness, possible increased risk of lipodystrophy	Should be taken only with food. Avoid St. John´s wort.
Once daily single tablet regimen		

TLE Fixed Dose Combination (Efavirenz, Lamivudine, Tenofovir)	See above for Efavirenz, Lamivudine and Tenofovir.	Take with or without food.
Atanazavir/Ritonavir /Tenofovir (ATV/r/FTC/TDF)	See above for Atanazavir, Ritonavir and Tenofovir.	Take with food.
Isoniazid	Food reduces absorption of isoniazid	Do not take with food. Take 1 hour before or 2 hours after meals
	May affect vitamin B6 metabolism	Daily consumption of food sources of vitamin B6 such as white beans, maize avocado, meat, and fish, or vitamin B6 (25 to 50mg daily) supplementation is recommended
	Increased risk of hepatitis when combined with alcohol	Avoid alcohol
	Anorexia i.e loss of appetite	Eat small and frequent meals.
	Diarrhea	Drink plenty of fluids and eat energy- and nutrient-rich foods.
Rifampicin	Gastrointestinal irritation, anaemia, jaundice, pancreatitis, altered taste, anorexia	Take on an empty stomach, 1 hour before or 2 hours after a meal. Supplement with 10 mg vitamin B6 daily. Do not take with alcohol.
Rifapentine	Stomach upset, nausea, vomiting, loss of appetite, or headache may occur.	Take with food. Taking rifapentine with food increases its bioavailability and reduces gastrointestinal upset. Rifapentine tablets can be crushed and mixed with semisolid food if necessary
Co-trimoxazole	Rash, itching, sore throat, fever or chills, severe diarrhea (watery or bloody stools) that may occur with or without fever and stomach cramps (may occur up to 2 months or more after your treatment) shortness of breath, cough	Take it with food, although you can still take it on an empty stomach. Drink plenty of fluid such as water while you are taking Co-Trimoxazole
Rifamycin	Temporary discoloration (yellow, reddish-orange, or brown color) of your skin, teeth, saliva, urine, stool, sweat, and tears), itching, Flushing, headache, drowsiness, dizziness. lack of coordination.	Take 1 hour before or 2 hours after meal. May take with small snack if needed. Take 1 hour before antacids. Avoid alcohol

Annexes XV: List of Workshop participants and individuals' reviewers participated in the review of the National guideline.

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